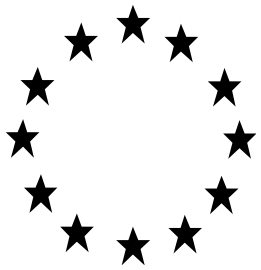
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

COMPETENT AUTHORITY REPORT



Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate)

Product type 2, 3, 4, 5

Evaluating Competent Authority: Slovenia

5 MAY 2023

Substance Name: Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate)

EC Number: 274-778-7

CAS Number: 70693-62-8

Applicant: KMPS Registration Group

Slovenia	KMPS	PT 2,3,4,5

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STATEMENT OF SUBJECT MATTER AND PURPOSE

This assessment report has been established as a result of the evaluation of the active substance trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) in product-type 2 (Disinfectants and algaecides not intended for direct application to humans or animals), PT 3 (Veterinary hygiene), PT 4 (Food and feed area) and PT 5 (Drinking water), carried out in the context of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

On 31 July 2007 the Slovenian Competent Authority competent authorities received a dossier from the applicant. The Evaluating Competent Authority accepted the dossier as complete for the purpose of the evaluation on 13 February 2008.

On 23 September 2022, the Evaluating Competent Authority submitted to ECHA a copy of the assessment report containing the conclusions of the evaluation, hereafter referred to as the competent authority report (CAR). Before submitting the CAR to ECHA, the applicant was given the opportunity to provide written comments in line with Article 8(1) of Regulation (EU) No 528/2012.

In order to review the CAR and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by ECHA. Revisions agreed upon were presented at the Biocidal Products Committee and its Working Groups meetings and the competent authority report (CAR) was amended accordingly.

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) for product-types 2, 3, 4 and 5 and, should it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of the assessment report, which is available from the web-site of ECHA shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data for that purpose was granted to that applicant.

CONCLUSION

Overall conclusion

The overall conclusion of the eCA is that trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) in product types 2, 3, 4 and 5 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

Exclusion, substitution and POP criteria

Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		**Conclusions**	
CMR properties	Carcinogenicity (C)	no classification required	KMPS does not fulfil criterion (a), (b) and (c) of Article 5(1).
	Mutagenicity (M)	no classification required	
	Toxic for reproduction (R)	no classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not P or vP	KMPS does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1).
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B or vB	
	Toxic (T)	Not T	
Endocrine disrupting properties	KMPS is not considered to have endocrine disrupting properties. KMPS does not fulfil criterion (d) of Article 5(1).		
Respiratory sensitisation properties	No classification required. KMPS does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	KMPS does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	KMPS does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution. The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR" and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR" agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for

the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

POP criteria

POP criteria are not applicable to inorganic substances, such as trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate).

Proposal for approval of the active substance trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) in product-types 2, 3, 4, 5

In view of the conclusions of the evaluation, it is proposed that trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: ≥ 890 g/kg (≥ 89 w/w), potassium peroxydisulphate (relevant impurity): ≤ 20 g/kg (≤ 2 % w/w).

2. The authorisations of biocidal products are subject to the following condition(s):

    a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

    b. In view of the possible risks identified for the uses assessed, the product assessment shall pay particular attention to:

        i. Professional users.

        ii. Non-professional users (for PT 2).

        iii. Surface water due to chronic emission following private swimming pool disinfection (for PT 2).

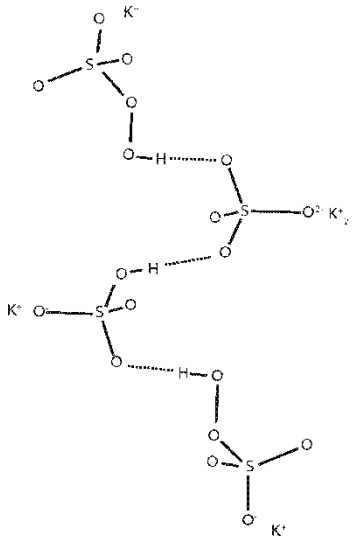
The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012 as the active substance is proposed to be classified as Acute Tox. 4 (H302), Skin Corr. 1 (H314), Eye Dam. 1 (H318), STOT RE 1 (H372 (eyes)), Aquat. Acute 1 (H400) and Aquat. Chronic 3 (H412).

ASSESSMENT REPORT

Summary

1 PRESENTATION OF THE ACTIVE SUBSTANCE

1.1 IDENTITY OF THE ACTIVE SUBSTANCE

Main constituents	
Common name	Potassium monopersulfate - KMPS Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) Potassium peroxymonosulfate
Chemical name (IUPAC name)	Pentapotassium bis((hydroperoxysulfonyl)oxidanide) hydrogen sulfate sulfate
EC number	274-778-7
CAS number	70693-62-8
Index number in Annex VI of CLP	-
Minimum purity / content	≥ 89 % (w/w)
Structural formula	

Initially, pentapotassium bis(peroxymonosulphate) bis(sulphate) was a notified name for the active substance. It was established that the name is incorrect, primarily due to a violation considering a charge balance. Consequently, the active substance has been renamed to trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) where the positions of the protons are not specified. The active substance trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) (hereafter: KMPS*) as manufactured comprises the hydrogen-bonded four-membered chain of the so-called triple salt (built by potassium peroxomonosulfate ($KHSO_5$), potassium hydrogensulfate ($KHSO_4$) and potassium sulphate (K_2SO_4)), which represents the active ingredient, some impurities and

a small amount of residual humidity. A formula written as $2KHSO_5.KHSO_4$. K_2SO_4 is not a true description of the actual chemical structure, since the structure does not consist of such three types of structural fragments ($KHSO_5$, $KHSO_4$ and K_2SO_4). Each potassium ion in the crystal structure is surrounded by oxygen atoms from all type of sulphate anions and hence the currently accepted correct formula is $K_5(HSO_5)2(HSO_4)(SO_4)$. This compound $K_5(HSO_5)_2(HSO_4)(SO_4)$ is a conveniently stabilized crystalline form of Caro's acid, H_2SO_5, which itself is unstable. The biocidal effectiveness is due to the oxidative property of the peroxo- component in the substance, the peroxomonosulphate ion, HSO_5^-.
* The acronym KMPS stands for potassium monopersulfate, which is the common name for trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate). Pure potassium monopersulfate ($KHSO_5$) cannot be isolated in a stable, solid form. It exists as a component of the so-called triple salt. Therefore, KMPS is used to represent the active substance molecule trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate).

Relevant impurity and additive		
IUPAC name or chemical name or EC name	**Maximum concentration**	**Index number in Annex VI of CLP**
Impurity		
Dipotassium peroxodisulphate ($K_2S_2O_8$) CAS 7727-21-1	≤ 2 % (w/w)	016-061-00-1

1.2 INTENDED USES AND EFFECTIVENESS

PT2:
Use of the active substance

Product type	PT 2: Disinfectants and algaecides not intended for direct application to humans or animals
Intended use pattern(s)	- Disinfection of swimming pools - Dipping of equipment - Surface disinfection of industrial areas by wiping with mop - Surface disinfection of industrial areas by manual spraying (low pressure)
Users	- Professional users - Non-professional users (general public) for swimming pool disinfection only

Effectiveness of the active substance

Function	Bactericide, yeasticide, fungicide, virucide
Organisms to be controlled	Bacteria Yeasts and fungi Viruses
Limitation of efficacy including resistance	The studies provided are sufficient to demonstrate innate efficacy for active substance approval. KMPS is an inorganic substance with an unspecific mode of

	action (multisite oxidation process), therefore the development of resistance to KMPS is highly unlikely. Potential remedies should be available if true resistance is ever observed with KMPS.
Mode of action	KMPS releases reactive oxygen, which oxidises macromolecules of the cell wall, membranes and virus capsids leading to the cell wall disruption, loss of membrane integrity and disintegration of virus capsids. In addition, after penetration into cells or viruses, intracellular molecules such as amino acids, polypeptides, RNA and DNA are also oxidised leading to the disruption of protein synthesis and cell death.

PT3:
Use of the active substance

Product type	PT 3: Veterinary hygiene
Intended use pattern(s)	- Terminal disinfection of animal houses using a low pressure sprayer - Foot dips
Users	Professional users

Effectiveness of the active substance

Function	Bactericide, yeasticide, fungicide, virucide
Organisms to be controlled	Bacteria Yeasts and fungi Viruses
Limitation of efficacy including resistance	The studies provided are sufficient to demonstrate innate efficacy for active substance approval. KMPS is an inorganic substance with an unspecific mode of action (multisite oxidation process), therefore the development of resistance to KMPS is highly unlikely. Potential remedies should be available if true resistance is ever observed with KMPS.
Mode of action	KMPS releases reactive oxygen, which oxidises macromolecules of the cell wall, membranes and virus capsids leading to the cell wall disruption, loss of membrane integrity and disintegration of virus capsids. In addition, after penetration into cells or viruses, intracellular molecules such as amino acids, polypeptides, RNA and DNA are also oxidised leading to the disruption of protein synthesis and cell death.

PT4:
Use of the active substance

Product type	PT 4: Food and feed area

Intended use pattern(s)	- Surface disinfection in food and feeding areas by wiping with mop - Surface disinfection in food and feeding areas by manual spraying
Users	Professional users

Effectiveness of the active substance

Function	Bactericide, yeasticide, fungicide, virucide
Organisms to be controlled	Bacteria Yeasts and fungi Viruses
Limitation of efficacy including resistance	The studies provided are sufficient to demonstrate innate efficacy for active substance approval. KMPS is an inorganic substance with an unspecific mode of action (multisite oxidation process), therefore the development of resistance to KMPS is highly unlikely. Potential remedies should be available if true resistance is ever observed with KMPS.
Mode of action	KMPS releases reactive oxygen, which oxidises macromolecules of the cell wall, membranes and virus capsids leading to the cell wall disruption, loss of membrane integrity and disintegration of virus capsids. In addition, after penetration into cells or viruses, intracellular molecules such as amino acids, polypeptides, RNA and DNA are also oxidised leading to the disruption of protein synthesis and cell death.

PT5:
Use of the active substance

Product type	PT 5: Drinking water
Intended use pattern(s)	- Disinfection of animal drinking water: Continuous water sanitation by dosing the header tank or application via a dosing system
Users	Professional users

Effectiveness of the active substance

Function	Bactericide, yeasticide, fungicide, virucide
Organisms to be controlled	Bacteria Yeasts and fungi Viruses
Limitation of efficacy including resistance	The studies provided are sufficient to demonstrate innate efficacy for active substance approval. KMPS is an inorganic substance with an unspecific mode of action (multisite oxidation process), therefore the development of resistance to KMPS is highly unlikely. Potential

	remedies should be available if true resistance is ever observed with KMPS.
Mode of action	KMPS releases reactive oxygen, which oxidises macromolecules of the cell wall, membranes and virus capsids leading to the cell wall disruption, loss of membrane integrity and disintegration of virus capsids. In addition, after penetration into cells or viruses, intracellular molecules such as amino acids, polypeptides, RNA and DNA are also oxidised leading to the disruption of protein synthesis and cell death.

1.3 CLASSIFICATION AND LABELLING

1.3.1 Classification and labelling for the active substance

Hazard class/ property	**Proposed classification**
Physical hazards	
Explosives	Data conclusive, but not sufficient for classification.
Flammable gases	Not applicable, the active substance is a solid.
Flammable aerosols	Not applicable, the active substance is a solid.
Oxidising gases	Not applicable, the active substance is a solid.
Gases under pressure	Not applicable, the active substance is a solid.
Flammable liquids	Not applicable, the active substance is a solid.
Flammable solids	Data conclusive, but not sufficient for classification.
Self-reactive substances	Data conclusive, but not sufficient for classification.
Pyrophoric liquids	Not applicable, the active substance is a solid.
Pyrophoric solids	Data conclusive, but not sufficient for classification.
Self-heating substances and mixtures	Data conclusive, but not sufficient for classification.
Substances which in contact with water emit flammable gases	Data conclusive, but not sufficient for classification.
Oxidising liquids	Not applicable, the active substance is a solid.
Oxidising solids	Data conclusive, but not sufficient for classification.
Organic peroxides	Not applicable.
Corrosive to metals	Not applicable, the active substance is a solid.
Human health hazards	
Acute toxicity via oral route	Acute Tox 4, H302
Acute toxicity via dermal route	Data conclusive, but not sufficient for classification.

Hazard class/ property	Proposed classification
Acute toxicity via inhalation route	Data conclusive, but not sufficient for classification.
Skin corrosion/irritation	Skin Corr 1, H314
Serious eye damage/eye irritation	Eye Dam 1, H318
Respiratory sensitisation	Data conclusive, but not sufficient for classification.
Skin sensitisation	Data conclusive, but not sufficient for classification; labelling with EUH208 due to impurity dipotassium peroxodisulphate (CAS 7727-21-1)*
Germ cell mutagenicity	Data conclusive, but not sufficient for classification.
Carcinogenicity	Data conclusive, but not sufficient for classification.
Reproductive toxicity	Data conclusive, but not sufficient for classification.
Specific target organ toxicity-single exposure	Data conclusive, but not sufficient for classification.
Specific target organ toxicity-repeated exposure	STOT RE 1, H372 (eyes)
Aspiration hazard	Hazard class not applicable.
Environmental hazards	
Hazardous to the aquatic environment	Aquatic Acute 1, H400 (M=1) and Aquatic Chronic 3, H412
Hazardous to the ozone layer	Data conclusive, but not sufficient for classification.

* As KMPS contains impurity dipotassium peroxodisulphate ($K_2S_2O_8$) which has a harmonised classification as Skin Sensitiser 1, H317 and Respiratory Sensitiser 1, H334 and is present in a concentration greater than that specified in Table 3.4.6 of Annex I of Regulation (EC) 1272/2008 the active substance KMPS shall be labelled with EUH208 "Contains dipotassium peroxodisulphate (CAS 7727-21-1). May produce an allergic reaction."

Current Classification and Labelling according to Regulation (EC) No 1272/2008:

A harmonised classification for the active substance KMPS is not available and the active substance KMPS is not listed in Annex VI of Regulation (EC) No 1272/2008. A CLH dossier for KMPS was submitted to ECHA in August 2022. Since the decision of the RAC regarding harmonized classification and labelling of KMPS is not yet available, the conclusions regarding classification and labelling is preliminary and the final decision of the RAC should be applied.

Proposed Classification and Labelling according to Regulation (EC) No 1272/2008:

Classification		**Labelling**					
Hazard Class and Category	**Hazard statements**	**Pictograms**	**Signal word**	**Hazard statements**	**Suppl. Hazard statements**	**Precautionary statements**	**SCLs and M-factors**
Acute Tox 4 Skin Corr. 1 Eye Dam. 1 STOT RE 1 Aquat. Acute 1 Aquat. Chronic 3	H302 H314 H318 H372 (eyes) H400 H412	GHS07 GHS05 GHS09	Danger	H302 H314 H372 (eyes) H410	EUH071 EUH208*	P260 P264 P270 P273 P280 P301+P330+P331 P303+P361+P353 P305+P351+P338 P310 P304+P340 P363 P391 P405 P501	M=1

* EUH208 "Contains dipotassium peroxodisulphate (CAS 7727-21-1). May produce an allergic reaction."

1.3.2 Classification and labelling for the representative product

Proposed Classification and Labelling according to Regulation (EC) No 1272/2008 for the representative theoretical product, containing 50 % KMPS:

Classification		**Labelling**					
Hazard Class and Category	**Hazard statements**	**Pictograms**	**Signal word**	**Hazard statements**	**Suppl. Hazard statements**	**Precautionary statements**	**SCLs and M-factors**
Acute Tox 4 Skin Corr. 1 Eye Dam. 1 STOT RE 1 Aquat. Acute 1 Aquat. Chronic 3	H302 H314 H318 H372 (eyes) H400 H412	GHS07 GHS05 GHS09	Danger	H302 H314 H372 (eyes) H410	EUH071 EUH208*	P260 P264 P270 P273 P280 P301+P330+P331 P303+P361+P353 P305+P351+P338 P310 P304+P340 P363 P391 P405 P501	/

* EUH208 "Contains dipotassium peroxodisulphate (CAS 7727-21-1). May produce an allergic reaction."

2 SUMMARY OF THE HUMAN HEALTH RISK ASSESSMENT

Summary of the assessment of effects on human health

Endpoint	Brief description
Toxicokinetics	No ADME study was performed with KMPS. Due to the high reactivity of KMPS and its immediate dissociation into potassium and sulphate ions when in contact with wet tissues, oral, dermal and inhalation absorption of KMPS itself is not considered relevant. Absorption: No value for the oral absorption of KMPS was determined. Oral absorption data on dissociation products is available: potassium ions are largely absorbed (85 - 90%) and SO_4^{2-} is absorbed at more than 80%. Both ions constitute physiologically essential metabolites in the human body, which can efficiently be excreted, and are not toxic *per se* even when becoming systemically available. KMPS exerts only local effects (i.e. corrosion) at the site of first contact due to direct chemical reactivity. Any potential systemic effects are considered secondary to this local mode of action. Metabolism: Potassium and sulphate ions are both simple inorganic compounds, which cannot be further degraded neither chemically nor biologically. Excretion: KMPS dissociation products, potassium and sulphate ions, are effectively eliminated: the potassium ion is eliminated mostly by urine, minor excretion by sweat or faeces, while sulphate is eliminated mostly by urine.
Acute toxicity	Acute oral toxicity study in rats. Oral LD_{50} = 500 mg/kg bw KMPS was determined. Thereafter classification Acute Tox. 4, H302 is proposed for KMPS. Acute dermal toxicity study in rats. Dermal LD_{50} > 2000 mg/kg bw of KMPS. Thus, KMPS does not warrant classification for acute toxicity via the dermal route. Acute inhalation study in rats. Acute LC_{50} > 5.0 mg/L KMPS. Thus, KMPS does not warrant classification for acute toxicity via the inhalation route.
Corrosion and irritation	KMPS was tested for skin irritation in rabbits for 4 h under occlusive dressing. Severe erythema and oedema of treated skin were observed, which persisted for 72 h after exposure. For erythema, mean score 24-72 h after exposure in all three animals was 4.0. Erythema was irreversible within the post-exposure period of 14 days. Oedema were less severe. The mean scores (24-72 hrs) were 0.67 in two animals and 0.33 in one animal. Oedema completely resolved in 3 days. KMPS was found to be corrosive to the skin of rabbits. The classification as Skin Corr. 1, H314, is proposed for KMPS. KMPS was tested in two skin sensitisation/irritation human volunteer studies. In the first study, 109 participants received 7100 ppm KMPS for 24 hrs under occlusion for 4 days/week for 3 week. In the second study 25 volunteers were included per concentration tested and received 12, 150 and 7000 ppm under occlusive conditions. In both studies aqueous solutions containing 7000 or 7100 ppm of KMPS have been demonstrated to be not irritating to human skin when applied for more than 24 h under occlusive conditions, except for 1 participant who

	exhibited signs of mild skin irritation. However, with repeated exposure to KMPS for 24 h under occlusive conditions at 0.71 or 0.70 %, the incidence and severity of skin reactions was increasing. An eye irritation study was performed with KMPS in New Zealand white rabbits. Severe ocular lesions were observed at 1 and 24 hrs after instillation of the test substance. KMPS causes severe eye damage in treated animals. Classification as Eye Dam. 1, H318 is proposed for KMPS; however, no additional labelling with H318 is required due to the classification and labelling of KMPS as Skin Corr. 1, H314. Based on the chemical mode of action of KMPS and on the results obtained in a skin corrosion/irritation study, KMPS can be expected to have respiratory tract irritating potential. KMPS is proposed to be labelled EUH071 (Corrosive to the respiratory tract).
Sensitisation	Guinea pig maximisation test (Magnusson-Kligman test): KMPS is not a skin sensitiser. As KMPS contains impurity dipotassium peroxodisulphate ($K_2S_20_8$) which has a harmonised classification as Skin Sensitiser 1, H317 and Respiratory Sensitiser 1, H334 and is present in a concentration greater than that specified in Table 3.4.6 of Annex I of Regulation (EC) 1272/2008 the active substance KMPS shall be labelled with EUH208 "Contains dipotassium peroxodisulphate (CAS 7727-21-1). May produce an allergic reaction.
Repeated dose toxicity	14-days rat gavage study: NOAEL > 1000 mg/kg bw/day (NOAEC >100 mg/mL) No clinical signs indicative of systemic toxicity were noted. 90-days rat oral study: NOAEL 200 mg/kg bw/day (20 mg/mL), LOAEL: 600 mg/kg bw/day (60 mg/mL) Critical effect: irritation of gastrointestinal tract indicated by clinical signs (salivation, piloerection, abnormal gait, gasping, hunched posture, noisy respiration, wet coat, and paddling of forepaws), decreased body weight, food consumption and food conversion efficiency, thickening of the forestomach and inflammation, oedema, haemorrhage in the mucosal and submucosal areas, epithelial necrosis, ulceration and hyperplasia. 14-days inhalation study: NOAEC for local effects: 0.0014 mg/L (1.4 mg/m³), LOAEC: 0.0101 mg/L (10.1 mg/m³) Critical effect: Local effects on respiratory tract. Clinical signs of ocular and respiratory irritation were noted: Eye irritation (alopecia around the eye, conjunctival swelling, severe opacity, corneal ulceration and haemorrhage, corneal vascularisation, discharge and crusty scab around the eyes) at mid and high test-level; slight lung noise (at high test-level). Microscopic examination revealed the following eye and eyelid lesions: blepharitis, keratitis, corneal vascularisation, iritis, exflammatory exudate in the anterior and posterior chambers of the eye, haemorrhage mainly in the vitreous body of the eye and degeneration of the lens (cataract). The 13-day observation period allowed only partial recovery from ocular effects. The classification as STOT RE 1, H372 ("Causes damage to eyes through prolonged or repeated exposure) is proposed for KMPS.
Genotoxicity	Negative in bacteria reverse mutation assay. KMPS induced a significant increase in the proportions of cells with chromosomal aberrations in both the presence and absence of S9 mix,

	indicating its clastogenic activity. In a first mammalian gene mutation assay (Mouse lymphoma L5178Y cells (TK±)), KMPS significantly increased frequencies of gene mutations in the presence or absence of S9 mix. However, in a recently conducted second, fully guideline compliant assay, performed at higher doses as the first assay, KMPS was not mutagenic nor genotoxic *in vitro*. No increase in formation of micronuclei was seen in an *in vivo* mouse micronucleus assay. An *in vivo* Comet assay in rats was negative both at the first sites of contact (glandular stomach, forestomach and duodenum) and systemically (liver). KMPS is genotoxic *in vitro*, but not *in vivo*.
Carcinogenicity	No study performed. Waiving is justified.
Reproductive toxicity	No two-generation reproductive study was performed. Waiving is justified. Rat developmental study: Maternal/fetal NOAEL: 250 mg/kg bw/day (corresponding to a NOAEC 25 mg/mL) Maternal/fetal LOAEL 750 mg/kg bw/day (corresponding to a LOAEC 75 mg/mL); based on body weight gain, food consumption and stomach findings. Developmental NOAEL ≥ 750 mg/kg bw/day (corresponding to a NOAEC 75 mg/mL), LOAEL not determined KMPS was not teratogenic to rat foetuses. Rabbit developmental study not performed. Waiving is justified.
Neurotoxicity	No study performed. Waiving is justified.
Immunotoxicity	No study performed. Waiving is justified.
Disruption of the endocrine system	KMPS is not assumed to be an endocrine disrupting chemical.
Other effects	No other effects were reported.

Reference values

	Study	**NOAEL/ LOAEL**	**Overall assessment factor**	**Value**
Inhalation AEC	14-day inhalation study in rat (KMPS tested as aerosol dust)	NOAEC: 1.4 mg/m^3 (0.0014 mg/L) LOAEC: 10.1 mg/m^3 (0.0101 mg/L)	8	0.175 mg/m^3

Due to rapid dissociation of KMPS at first contact site in organism into potassium and sulphate ions and lack of primary systemically toxic effects after exposure to KMPS no systemic reference values were derived for KMPS. It was agreed at WG I 2023 that NOAEC values are considered unnecessary due to the risk management measures that will be applied due to the classification of KMPS for corrosive properties. Therefore, only $AEC_{inhalation}$ has been derived. The $AEC_{inhalation}$ value of 0.175 mg/m^3 concerns the active substance as manufactured.

Risk characterisation

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Brief description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
PT2 - Disinfectants and algaecides not intended for direct application to humans or animals			
2.1.1	Mixing & loading of granules – manual placing	Primary exposure of professionals during manual placing of KMPS granules (50 % KMPS) into dosing device.	professionals
2.1.2	Mixing & loading of granules – manual dosing	Primary exposure of professionals during manual dosing and dissolving of KMPS granules (50 % KMPS).	professionals
2.2.1	Application - Pool disinfection	Primary exposure of professionals during automated dosing of KMPS solution into pool water.	professionals
2.2.2	Application – Dipping of equipment	Primary exposure of professionals during dipping of equipment in the treatment solution.	professionals
2.2.3	Application - Wiping	Primary exposure of professionals during wiping of surfaces in industrial areas with a mop.	professionals
2.2.4	Application - Spraying	Primary exposure of professionals during manual spraying of KMPS solution onto surfaces in industrial areas at low pressure.	professionals
2.3.1	Post-application – Handling empty containers	Primary exposure during handling of empty containers.	professionals
2.3.2	Post-application – Disposal of treatment solution	Primary exposure of professionals during disposal of treatment solution (emptying of dipping bath, bucket/spray equipment).	professionals
3.1	Mixing & loading of tabs – manual dosing	Primary exposure during manual dosing of KMPS tabs (50 % KMPS) into pool water.	non-professionals

3.2	Application - Pool disinfection	The application of KMPS is the manual dosing of KMPS tabs in the pool water; no additional application phase exists.	non-professionals
3.3	Post-application – Handling empty containers	Primary exposure during handling of empty containers.	non-professionals
4.1	Secondary exposure: Bystander during mixing & loading of granules - manual placing	Secondary inhalation exposure of professional bystanders during manual placing of KMPS granules (50 % KMPS).	professional bystander
4.2	Secondary exposure: Bystander during dipping	Secondary inhalation exposure of bystanders during disinfection of equipment by dipping.	professional bystander
4.3	Secondary exposure: Bystander during wiping	Secondary inhalation exposure of bystanders during surface disinfection by wiping with mop.	professional bystander
4.4	Secondary exposure: Bystander during spraying	Secondary inhalation exposure of bystanders during surface disinfection by manual spraying.	professional bystander
4.5	Secondary exposure: Swim instructor	Secondary inhalation exposure of a swim instructor supervising swimmers.	professional bystander
4.6	Secondary exposure: Swimming in pool	Secondary oral, dermal and inhalation exposure of general public (adult, child, baby) when swimming in disinfected pool water.	general public
PT3- Veterinary hygiene			
2.1	Mixing & loading of granules – manual dosing	Primary exposure of professionals during manual dosing and dissolving of KMPS granules (50 % KMPS).	professionals
2.2.1	Application - Spraying	Primary exposure of professionals during manual spraying of animal houses at low pressure.	professionals
2.2.2	Application – Foot dips	Primary exposure of professionals during disinfection of boots in foot dips.	professionals

2.3.1	Post-application – Handling empty containers	Primary exposure during handling of empty containers.	professionals
2.3.2	Post-application – Disposal of treatment solution	Primary exposure of professionals during disposal of treatment solution (emptying of spray equipment, foot dip).	professionals
4.1	Secondary exposure: Bystander during spraying	Secondary inhalation exposure of bystanders during terminal disinfection of animal houses using a low pressure sprayer.	professional bystander
PT4 - Food and feed area			
2.1	Mixing & loading of granules – manual dosing	Primary exposure of professionals during manual dosing and dissolving of KMPS granules (50 % KMPS).	professionals
2.2.1	Application - Wiping	Primary exposure of professionals during wiping of surfaces in food and feed areas with a mop.	professionals
2.2.2	Application - Spraying	Primary exposure of professionals during manual spraying of KMPS solution onto surfaces in food and feed areas at low pressure.	professionals
2.3.1	Post-application – Handling empty containers	Primary exposure during handling of empty containers.	professionals
2.3.2	Post-application – Disposal of treatment solution	Primary exposure of professionals during disposal of treatment solution (emptying of bucket, spray equipment).	professionals
4.1	Secondary exposure: Bystander during wiping	Secondary inhalation exposure of bystanders during surface disinfection by wiping with mop.	professional bystander
4.2	Secondary exposure: Bystander during spraying	Secondary inhalation exposure of bystanders during surface disinfection by manual spraying.	professional bystander
PT5 - Drinking water			

2.1	Mixing & loading of granules – manual placing	Primary exposure of professionals during manual placing of KMPS granules (50 % KMPS) into dose header tank or dosing system.	professionals
2.2	Application – Water disinfection	The product is added directly into the dose header tank or dosing system; no additional application phase exists.	professionals
2.3	Post-application – Handling empty containers	Primary exposure during handling of empty containers.	professionals
4.1	Secondary exposure: Bystander during mixing & loading of granules – manual placing	Secondary inhalation exposure of professional bystanders during manual placing of KMPS granules (50 % KMPS).	professional bystander
4.2	Secondary exposure: Dermal contact to treated water	Secondary dermal exposure of professionals when in contact with treated animal drinking water.	professionals

Conclusion of risk characterisation for professional user

Scenario, Tier, RPE	Relevant reference value	External inhalation exposure mg /m³	Estimated exposure/ long-term AEC_{inh} (%)	Acceptable (yes/no)
PT2 - Disinfectants and algaecides not intended for direct application to humans or animals				
Mixing & loading of granules – manual placing, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m³	0.86	491	No
Mixing & loading of granules – manual placing, Tier 2, RPE10	$AEC_{inhalation}$ 0.175 mg/m³	0.086	49	Yes
Mixing & loading of granules – manual placing, Tier 3, RPE4	$AEC_{inhalation}$ 0.175 mg/m³	0.063	36	Yes
Mixing & loading of granules – manual dosing, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m³	n.r.	n.r.	Yes
Application – Pool disinfection, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m³	n.r. (automated dosing)	n.r. (automated dosing)	Yes
Application – Dipping of equipment, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m³	0.001	0.6	Yes
Application – Wiping, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m³	0.11	65	Yes
Application – Spraying, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m³	0.52	297	No
Application – Spraying, Tier 2, RPE4	$AEC_{inhalation}$ 0.175 mg/m³	0.13	74	Yes
Post-application – Handling empty containers, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m³	n.r. (negligible)	n.r. (negligible)	Yes
Post-application – Disposal of treatment solution, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m³	0.005	3	Yes

PT3- Veterinary hygiene				
Mixing & loading of granules – manual dosing, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	n.r. (negligible)	n.r.	Yes
Application – Spraying, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	0.61	347	No
Application – Spraying, Tier 2, RPE4	$AEC_{inhalation}$ 0.175 mg/m^3	0.15	87	Yes
Application – Foot dips, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	n.r.	n.r.	Yes
Post-application – Handling empty containers, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	n.r. (negligible)	n.r. (negligible)	Yes
Post-application – Disposal of treatment solution, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	0.008	4	Yes
PT4 - Food and feed area				
Mixing & loading of granules – manual dosing, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	n.r. (negligible)	n.r.	Yes
Application – Wiping, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	0.11	65	Yes
Application – Spraying, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	0.52	297	No
Application – Spraying, Tier 2, RPE4	$AEC_{inhalation}$ 0.175 mg/m^3	0.13	74	Yes
Post-application – Handling empty containers, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	n.r. (negligible)	n.r.	Yes
Post-application – Disposal of treatment solution, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	0.005	3	Yes

PT5 - Drinking water				
Mixing & loading of granules – manual dumping, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	0.86	491	No
Mixing & loading of granules – manual dumping, Tier 2, RPE 10	$AEC_{inhalation}$ 0.175 mg/m^3	0.086	49	Yes
Mixing & loading of granules – manual dumping, Tier 2, RPE 4	$AEC_{inhalation}$ 0.175 mg/m^3	0.063	36	Yes
Application – Water disinfection, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	n.r. (automated dosing)	n.r. (automated dosing)	Yes
Post-application – Handling empty containers, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	n.r. (negligible)	n.r. (negligible)	Yes

Where it was concluded that RPE is needed for in-use concentrations, the goggles should be used due to the classification STOT RE 1, H372 (eyes):
- PT2: Application – Spraying,
- PT3: Application – Spraying,
- PT4: Application – Spraying.

Scenario	**Generic concentration limit for skin and eye irritation**	**Deposit on skin**	**Acceptable** (yes/no)
PT2 - Disinfectants and algaecides not intended for direct application to humans or animals			
Mixing & loading of granules – manual placing	1 %	50 %	Yes, with PPE (protective gloves, coverall and goggles)
Mixing & loading of granules – manual dosing	1 %	50 %	Yes, with PPE (protective gloves, coverall and goggles)
Application – Pool disinfection	1 %	n.r. (automated dosing)	Yes
Application – Dipping of equipment	1 %	0.5 %	Yes
Application – Wiping	1 %	0.5 %	Yes
Application – Spraying	1 %	0.5 %	Yes
Post-application – Handling empty containers	1 %	n.r. (negligible)	Yes
Post-application – Disposal of treatment solution	1 %	0.5 %	Yes
PT3- Veterinary hygiene			
Mixing & loading of granules – manual placing	1 %	50 %	Yes, with PPE (protective gloves, coverall and goggles)

Application – Spraying	1 %	0.8 %	Yes
Application – Foot dips	1 %	0.8 %	Yes
Post-application – Handling empty containers	1 %	n.r. (negligible)	Yes
Post-application – Disposal of treatment solution	1 %	0.8 %	Yes
PT4 - Food and feed area			
Mixing & loading of granules – manual placing	1 %	50 %	Yes, with PPE (protective gloves, coverall and goggles)
Application – Wiping	1 %	0.5 %	Yes
Application – Spraying	1 %	0.5 %	Yes
Post-application – Handling empty containers	1 %	n.r. (negligible)	Yes
Post-application – Disposal of treatment solution	1 %	0.5 %	Yes
PT5 - Drinking water			
Mixing & loading of granules – manual dumping	1 %	50%	Yes, with PPE (protective gloves, coverall and goggles)
Application – Water disinfection	1 %	n.r. (automated dosing)	Yes
Post-application – Handling empty containers	1 %	n.r. (negligible)	Yes

Conclusion of risk characterisation for non-professional user

Scenario, Tier, RPE	**Relevant reference value**	**External inhalation exposure** mg /m^3	**Estimated exposure/ long-term AEC$_{inh}$** (%)	**Acceptable** (yes/no)
PT2 - Disinfectants and algaecides not intended for direct application to humans or animals				
Mixing & loading of tabs – manual dosing, Tier 1, no RPE	AEC$_{inhalation}$ 0.175 mg/m^3	n.r. (negligible)	n.r. (negligible)	Yes
Application – Pool disinfection, Tier 1, no RPE	AEC$_{inhalation}$ 0.175 mg/m^3	n.r.	n.r.	Yes
Post-application – Handling empty containers, Tier 1, no PPE	AEC$_{inhalation}$ 0.175 mg/m^3	n.r. (negligible)	n.r. (negligible)	Yes

Scenario	**Generic concentration limit for skin and eye irritation**	**Deposit on skin**	**Acceptable** (yes/no)
PT2 - Disinfectants and algaecides not intended for direct application to humans or animals			
Mixing & loading of tabs – manual dosing	1 %	50 %	Yes, with product integrated RMM (labelling according to CLP, clear

			instructions for use and storage, product formulation that reduces dusting (e.g. granules, tablets, water soluble packaging, films covering surface), child proof closure, small package size, dose scoop or tool delivered with the product)
Application – Pool disinfection	1 %	n.r.	Yes
Post-application – Handling empty containers	1 %	n.r. (negligible)	Yes

Conclusion of risk characterisation for indirect exposure

Scenario, Tier, RPE	**Relevant reference value**	**External inhalation exposure** mg /m^3	**Estimated exposure/ long-term AEC$_{inh}$** (%)	**Acceptable** (yes/no)
PT2 - Disinfectants and algaecides not intended for direct application to humans or animals				
Bystander during mixing & loading of granules – manual placing, Tier 1, no RPE	AEC$_{inhalation}$ 0.175 mg/m^3	0.86	491	No
Bystander during mixing & loading of granules – manual placing, Tier 2, RPE10*	AEC$_{inhalation}$ 0.175 mg/m^3	0.086	49	Yes
Bystander during mixing & loading of granules – manual placing, Tier 3, RPE4*	AEC$_{inhalation}$ 0.175 mg/m^3	0.063	36	Yes
Bystander during dipping, Tier 1, no RPE	AEC$_{inhalation}$ 0.175 mg/m^3	0.001	0.6	Yes
Bystander during wiping, Tier 1, no RPE	AEC$_{inhalation}$ 0.175 mg/m^3	0.11	65	Yes
Bystander during spraying, Tier 1, no RPE	AEC$_{inhalation}$ 0.175 mg/m^3	0.52	297	No
Bystander during spraying, Tier 2, RPE4*	AEC$_{inhalation}$ 0.175 mg/m^3	0.13	74	Yes
Swim instructor, Tier 1, no RPE	AEC$_{inhalation}$ 0.175 mg/m^3	n.r.	n.r.	Yes
Swimming in the pool, Tier 1, no RPE	AEC$_{inhalation}$ 0.175 mg/m^3	n.r.	n.r.	Yes
PT3- Veterinary hygiene				

Bystander during spraying, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	0.61	347	No
Bystander during spraying, Tier 2, RPE4*	$AEC_{inhalation}$ 0.175 mg/m^3	0.15	87	Yes
PT4 - Food and feed area				
Bystander during wiping, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	0.11	65	Yes
Bystander during spraying, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	0.52	297	No
Bystander during spraying, Tier 2, RPE4*	$AEC_{inhalation}$ 0.175 mg/m^3	0.13	74	Yes
PT5 - Drinking water				
Bystander during mixing & loading of granules – manual placing, Tier 1, no RPE	$AEC_{inhalation}$ 0.175 mg/m^3	0.86	491	No
Bystander during mixing & loading of granules – manual placing, Tier 2, RPE10*	$AEC_{inhalation}$ 0.175 mg/m^3	0.086	49	Yes
Bystander during mixing & loading of granules – manual placing, Tier 2, RPE4*	$AEC_{inhalation}$ 0.175 mg/m^3	0.063	36	Yes

* For professional bystanders, the same set of RMM/PPE is assumed as for the worker performing the task.

Where it was concluded that RPE is needed for in-use concentrations, the goggles should be used due to the classification STOT RE 1, H372 (eyes):
- PT2: Application – Spraying,
- PT3: Application – Spraying,
- PT4: Application – Spraying.

Scenario	**Generic concentration limit for skin and eye irritation**	**Deposit on skin**	**Acceptable** (yes/no)
PT2 - Disinfectants and algaecides not intended for direct application to humans or animals			
Bystander during mixing & loading of tabs – manual placing	1 %	n.r.	Yes
Bystander during dipping, Tier 1	1 %	n.r.	Yes
Bystander during wiping, Tier 1	1 %	n.r.	Yes

Bystander during spraying, Tier 1	1 %	n.r.	Yes
Swim instructor, Tier 1	1 %	0.013 %	Yes
Swimming in the pool	1 %	0.013 %	Yes
PT3- Veterinary hygiene			
Bystander during spraying	1 %	n.r.	Yes
PT4 - Food and feed area			
Bystander during wiping	1 %	n.r.	Yes
Bystander during spraying	1 %	n.r.	Yes
PT5 - Drinking water			
Bystander during mixing & loading of granules – manual placing	1 %	n.r.	Yes
Dermal contact with treated water	1 %	0.08 %	Yes

Conclusion of risk characterisation for dietary exposure

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation. Only the breakdown products K^+ and SO_4^{2-} ions will remain to become systemically available, and are thus the only relevant species for toxicokinetic and metabolic considerations. As both breakdown products (i.e. potassium ions and sulphate ions) constitute physiologically essential metabolites in the human body which are efficiently excreted via the urine after oral uptake, no assessment of systemic livestock and dietary exposure is deemed necessary for intended uses in PT3, PT4 and PT5.

3 SUMMARY OF THE ENVIRONMENTAL RISK ASSESSMENT

Fate and behaviour in the environment

Summary table on compartments exposed and assessed		
Compartment	**Exposed (Y/N)**	**Assessed (Y/N)**
STP	Y	Y
Surface water	Y	Y
Sediment	Y	Y
Soil	Y	Y
Groundwater	Y	Y
Air	Y	Y

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	614.76	g/mol	
Vapour pressure (at 20°C)	$1.2 \cdot 10^{-4}$	Pa	
Water solubility (at 20°C)	$3.64 \cdot 10^{5}$	mg/L	
Henry's law constant (at 20°C)	$2.04 \cdot 10^{-7}$	$Pa \cdot m^3 \cdot mol^{-1}$	
Log10 Octanol/water partition coefficient	-3.90	-	Calculated value
DT_{50} for degradation in STP	0.844	h (at 12 ºC)	Geometric mean value
DT_{50} for degradation in manure/slurry	0.844	h (at 12 ºC)	Geometric mean value
DT_{50} for hydrolysis in surface water	6.04	day (at 20 ºC)	Corresponds to 145 h
DT_{50} for degradation in soil	1	hr (at 12 ºC)	Geometric mean value
DT_{50} for degradation in air	96	hr	

Effects assessment

Summary table on calculated PNEC values	
Compartment	**PNEC**
Freshwater	0.0222 mg/L
Freshwater (intermittent release)	0.087 mg/L
Saltwater	0.00222 mg/L
STP	1 mg/L
Soil	0.00265 mg/kg wwt

Exposure assessment

Summary table on calculated PEC values						
Scenario	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**$PEC_{soil/STP}$**	**$PEC_{soil/slurry}$**	**PEC_{air}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/ kg_{wwt}]	[mg/ kg_{wwt}]	[mg/m^2]
PT2a, public swimming pool, chronic release	4.22E-02	4.22E-03	3.31E-03	4.01E-08	n.r	1.87E-13
PT2a, public swimming pool, acute release	5.57E-01	5.57E-02	4.37E-02	5.29E-07	n.r	2.47E-12
PT2b, private swimming pools, chronic release, S-EU	3.98E-01	3.98E-02	3.13E-02	3.78E-07	n.r	1.77E-12
PT2b, private swimming pools, chronic release, N-EU	7.24E-02	7.24E-03	5.68E-03	6.87E-08	n.r	3.21E-13
PT2b, private swimming pools, acute release, S-EU	1.67E-01	1.67E-02	1.31E-02	1.59E-07	n.r	7.42E-13
PT2b, private swimming pools, acute release, N-EU	3.34E-02	3.34E-03	2.62E-03	3.17E-08	n.r	1.48E-13
PT2c, surface disinfection of industrial areas	8.12E-03	8.12E-04	6.37E-04	7.70E-09	n.r	3.60E-14
PT2d, disinfection of equipment by dipping, other instruments	2.61E-02	2.61E-03	2.05E-03	2.48E-08	n.r	1.16E-13

PT2d, disinfection of equipment by dipping, pre-disinfection dipping	2.43E-02	2.43E-03	1.91E-03	2.31E-08	n.r	1.08E-13
PT3a, disinfection of animal housing, STP	6.26E-02	6.26E-03	4.92E-03	5.95E-08	n.r	2.78E-13
PT3a, disinfection of animal housing, slurry/manure // arable land	n.r	n.r	n.r	n.r	2.00E-05	n.r
PT3a, disinfection of animal housing, slurry/manure // grassland	n.r	n.r	n.r	n.r	2.00E-05	n.r
PT3b, disinfection of footwear, STP	1.30E-03	1.30E-04	1.02E-04	1.23E-09	n.r	5.76E-15
PT3b, disinfection of footwear, slurry/manure // arable land	n.r	n.r	n.r	n.r	1.10E-04	n.r
PT3b, disinfection of footwear, slurry/manure // grassland	n.r	n.r	n.r	n.r	1.10E-04	n.r
PT4a, disinfection of slaughterhouses and butcheries	8.12E-02	8.12E-03	6.37E-03	7.70E-08	n.r	3.60E-13
PT4b, disinfection of large catering kitchens	1.62E-02	1.62E-03	1.27E-03	1.54E-08	n.r	7.21E-14
PT5, disinfection of animal drinking water	Covered by PT 3 scenarios					

Risk characterization

Summary table on calculated PEC/PNEC values			
Scenario	**PEC/PNEC$_{STP}$**	**PEC/PNEC$_{SW}$**	**PEC/PNEC$_{soil}$**
PT2a, public swimming pool, chronic release	4.22E-02	1.90E-01	1.51E-05
PT2a, public swimming pool, acute release	5.57E-01	6.40E-01	2.00E-04
PT2b, private swimming pools, chronic release, S-EU	3.98E-01	**1.79**	1.43E-04
PT2b, private swimming pools, chronic release, N-EU	7.24E-02	3.26E-01	2.59E-05
PT2b, private swimming pools, acute release, S-EU	1.67E-01	1.92E-01	5.99E-05
PT2b, private swimming pools, acute release, N-EU	3.34E-02	3.84E-02	1.20E-05
PT2c, surface disinfection of industrial areas	8.12E-03	3.66E-02	2.91E-06
PT2d, disinfection of equipment by dipping, other instruments	2.61E-02	1.18E-01	9.36E-06
PT2d, disinfection of equipment by dipping, pre-disinfection dipping	2.43E-02	1.10E-01	8.72E-06
PT3a, disinfection of animal housing, STP	6.26E-02	2.82E-01	2.24E-05
PT3a, disinfection of animal housing, slurry/manure // arable land	n.r	n.r	7.56E-03
PT3a, disinfection of animal housing, slurry/manure // grassland	n.r	n.r	7.56E-03
PT3b, disinfection of footwear, STP	1.30E-03	5.85E-03	4.65E-07
PT3b, disinfection of footwear, slurry/manure // arable land	n.r	n.r	4.16E-02
PT3b, disinfection of footwear, slurry/manure // grassland	n.r	n.r	4.16E-02
PT4a, disinfection of slaughterhouses and butcheries	8.12E-02	3.66E-01	2.91E-05
PT4b, disinfection of large catering kitchens	1.62E-02	7.31E-02	5.81E-06
PT5, disinfection of animal drinking water	Covered by PT 3 scenarios		

Conclusions

Atmosphere
Risks relevant to biotic and abiotic effects to the atmosphere are negligible due to the low concentrations of KMPS in the air and expected rapid degradation.

Sewage treatment plants
$PEC/PNEC_{STP}$ values calculated from the proposed uses of KMPS as disinfectant in PT 2, 3 and 4 are below 1, indicating acceptable risks to organisms involved in the biological processes of the sewage treatment works. The risk for the use of KMPS in PT5 (Disinfection of animal drinking water) is considered covered by the risk assessments performed for the uses in PT3.

Aquatic compartment
$PEC/PNEC_{sw}$ values calculated from the proposed uses of KMPS as disinfectant in PT 2, 3 and 4 are below 1, indicating acceptable risks to the organisms in the water column (freshwater)), with the exception of chronic emission due to cleaning of filtration systems following use in private swimming pools in the Southern EU scenario (PT2b). The risk for the use of KMPS in PT5 (Disinfection of animal drinking water) is considered covered by the risk assessments performed for the uses in PT3. The physico-chemical properties of KMPS (measured log K_{OW} < 0.3, calculated log K_{OW} = -3.90) and its rapid degradation in surface water suggest that the active substance is not likely to partition into sediment to a significant extent. Given the negligible exposure, the risk to sediment organism can be considered acceptable.

Terrestrial compartment
$PEC/PNEC_{soil}$ values calculated from the proposed uses of KMPS as disinfectant in PT 2, 3 and 4 are below 1. Therefore the risk to the terrestrial environment and hence, soil organisms, from the proposed use of KMPS as disinfectant in PT 2, 3 and 4 is considered acceptable. The risk for the use of KMPS in PT5 (Disinfection of animal drinking water) is considered covered by the risk assessments performed for the uses in PT3.

Groundwater
For inorganic rapidly reacting substances (e.g. substances reacting with organic matter such as e.g. hydrogen peroxide) no groundwater exposure assessment is needed in line with the TAB ENV 208 (November 2021) since it is very unlikely that substance will reach groundwater. Since KMPS is also a peroxide and likewise rapidly reacting than hydrogen peroxide, a quantitative groundwater assessment is not required.

4 ASSESSMENT OF EXCLUSION, SUBSTITUTION CRITERIA AND POP

Conclusion on exclusion criteria	KMPS does not meet the exclusion criteria laid down in Article 5 of BPR.
Conclusion on CMR	KMPS does not fulfil criterion (a), (b) and (c) of Article 5(1) BPR.
Conclusion on ED assessment	KMPS is not considered to have endocrine disrupting properties. KMPS does not fulfil criterion (d) of Article 5(1) BPR.
Conclusion on PBT and vP/vB criteria	KMPS does not fulfil criterion (e) of Article 5(1) BPR.

Conclusion on substitution criteria	KMPS does not meet the substitution criteria laid down in Article 10(1)a-f of BPR.

Conclusion on LRTAP/POP assessment	KMPS does not fulfil criteria for LRTAP/POP.

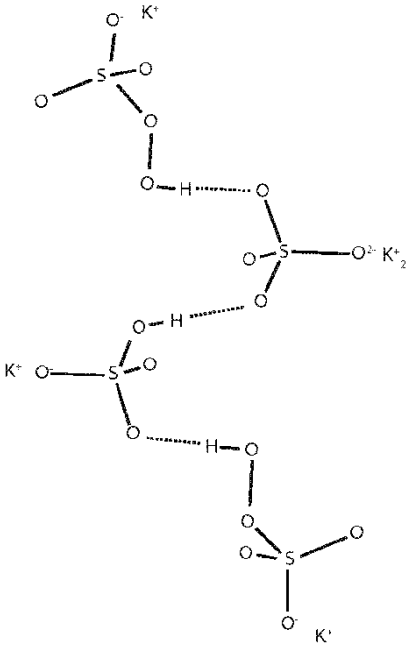
Part A Assessment of intrinsic properties and effects of the active substance

1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

Summary table on substance identity	
Common name (ISO name, synonyms)	Potassium monopersulfate - KMPS Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) Potassium peroxymonosulfate
Chemical name (IUPAC name)	Pentapotassium bis((hydroperoxysulfonyl)oxidanide) hydrogen sulfate sulfate
EC number	274-778-7
CAS number	70693-62-8
Molecular formula	$K_5H_3S_4O_{18}$
SMILES notation	[K+].[K+].[K+].[K+].[K+].O=S([O-])(=O)OO.[O-]S(=O)(=O)O.[O-]S([O-])(=O)=O.[O-]S(=O)(=O)OO
Molar mass	614.76 g/mol

Structural formula



Method of manufacture
The manufacturing process of KMPS is extremely standardised with very small possibilities of variations. Therefore, the processes of manufacture for both KMPS sources comprise the same steps: manufacture of Caro's acid, neutralization, crystallization, drying and centrifugation. More detailed information is included in the Confidential part of DOC III.

1.2 COMPOSITION OF THE SUBSTANCE (COMMON SPECIFICATIONS)

Main constituents			
Constituent (chemical name)	**Typical concentration (%(w/w))**	**Concentration range (%(w/w))**	**Remarks / Discussion**
Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate)	≥ 89	-	-

Relevant impurity			
Constituent (chemical name)	**Typical concentration (%(w/w))**	**Concentration range (%(w/w))**	**Remarks / Discussion**
Dipotassium peroxodisulphate ($K_2S_2O_8$)	≤ 2	-	-

1.3 PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

Property	Result	Test method applied or description in case of deviation	Remarks / Discussion / Justification for waiving	References
Aggregate state at 20°C and 101.3 kPa	Powder	Visual	KMPS P-16, Batch No.: H-27841, composition (by weight): 99.1%	[redacted] (2007), Doc. No. 119-003 A3.3/01
Physical state (appearance) at 20°C and 101.3 kPa	Solid	Visual	KMPS P-16, Batch No.: H-27841, composition (by weight): 99.1%	[redacted] (2007), Doc. No. 119-003 A3.3/01
Colour at 20°C and 101.3 kPa	White	Visual	KMPS P-16, Batch No.: H-27841, composition (by weight): 99.1%	[redacted] (2007), Doc. No. 119-003 A3.3/01
Odour at 20°C and 101.3 kPa	Odourless	European Standard NF EN 12678	As given in section 4 of NF EN 12678.	Anonymous (2001), Doc. No. 989-001 A3.3/02
Melting point	The substance decomposes before melting. An exothermic peak in the region 140-200 °C has been interpreted as decomposition process.	EC method A.1 (Melting temperature device with metal block)	Oxone® Monopersulfate compound, Batch No.: H-24607, composition (by weight): 99.1% The test substance decomposes before melting and therefore does not possess a melting point under the test conditions.	[redacted] (2002), Doc. No. 119-001 A3.1/01
Boiling point	The test substance does not possess a boiling temperature at normal atmospheric pressure. A single exotherm in the region 140-200 °C, which can be attributed to samples decomposition.	EC method A.2 (Differential scanning calorimetry) OECD Test Guideline103	Oxone® Monopersulfate compound, Batch No.: H-24607, composition (by weight): 99.1%	[redacted] (2002), Doc. No. 119-001 A3.1/01
Relative density	2.35 at 20 °C	EC method A.3 (Pyknometer)	Oxone® Monopersulfate compound, Batch No.: H-24607, composition (by weight): 99.1%	[redacted] (2002), Doc. No. 119-001 A3.1/01

Property	Result	Test method applied or description in case of deviation	Remarks / Discussion / Justification for waiving	References
Vapour pressure	< 1.2 x 10^{-4} Pa at 20 ºC (extrapolated) < 1.7 x 10^{-4} Pa at 25 ºC (extrapolated)	EC method A4 (Effusion method – vapour pressure balance)	Oxone® Monopersulfate compound, Batch No.: H-24607, composition (by weight): 99.1% The test was performed between temperatures of 27 °C and 96 °C. As the readings for the first run were taken close to 25°C, the extrapolated results from this run are taken as the upper limit for the vapour pressure of the test substance. Additionally, the vapour pressure at 20 ºC is calculated by extrapolation.	[redacted] (2002), Doc. No. 119-001 A3.1/01
Henry's law constant	2.04 x 10^{-7} Pa x m³ x mol^{-1}	Calculated	Calculated using the vapour pressure at 20 ºC (<1.21 x 10^{-4} Pa), the molecular mass (614.76 g/mol) and the solubility in water at 20 ºC (364 g/L).	[redacted] (2007), A3.2/01
Surface tension	σ = 72.9 mN/m temperature: 23 °C	EC method A.5 OECD Test Guideline 115	KMPS P-16, Batch No.: H-27841, composition (by weight): 99.1%	[redacted] (2007), Doc. No. 119-003 A3.3/01
Water solubility at 20 °C	364 g/L at 20 °C	EC method A6 (Flask method)	Oxone® Monopersulfate compound, Batch No.: H-24607, composition (by weigt): 99.1%	[redacted] (2002), Doc. No. 119-001 A3.1/01
	pH 4: 25-30 % (w/v) pH 7: 25-30 % (w/v) pH 9: 25-30 % (w/v) temperature: 22°C 25-30% (w/v) correspond to 250-300 g/L	OECD Test Guideline 105	KMPS P-16, Batch No.: H-27841, composition (by weight): 99.1%	[redacted] (2007), Doc. No. 119-003 A3.3/01

Property	Result	Test method applied or description in case of deviation	Remarks / Discussion / Justification for waiving	References
Partition coefficient (n-octanol/water) and its pH dependency	log Pow < 0.30 temperature: 20 °C pH: pH dependence of the partition coefficient is not expected as the substance is a salt of strong acid(s) and is completely dissociated in water.	EC method A8 (Flask method)	Oxone® Monopersulfate compound, Batch No.: H-24607, composition (by weight): 99.1%	[redacted] (2002), Doc. No. 119-001 A3.1/01
	Calculated: log Kow = -3.90	Calculated	-	[redacted] (2007) Doc. No. 114-003
Thermal stability and identity of breakdown products	An exotherm peak in the region 140-200 °C has been interpreted as decomposition process. An endotherm peak is in the range 235-250 °C. According to the results, the product is not thermally stable. The identity of breakdown products is not known.	OPPTS 830.6313	KMPS P-16, Batch No.: H-24607, composition (by weight): 99.1%	[redacted] (2002), Doc. No. 119-001 A3.1/01
Reactivity towards container material	Packaging, multi-wall plastic lined paper bag, showed no signs of reactivity with the test substance after 12 months at room temperature.	OPPTS 830.6317	KMPS P-16, Batch No.: H-27841, composition (by weight): 99.1%	[redacted] (2008), Doc. No.145-001 A3.17/01
	Packaging, multi-wall plastic lined paper bag, showed no signs of reactivity with the test substance after 14 days at 54 °C.	OPPTS 830.6317 OPPTS 830.6313	KMPS P-16, Batch No.: H-27841, composition (by weight): 99.1%	[redacted] (2007), Doc. No. 119-003 A3.3/02
	Many years of practical commercial experience with KMPS show that the packaging materials used are compatible with the active substance. Furthermore reference is made	-	-	-

Property	Result	Test method applied or description in case of deviation	Remarks / Discussion / Justification for waiving	References
	to UN recommendation dangerous goods edition 15, packaging instructions P002, IBC 08.			
Dissociation constant	pKa1 = 2.47 pKa2 = 7.06 temperature: 25 °C	OPPTS 830.6313	Oxone®, Batch No.: H-28462, composition (by weight): 99.1% The dissociation constants of the test substance were determined at a temperature of 25 °C	[redacted] (2007), Doc. No. 119-004 A3.1/02
Viscositiy	-	-	Not applicable, KMPS is a solid and not a liquid.	-
Solubility in organic solvents, including effect of temperature on solubility	-	-	Due to its oxidising properties, KMPS would react with organic solvents and therefore testing is technically not feasible.	-
Stability in organic solvents used in biocidal products and identity of relevant degradation products	-	-	Due to the reactivity of KMPS with organic solvents, it is not possible to formulate stable biocidal products of KMPS with organic solvents.	-
Absorption spectra data UV/VIS IR	The recorded UV/VIS-spectra confirm the molecular structure.	OPPTS 830.7050	Oxone®, Batch No.: H-28462, composition (by weight): 99.1% Three different UV/VIS-spectra were run with the test substance: a. in water overlaid on water blank b. in acid (pH=1) overlaid on acid blank c. in base (pH=13) overlaid on base blank	[redacted] (2007), Doc. No. 119-004 A3.1/02

Property	Result	Test method applied or description in case of deviation	Remarks / Discussion / Justification for waiving	References
NMR MS	A FTIR-spectrum confirms the molecular structure.		Oxone®, Batch No.: H-28462, composition (by weight): 99.1% The FTIR-spectrum of the test substance in a KBr pellet was recorded. 1H/13C NMR spectral methods are not applicable A MS spectral method is not applicable for peroxides.	

1.4 PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS

Property	Result	Test method applied or description in case of deviation*	Remarks / Discussion / Justification for waiving	References
Explosives	No positive results were obtained for the test substance in 21 successive drop impact tests conducted from a height of 140 cm.	EC method A.14: Test of Mechanical Sensitivity with Respect to Shock	Oxone® P16, Batch No.: H-27841, composition (by weight): 99.1% The test substance was not found to be sensitive to thermal, friction or impact stimuli. KMPS is not explosive.	[redacted] (2007), Doc. No. 141-001 A3.15/01
	No positive results were obtained for the test substance in any of the 6 trials.	EC method A.14: Test of Mechanical Sensitivity with respect to Friction		
	No explosions were observed for the test substance with 2 mm diameter orifice plates.	EC method A.14: Test of Thermal Sensitivity		
Flammable gases	Not applicable, the active substance is a solid.			
Flammable aerosols	Not applicable, the active substance is a solid.			
Oxidising gases	Not applicable, the active substance is a solid.			
Gases under pressure	Not applicable, the active substance is a solid.			
Flammable liquids	Not applicable, the active substance is a solid.			
Flammable solids	Neither ignitability nor combustion propagation by the KMPS was detected.	EC method A.10: Flammability (solids)	Oxone®, Batch No.: H-28462, composition (by weight): 99.1% KMPS did not ignite and propagate combustion, therefore it is not	[redacted] (2007), Doc. No. 119-004 A3.1/02

Property	Result	Test method applied or description in case of deviation*	Remarks / Discussion / Justification for waiving	References
			considered to be highly flammable.	
Self-reactive substances and mixture	Non-submission justification. Self-reactive properties, self-heating behavior, auto-ignitability and explosivity are the consequence of the same phenomenon, although with different times scales ($e.g$ fast kinetics for explosions versus moderate kinetics for self-heating reactions) and magnitude of hazards, described in the case of solids by the Frank-Kamenetzky theory: accumulation of energy in the system by excess of the rate of energy released by chemical reactions (Arrhenius term) with respect to the rate of dissipation (function of thermal conductivity of the substance and of the packaging), represented by the Damköhler number. $KMPS$ does not possess self-reactive properties to be classified in any of the A-H types of the Class 4, Division 4.1 based on: 1. Short-time exothermic event independent of temperature: an indistinguishable feature of substances undergoing self-decomposition reactions is the exponential acceleration of the kinetics with temperature. The results of the study shown in Doc. No. 141-0001 "KMPS: LABORATORY STUDY OF RELATIVE SELFIGNITION TEMPERATURE" show a short exothermic event in the temperature-time plane with an onset T < 150 °C and maximum energy release at T < 300 °C followed by abrupt relaxation to thermal equilibrium with oven temperature. No evolution of self-accelerating energy release was detected in the temperature ramping during the test. Instead of it, two endothermic signals were registered (probably fusion of part of the triple salt components, rearrangement of the crystalline structure). 2. Thermodynamic limitation of combustion reactions: $KMPS$ is a strong oxidizing agent with a reduction potential much higher than oxygen or even hydrogen peroxide (redox potential E°_{KMPS}>1.8 V). Combustion reactions (principal source of systems experiencing thermal runways) are not possible: oxygen does not have sufficient oxidative power compared to $KMPS$. The nature of the exothermic event in the self-ignitability study is likely to be associated with less energetic reactions such as homolytic cleavages of the O-O bond. The presence of a single short-lived exothermic signal with no exponential increase with temperature in test A.16 and the thermodynamic limitation of exothermic reactions with oxidizing species such as Oxygen ($E^{\circ}_{KMPS} > E^{\circ}_{O_2}$) exclude the possibility of self-reactive character in $KMPS$. Therefore, the tests designed for A-H types of Class 4, Division 4.1 are not scientifically necessary.			
Pyrophoric liquids	Non-submission justification. The data for this endpoint is not applicable based on the definition set up in the section 2.13.2 of the Guidance on the Application of the CLP Criteria: the active substance is not a liquid.			
Pyrophoric solids	Ignition times ≤ 5 min.	EC method A.13: Pyrophoric properties of solids and liquids	Oxone®, Batch No.: H-28462, composition (by weight): 99.1%	[redacted] (2007), Doc. No. 119-004 A3.1/02

Property	Result	Test method applied or description in case of deviation*	Remarks / Discussion / Justification for waiving	References
			The pyrophoric properties of the test substance were determined at a temperature of 21 °C. The substance is not ignitable.	
Self-heating substances and mixtures	Non-submission justification. The absence of self-heating properties in $KMPS$ is supported by the outcome in following test of Regulation 440/2008 : Method A.10. Flammability (solids): negative ([redacted] 2007) Method A.16. Relative self-ignition temperature for solids: negative ([redacted] 2008) Method A.17. Oxidizing solids: negative (Turner, B. 2003). All test cited above show negative results, not indicating any hazardous situations. In particular, continuing temperature rise characteristic of self-heating materials were absent in the method A.16, where only a weak, short-lived exothermic signal at T = 127 °C was detected. The classical equation for temperature rise in self-heating substances is given below: $$V\rho\frac{dT}{dt} = \Delta HV\rho Ae^{\left(-\frac{E_A}{RT}\right)} - \frac{Sh}{V\rho}(T - T_0)$$ with $\Delta H =$ change in enthalpy during chemical reaction, V = volume enclosing the material, ρ = density of the material, E_A = activation energy, S = surface area enclosing the material, h = heat transfer coefficient and T_0 is the initial temperature. The Arrhenius term, fingerprint of this hazard, is not present in the outcome of $KMPS$ tested at temperatures up to 400 °C (far above the indicated maximum temperatures in self-heating test): $KMPS$ does not exhibit self-heating properties.			
Substances and mixtures which in contact with water emit flammable gases	Maximum generation of 6 mL of non-flammable gases per 10 g of sample. KMPS is not hazardous when in contact with water.	EC method A.12 Flammability (contact with water)	Oxone®, Batch No.: H-28462, composition (by weight): 99.1% The flammability (contact with water) of the test substance was determined at a temperature of 22 °C.	[redacted] (2007), Doc. No. 119-004 A3.1/02

Property	Result	Test method applied or description in case of deviation*	Remarks / Discussion / Justification for waiving	References
			The substance in contact with water does not emit flammable gases.	
Oxidising liquids	Non-submission justification. The data for this endpoint is not applicable based on the definition set up in the section 2.13.2 of the Guidance on the Application of the CLP Criteria: the active substance is not a liquid.			
Oxidising solids	Incomplete burning of cellulose mixtures.	EC method A.17: Oxidising properties (solids)	Oxone®, Batch No.: H-24607, composition (by weight): 99.1%	[redacted] (2003), Doc. No. 143-003 A3.16/01
	Does not ignite and burn. Mean burning time greater than that of a 3:7 mixture (by mass) of potassium bromate and cellulose.	UN Test O.1 (Manual of Tests and Criteria 2nd revised version)	The test substance samples did not burn to completion and therefore exceeded the burning time of the 3:7 ratio of the reference substance. No oxidising solid.	[redacted] (2002) Doc. No.: 143-001 A3.16/02
Organic peroxide	The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.			
Corrosive to metals	Non-submission justification. According to section 2.16.4.1of CLP, "only substances and mixtures for which the application of the UN Test C.1 (described in part III, Section 37.4.1.1 of the UN-MTC) is relevant and needs to be considered. Only solids having a melting point lower than 55 °C must be tested. A screening of the temperature for solid-liquid phase transition of the three components in the triple salt KMPS was performed. All components have melting point above 55 °C.			
Auto-ignition temperature (liquids and gases)	Non-submission justification. The data for this endpoint is not applicable based on the description set up in the section 1.1 of the Method A.15: the active substance is not a liquid or gas.			
Relative self ignition	Maximum sample temperature	EC method A.16: Relative self-	Maximum sample temperature	[redacted] (2008),

Property	Result	Test method applied or description in case of deviation*	Remarks / Discussion / Justification for waiving	References
temperature for solids	during the test (diagram Temperature-time in Appendix 2 of the study report) is T_{sample}=275°C.	ignition temperature for solids	during the test (diagram Temperature-time in Appendix 2 of the study report) is T_{sample} = 275 °C.	Doc. No. 142-001 A3.11/01
Dust explosion hazard	Not applicable	Not applicable	The study does not need to be conducted because the substance is not a dust.	Not applicable

*General remark: Physical hazards and respective characteristics were not tested according to the UN Recommendation on the Transport and Dangerous Goods required in the BPR, since the dossier was submitted according to the BPD requirements.

1.5 HAZARD IDENTIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

The active substance KMPS is an inorganic salt with a very low vapour pressure and it does not evolve highly flammable gases. It did not ignite and propagate combustion; therefore it is not considered to be highly flammable. The test substance KMPS is not hazardous when in contact with water. The test substance KMPS was also not found to:
- be sensitive to thermal, friction or impact stimuli,
- possess oxidising properties,
- be a self-heating material,
- be pyrophoric.

There is no hazard identified associated to the physico-chemical properties of the active substance KMPS.

1.6 ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

1.6.1 Analysis of the active substance as manufactured

Analytical methods are available in the confidential appendix.

1.6.2 Residue analysis

KMPS is an inorganic salt with an ionic structure which is readily soluble in water and will therefore dissociate completely in aqueous solution. KMPS can be characterised by a very low vapour pressure (<1.7 x 10^{-4} Pa at 25 °C), a calculated Henry's Law Constant (2.04 x 10^{-7} Pa x m³ x mol-1) and a partition coefficient n-octanol/water (< 0.30 measured at 20°C and -3.90 calculated).

Furthermore KMPS dissipates quickly to potassium ions, hydrogensulfate ions, oxygen and water. These substances are ubiquitous and of no particular concern.

Residues in water

An analytical method identifying residues of KMPS in water was not developed. Because of the unstable nature of KMPS and the innocuousness of its decomposition products, as described above, the development of such a method was considered as being scientifically not justified.

Residues in soil

In addition to the above said and to the fact that soil is not a relevant compartment for KMPS, it could be shown that KMPS decomposes rapidly in soil by getting into contact with organic and catalytic substances present in the soil. DT_{50} values were found to be < 11 minutes (see Doc IIIA section 7.2.1). No analytical method for the detection and identification of residues of KMPS in soil is therefore necessary.

Residues in air

The active substance is not volatile, but the presence in air because of dusting or formation of aerosols during spraying cannot be excluded.
Regarding dust formation an analytical method to measure dust exposure is available: NIOSH 0500 (https://www.cdc.gov/niosh/docs/2003-154/pdfs/0500.pdf). This method is commonly used for Industry Hygiene practices.
Since a monitoring method in air is required for spray applications according to the guidance, but not available, therefore the method has been required by the APCP WG.

Residues in food

Given the unstable nature of KMPS, considering its phys.-chem. parameters it can be concluded that KMPS does not bioaccumulate and is therefore not expected to concentrate in the food chain. The development of an analytical method for detection of residues of KMPS in or on food or feedstuffs was consequently considered as being scientifically not justified.

Residues in body fluids

KMPS is an unstable inorganic salt with no indication that the substance is to be classified

as very toxic or toxic. The development of an analytical method for the detection and identification of KMPS in in animal and human body fluids and tissues is therefore not necessary.

2 EFFECTS AGAINST TARGET ORGANISMS

2.1 FUNCTION AND FIELD OF USE ENVISAGED

The active substance KMPS shows a broad spectrum of antimicrobial activity and can function as a bactericide, yeasticide, fungicide and virucide. The uses assessed in the dossier are from the Main Group 1: Disinfectants, for the Product Types 2, 3, 4 and 5 (see table below).

KMPS is intended to be used by professional users to control pathogenic microorganisms causing infectious diseases of man and animals and to avoid contamination and consequently spoiling of food or feed. KMPS can be used by non-professional users (general public) for the disinfection of swimming pools only.

MG/PT	**Field of use envisaged**	**Likely concentration at which KMPS will be used**
MG01/PT2	Disinfection of swimming pools - professional and non-professional (general public) use	Shock-dosing: 500 mg/L pool water Maintaining dose: 130 mg/L pool water
	Dipping of equipment - professional use	5 g/L
	Surface disinfection of industrial areas by wiping with mop - professional use	5 g/L
	Surface disinfection of industrial areas by manual spraying (low pressure) - professional use	5 g/L
MG01/PT3	Terminal disinfection of animal houses using a low pressure sprayer - professional use	8 g/L
	Foot dips - professional use	8 g/L
MG01/PT4	Surface disinfection of food and feeding areas by wiping with mop - professional use	5 g/L
	Surface disinfection of food and feeding areas by manual spraying (low pressure) - professional use	5 g/L
MG01/PT5	Animal drinking water: continuous water sanitation by dosing the header tank or application via a dosing system - professional use	0.8 g/L

2.2 INTENDED USES

PT2:

Summary table of intended uses	
Product Type	PT 2: Disinfectants and algaecides not intended for direct application to humans or animals
Product description	The representative product is a theoretical (model) product, containing 50 % KMPS, formulated as granules. KMPS is used as a disinfectant for surfaces, equipment and in swimming pool water.
Target organisms (including development stage)	Bacteria Yeasts and fungi Viruses
Description of use(s)	**Use #1: PT2 – Disinfection of swimming pools (professional use)** Granules are dosed manually into a dosing device connected to a pump and the product is automatically dosed into the pool water. Product can be used for maintenance treatment or shock dosing, which is performed in case of high microbial loads and it is done outside of opening hours and/or overnight. The pool is not used by swimmers during shock treatment and the presence of personnel in the swimming hall is not expected. **Use #2: PT2 – Dipping of equipment (professional use)** Granules are dosed manually with a scoop or comparable tool into a vessel filled up to a mark with water. Granules are dissolved by gentle manual stirring with an adequate tool. Contaminated equipment is submerged into the dipping bath by professionals and max. after 60 min contact time removed from the bath using a fork or tray. Contact time can be different when substantiated by the presented efficacy data at the product authorisation stage. The dipping solution has to be replaced depending on the present soil level. **Use #3: PT2 – Surface disinfection of industrial areas by wiping with mop (professional use)** Granules are dosed manually with a scoop or comparable tool into a bucket filled up to a mark with water. The granules are dissolved by gentle manual stirring with an adequate tool. Floors are wiped with a flat mop by professionals. A minimum amount of product solution should be added to ensure sufficient wetting of the treated surface. The contact time is max. 60 minutes and can be different when substantiated by the presented efficacy data at the product authorisation stage. **Use #4: PT2 – Surface disinfection of industrial areas by manual spraying (low pressure) (professional use)** Granules are dosed manually with a scoop or comparable tool into the reservoir of the spray equipment filled up to a mark with water. The granules are dissolved by gentle manual stirring with an adequate tool. The treatment solution is applied on the surface by low pressure sprayers. A minimum amount of product solution should be added to ensure sufficient wetting of the treated surface. The contact time is max. 60 minutes and can be different when substantiated by the presented efficacy data at the product authorisation stage. **Use #5: PT2 – Disinfection of swimming pools (non-professional use)** For the non-professional (general public) user, the product is delivered as

Summary table of intended uses	
	tabs, which are placed directly into the pool water. No application phase exists. Product can be used for maintenance treatment or shock dosing, which is performed in case of high microbial loads and it is done overnight. During shock treatment, swimming pool is not used by swimmers and presence of persons in the swimming hall is not expected.
Mode of action	KMPS releases reactive oxygen, which oxidises macromolecules of the cell wall, membranes and virus capsids in unspecific manner leading to the cell wall disruption, loss of membrane integrity and disintegration of virus capsids. In addition, after penetration into cells or viruses, intracellular molecules such as amino acids, polypeptides, RNA and DNA are also oxidised leading to the disruption of protein synthesis and cell death.
Objects to be protected	Humans
Concentration of product in the in-use formulation/product	Swimming pool water disinfection: undiluted granular product Equipment and surface disinfection: solution containing 10 g (theoretical) product/L
Concentration of active substance in the in-use formulation/product	Swimming pool water disinfection: granular product contains 50% w/w KMPS Equipment and surface disinfection: a treatment solution contains 5 g/L KMPS
Application rate(s)	5 g KMPS/L for equipment and surface disinfection 130 mg KMPS/L for maintenance treatment of swimming pool water max. 500 mg KMPS/L for shock treatment of swimming pool water
Frequency of application	Daily application Swimming pools: once per week (maintaining dose) and twice a year (shock treatment)
Season/period for use (where relevant)	Not relevant (except for disinfection of outdoor swimming pools)
Field of use (indoors/outdoors)	Indoors and outdoors
Category(ies) of user(s)	Professional and only for swimming pool disinfection non-professional (general public) users as well.

PT3:

Summary table of intended uses	
Product Type	PT 3: Veterinary hygiene
Product description	The representative product is a theoretical (model) product, containing 50 % KMPS, formulated as granules. KMPS is used as a disinfectant for surfaces in animal housing and in foot dips.
Target organisms (including development stage)	Bacteria Yeasts and fungi Viruses
Description of use(s)	**Use #1: PT3 – Terminal disinfection of animal houses using a low pressure sprayer (professional use)** Granules are dosed manually with a scoop or comparable tool into the reservoir of the spray equipment filled up to a mark with water. The granules are dissolved by gentle manual stirring with an adequate tool. The KMPS solution is sprayed onto walls, floors, etc. A minimum amount of product solution should be added to ensure sufficient wetting of the treated surface. The contact time is max. 120 min and can be different when substantiated by the presented efficacy data at the product authorisation stage. The terminal disinfection of animal houses by spraying is performed few times a year after depopulation and thorough cleaning of the animal house. The frequency of application varies with the type of animal housed. The disinfected surfaces are left to dry before repopulation of the animal house. **Use #2: PT3 – Foot dips (professional use)** Granules are dosed manually with a scoop or comparable tool into a vessel filled up to a mark with water. The granules are dissolved by gentle manual stirring with an adequate tool. Foot dips are placed at all main farm entrances and at entrances to farm buildings together with brushes. The contact time is max. 120 min and can be different when substantiated by the presented efficacy data at the product authorisation stage. One brush is used to remove organic matter prior to disinfection and one brush is used within the foot dip to wash the boot with the disinfection solution. The solution is replaced weekly or when heavily soiled.
Mode of action	KMPS releases reactive oxygen, which oxidises macromolecules of the cell wall, membranes and virus capsids in unspecific manner leading to the cell wall disruption, loss of membrane integrity and disintegration of virus capsids. In addition, after penetration into cells or viruses, intracellular molecules such as amino acids, polypeptides, RNA and DNA are also oxidised leading to the disruption of protein synthesis and cell death.
Objects to be protected	Animals
Concentration of product in the in-use formulation/product	Surface disinfection: solution containing 16 g (theoretical) product/L Foot dips: undiluted granular product
Concentration of active substance in the in-use formulation/product	Surface disinfection: treatment solution containing 8 g/L KMPS Foot dips: granular product contains 50% w/w KMPS
Application rate(s)	8 g KMPS/L for surface disinfection and foot dips
Frequency of application	Daily application for foot dips and few times a year for terminal disinfection of animal houses (after depopulation)
Season/period for use (where relevant)	Not relevant

Summary table of intended uses	
Field of use (indoors/outdoors)	Indoors
Category(ies) of user(s)	Professional users

PT4:

Summary table of intended uses	
Product Type	PT 4: Food and feed area
Product description	The representative product is a theoretical (model) product, containing 50 % KMPS, formulated as granules. KMPS is used as a surface disinfectant in food and feed areas.
Target organisms (including development stage)	Bacteria Yeasts and fungi Viruses
Description of use(s)	**Use #1: PT4 – Surface disinfection of food and feeding areas by wiping with mop (professional use)** Granules are dosed manually with a scoop or comparable tool into a bucket filled up to a mark with water. The granules are dissolved by gentle manual stirring with an adequate tool. Kitchen surfaces or objects are wiped with flat mop or cloth by professionals. A minimum amount of product solution should be added to ensure sufficient wetting of the treated surface. The contact time is max. 60 min and can be different when substantiated by the presented efficacy data at the product authorisation stage. **Use #2: PT4 – Surface disinfection of food and feeding areas by manual spraying (low pressure) (professional use)** Granules are dosed manually with a scoop or comparable tool into the reservoir of the spray equipment filled up to a mark with water. The granules are dissolved by gentle manual stirring with an adequate tool. The treatment solution is applied by low pressure sprayers. A minimum amount of product solution should be added to ensure sufficient wetting of the treated surface. The contact time is max. 60 min and can be different when substantiated by the presented efficacy data at the product authorisation stage.
Mode of action	KMPS releases reactive oxygen, which oxidises macromolecules of the cell wall, membranes and virus capsids in unspecific manner leading to the cell wall disruption, loss of membrane integrity and disintegration of virus capsids. In addition, after penetration into cells or viruses, intracellular molecules such as amino acids, polypeptides, RNA and DNA are also oxidised leading to the disruption of protein synthesis and cell death.
Objects to be protected	Humans, food and feed
Concentration of product in the in-use formulation/product	Surface disinfection (wiping and spraying): solution containing 10 g (theoretical) product/L
Concentration of active substance in the in-use formulation/product	Surface disinfection (wiping and spraying): treatment solution containing 5 g/L KMPS
Application rate(s)	5 g KMPS/L for surface disinfection
Frequency of application	Daily application
Season/period for use	Not relevant

Summary table of intended uses	
(where relevant)	
Field of use (indoors/outdoors)	Indoors
Category(ies) of user(s)	Professional users

PT5:

Summary table of intended use	
Product Type	PT 5: Drinking water
Product description	The representative product is a theoretical (model) product, containing 50 % KMPS, formulated as granules. KMPS is used as an animal drinking water disinfectant.
Target organisms (including development stage)	Bacteria Yeasts and fungi Viruses
Description of use(s)	**Use #1: PT5 – Continuous water sanitation by dosing the header tank or application via a dosing system (animal drinking water) (professional use)** Granules are dosed manually into the dose header tank or via a dosing system into the water pipe system. The water is treated continuously and used as animal drinking water.
Mode of action	KMPS releases reactive oxygen, which oxidises macromolecules of the cell wall, membranes and virus capsids in unspecific manner leading to the cell wall disruption, loss of membrane integrity and disintegration of virus capsids. In addition, after penetration into cells or viruses, intracellular molecules such as amino acids, polypeptides, RNA and DNA are also oxidised leading to the disruption of protein synthesis and cell death.
Objects to be protected	Animals
Concentration of product in the in-use formulation/product	Animal drinking water disinfection: undiluted granular product
Concentration of active substance in the in-use formulation/product	Animal drinking water disinfection: granular product contains 50% w/w KMPS
Application rate(s)	0.8 g KMPS/L for animal drinking water disinfection
Frequency of application	Continuous application
Season/period for use (where relevant)	Not relevant
Field of use (indoors/outdoors)	Indoors
Category(ies) of user(s)	Professional users

2.3 SUMMARY ON EFFICACY

2.3.1 Efficacy

The table: Experimental data on the efficacy of the active substance against target organism(s) is available in Appendix VI: **Confidential information**, Part A.- 2.3 SUMMARY ON EFFICACY.

Experimental data on the effectiveness of active substance KMPS against target organisms are obtained from both active substance sources owned by the KMPS Registration Group. Both companies have claimed confidentiality over the experimental data summarized in the Table in Appendix VI.

2.3.2 Mode of action

KMPS releases reactive oxygen, which oxidises macromolecules of the cell wall, membranes and virus capsids in unspecific manner leading to the cell wall disruption, loss of membrane integrity and disintegration of virus capsids. In addition, after penetration into cells or viruses, intracellular molecules such as amino acids, polypeptides, RNA and DNA are also oxidised leading to the disruption of protein synthesis and cell death.

2.3.3 Resistance

No resistance phenomenon has been reported with KMPS in the scientific literature for the time being.
Since KMPS is an inorganic substance with an unspecific mode of action (multisite oxidation process, see 2.3.2 Mode of action of this document) the development of resistance to KMPS is highly unlikely event.
Potential remedies should be available if resistance is ever observed with KMPS. These might include applying KMPS at the maximum approved dose level and frequency, adding an additional biocide (combination treatment) to broaden the spectrum of efficacy and/or provide different mechanisms of action, switching or alternating to another active ingredient which may improve efficacy by weakening the cells natural resistance defences.

2.4 CONCLUSION ON EFFICACY

The bactericidal activity of KMPS relative to the product types 2-5 was demonstrated originally with several suspension tests with and without organic load and microtiter plate assays (Appendix VI: Confidential information, Part A: Experimental Data Table - Doc. No. 336-0225). Test procedures were developed in-house following AOAC INTERNATIONAL standard protocols. Since the dossier was first submitted before the BPR guidance (April 2018) were available, these tests were considered acceptable at the time.
Different bacteria species (including Gram positive and Gram negative bacteria), range of active substance concentration and different contact times were tested. Four log reduction of bacteria and OD_{450} <0.3, depending on the test, were the requirements for demonstration of efficacy. These were achieved for Gram-positive *Staphylococcus aureus* and Gram negative *Pseudomonas aeruginosa* at 5 min and 30 sec contact time with 1500 and 500 ppm of KMPS, respectively. Several other species of bacteria were tested and showed similar results and in addition, 5 log reduction of *Vibrio parahaemolyticus* at 5 ppm KMPS and the presence of organic load was also demonstrated.

According to BPR guidance (April 2018), for active substance approval (MG 1, PT2-5) it is sufficient to demonstrate the innate activity (at least a "cidal" activity) in a suspension test against one or more representative target organism(s) for the activity claimed (e.g. bactericide, yeasticide), preferably according to the CEN norms (phase 1 tests and phase 2 step 1 tests). While the efficacy tests originally presented are not entirely in line with EN1040 (Phase 1 - 5 log reduction of *S. aureus* and *P. aeruginosa* in 5 min contact time at T=20°C), they are similar enough and thus were

considered in the evaluation. Results are included in the Part A: Experimental Data Table of the CAR.

Nevertheless, upon request, the applicant submitted several new phase 2 step 1 tests with KMPS done by CEN norms (Appendix VI: Confidential information, Part A: Experimental Data Table - Doc. No. 336-0402, Doc. No. 336-0403, Doc. No. 336-0404, Doc. No. 336-0405, Doc. No. 336-0406 and Doc. No. 336-0407). With these valid tests (EN1276, EN1650) bactericidal, yeasticidal and fungicidal activity was sufficiently demonstrated with KMPS active substance for intended uses PT2 and PT4 under clean and/or dirty conditions at several contact times. Using EN1656 and EN1657 standards, bactericidal and yeasticidal activity of KMPS was shown under low-level soiling conditions and at different contact times for PT3 uses. For PT5 use, a study done by modified EN1276 (modifications include soiling and contact time) demonstrated bactericidal activity of KMPS under clean conditions and 240 min contact time.

The KMPS concentration claimed by the applicant for surface disinfection is 5 g/L in PT2 and PT4 and 8 g/L in PT3. KMPS showed bactericidal activity at much lower in-use concentrations. For disinfection of swimming pool water with maintenance treatment, however, the claimed in-use concentration is 130 mg/L. At active substance approval stage, there is no need to restrict the intended dose range to that used in the efficacy studies if the dose proven efficacious is covered by the risk assessment. This is an issue for product authorisation, where it will be indeed necessary to demonstrate efficacy of the lowest in-use concentration. Furthermore, a minimum amount of product solution to be added to ensure sufficient wetting of the treated surface under certain contact time will also be defined at product authorisation stage. Several contact times, from 5 to 240 minutes, were tested in the efficacy studies and for the purpose of active substance approval this can be accepted. However, the exact contact time when substantiated by the presented efficacy data will be evaluated at the product authorisation stage.

We conclude that for the purpose of active substance approval the innate efficacy of KMPS is sufficiently demonstrated for all intended uses claimed by the applicant.

3 ASSESSMENT OF EFFECTS ON HUMAN HEALTH

3.1 TOXICOKINETICS

3.1.1 Short summary of the toxicokinetic information

No toxicokinetic and metabolism study of KMPS is available or has been performed. It should be noted that kinetic studies with the monopersulphate ion are technically not feasible due to the high instability of the compound.
A respective study is waived in accordance with Chapter 1.4.3 of the TNsG on Data Requirements, which states that a study can be waived if it is not scientifically necessary due to the intrinsic properties of the chemical or if other existing data can be used instead of the required data.

Intrinsic properties of KMPS
The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation. Only the breakdown products K^+ and SO_4^{2-} ions will remain to become systemically available, and are thus the only relevant species for toxicokinetic and metabolic considerations. Moreover, since the oxidative reactivity of KMPS is solely chemically driven, the mode of action of KMPS is considered independent of the target species and target organs.

Existing data on breakdown products
The breakdown products of KMPS, i.e. K^+ and SO_4^{2-}, ions are chemically and biologically not further degradable because they constitute simple basic structures of inorganic nature. Furthermore, both ions are physiological essential elements of all living organisms. Detailed information on absorption, distribution and excretion of potassium ions (Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the tolerable upper intake levels of Potassium; FAO/WHO expert consultation on Diet, Nutrition and Prevention of Chronic diseases, see Doc. No. 592-003) as well as sulphate ions (Morris and Levy, J. Toxicol.-Clin.Toxicol. 1983, 20:107-114, see Doc. No. 592-002) are available, which are briefly summarized below.

Potassium is a normal constituent of the human body and of human food, and it occurs widely in the environment, including all natural waters. A background document for development of WHO Guidelines for Drinking-water Quality states that currently, there is no evidence that potassium levels in municipally treated drinking-water, even water treated with potassium permanganate or potassium chloride, are likely to pose any risk for health of consumers. WHO document Potassium in drinking water maintains that it is not considered necessary to establish a health-based guideline value for potassium in drinking-water, stating the following reason for not establishing a guideline value: "Occurs in drinking-water at concentrations well below those of health concern." (Table 8.7 Naturally occurring chemicals for which guideline values have not been established; WHO, 2011).Notably, WHO recommends limiting the consumption of drinking-water potassium-based water treatment (principally potassium chloride for regeneration of ion exchange water softeners), affecting only individuals in high-risk groups (WHO, 2011). The latest dietary recommendations for healthy adults (age 16 and above) by WHO (2012) is to

increase potassium intake from food for reduction of blood pressure and risk of cardiovascular disease, stroke and coronary heart disease in adults to at least 90 mmol/day (3510 mg/day). WHO (2012) also suggests an increase in potassium intake from food to control blood pressure in children (age 2-16); the recommended 90 mmol/day should be adjusted downward, based on the energy requirements of children relative to those of adults. The later is set as conditional because only a few studies in children have considered the effects of increased potassium on possible adverse affect.The average daily intake of potassium is 2.7-4 g/day (EFSA Scientific Opinion on the use of potassium sulphate and sodium sulphate as sources of respectively potassium and sodium added for nutritional purposes to food supplements, EFSA Journal 2010; 8(12):1940). According to the Opinion on the tolerable upper intake levels of potassium, the available data are insufficient to establish a tolerable upper intake level (UL). Following a request from the European Commission, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) derived dietary reference values (DRVs) for potassium (Scientific opinion on dietary reference values for potassium. EFSA Journal 2016; 14(10):4592). Available data cannot be used to determine the average requirement of potassium but can be used as a basis for deriving an adequate intake (AI). A potassium intake of 3,500 mg/day is considered adequate for the adult population and an AI of 3,500 mg/day for adult men and women is proposed. For infants and children, the AIs are extrapolated from the AI for adults by isometric scaling and including a growth factor. An AI of 750 mg (19 mmol)/day is set for infants aged 7–11 months. For children, AIs from 800 mg (20 mmol)/day (1–3 years old) to 3,500 mg/day (15–17 years old) are set. Considering that the daily accretion rate of potassium in fetal and maternal tissues can be met by the adaptive changes which maintain potassium homeostasis during pregnancy, the AI set for adults applies to pregnant women. For lactating women, the amount of potassium needed to compensate for the losses of potassium through breast milk is estimated and an AI of 4,000 mg (102 mmol)/day is proposed. Long-term intake of potassium as potassium chloride (~ 3 g/day) in addition to normal intake via food has been shown to have no adverse effects. Although case reports indicate that very large doses of potassium supplements can cause heart abnormalities and death, the National Academies of Sciences, Engineering, and Medicine (NASEM) committee also concluded that these reports do not provide sufficient evidence to set an UL (https://ods.od.nih.gov/factsheets/Potassium-HealthProfessional/#change, updated June 2, 2022).

Following oral intake, potassium ions are largely absorbed in the gastrointestinal tract (85-90%). High potassium ion intake can be tolerated by the human body, as excess potassium ions are rapidly excreted in the urine or taken up into cells. Extracellular potassium constitutes around 2 % of the potassium in the body, and is important especially for regulation of membrane potential. Potassium ion concentrations in plasma are tightly regulated within a range of 3.5 to 5 mmol/L (Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on the tolerable upper intake levels of Potassium, Doc. No. 592-003).

The kidneys represent the major excretory route for potassium ions. It has been shown that potassium ion balance in the body can be maintained for intakes up to 390 mg potassium/kg bw/day as the kidney can efficiently adapt to high potassium intake (according to the Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on the tolerable upper intake levels of Potassium, Doc. No. 592-003).

In healthy people with normal kidney function, high dietary potassium intakes do not pose a health risk because the kidneys eliminate excess amounts in the urine. A delicate balance of potassium in the body involves a fine line of risk and benefit of potassium intake in different populations. Current guidelines recommend dietary potassium intake in the range of 90 to 120 mmol/day, well above the usual intake in worldwide populations. In some patients, however, excess dietary potassium intake results in hyperkalemia. Patients at risk include older patients and those with chronic kidney disease, congestive heart failure, or diabetes mellitus, especially with concomitant use of medications that inhibit the renin-angiotensin-aldosterone system inhibitors (RAAS) (Rodan, Pediatr Nephrol. 2017; 32(7): 1109–1121). For patients with conservative renal failure, it is recommended that the serum potassium level should be regulated in the range of 4.0–5.4 mEq/L. However, since renal potassium excretion decreases as renal function declines, potassium restriction starts to become necessary after later stages of chronic renal disease CKD (Yamada and Inaba, Nutrients. 2021 21;13(6):1751). The 2004 Kidney Disease Outcomes Quality initiatives guidelines recommended limiting potassium to approximately 51-102 mEq/day (2-4 g/day), while the more recent KDIGO 2012 recommended that individuals with CKD should receive expert dietary advice on potassium intake (reviewed in Larivée et al., Cardiology and Therapy. 2023; 12, 35–63). Clegg et al. (2020) concluded that further research is needed before dietary potassium restriction guidelines are made to prevent hyperkalemia in patients with advanced chronic kidney disease, as this generally varies according to the patient's age and comorbid conditions.

The sulphate ion is not considered to be toxic *per se* as it constitutes a physiologically essential mineral. Sulphate is produced by degradation and metabolism of sulphur organic and inorganic compounds present in food and drinking water. Gastrointestinal absorption of sulphate in humans can occur in the stomach, small intestine and colon. Absorption is a sodium-dependent active process. When soluble sulphate salts (e.g. sodium, potassium and ammonium sulphate) are consumed, more than 80% of oral sulphate doses are absorbed, as shown by isotopic tracer studies. After absorption, inorganic sulphate is freely distributed in blood and does not accumulate in tissues. The normal serum level of sulphate found in humans is 29 mg/L. Sulphates are usually eliminated by renal excretion in free unbound form or as conjugates of various chemicals (Scientific Opinion on the re-evaluation of sulphuric acid and its sodium, potassium, calcium and ammonium salts (E 513, 514 (i), 514 (ii), 515 (i), 515 (ii), 516 and 517) as food additive. EFSA Journal 2019;17(10):5868). In humans, 30.2 ± 17.2 % (mean ± SD) of the dose is excreted in the urine in the first 24 h after oral administration; for reference see Morris and Levy, Doc. No. 592-002). Sulphate that is not absorbed in the upper gastrointestinal tract passes to the large intestine and colon, where it is either excreted in the faeces, reabsorbed or reduced by anaerobic bacteria to metabolites, such as hydrogen sulphide (EFSA Journal 2019;17(10):5868). No upper intake level for sulphate exists, but in 2008, the EFSA Panel on Food Additives and Nutrient Sources added to Food concluded, that a daily intake of sulphate ion up to 100 mg sulphate ion/kg bw/day (6 g sulphate ion) does not give rise to concern (EFSA, 2008. Calcium sulphate for use as a source of calcium in food supplements Scientific Panel on Food Additives and Nutrient Sources added to food. The EFSA Journal, 814, 1-9).

Taken together, both breakdown products (i.e. potassium ions and sulphate ions) constitute physiologically essential metabolites in the human body which are efficiently

excreted via the urine after oral uptake.

Conclusion
In view of the chemical behaviour of KMPS, i.e. oxidation at the site of first contact leading to local corrosion/irritation, and taking into account the knowledge on the absorption, distribution and excretion of potassium and sulphate ions, the performance of a toxicokinetic and metabolism study with KMPS is scientifically unjustified.

3.1.1.1 Values and conclusions used for the risk assessment

Value(s) used in the Risk Assessment – Oral absorption	
Value(s)	KMPS : not relevant, breakdown to K^+ and SO_4^{2-} K^+: 85-90% SO_4^{2-}: is absorbed at more than 80%
Justification for the selected value(s)	No value for the oral absorption of KMPS was determined. Due to the high reactivity of KMPS and its immediate dissociation into potassium and sulphate ions when in contact with wet tissues, oral absorption of KMPS itself is not considered relevant. Regarding the breakdown products, i.e. potassium and sulphate ions, oral absorption data is available. Both ions constitute physiologically essential metabolites in the human body, which can efficiently be excreted, and are not toxic *per se* even when becoming systemically available. KMPS exerts only local effects (i.e. corrosion) at the site of first contact due to direct chemical reactivity. Any potential systemic effects are considered secondary to this local mode of action. Consequently, only a local risk assessment needs to be performed and values relevant for a systemic risk assessment such as oral absorption are not deemed necessary.

Value(s) used in the Risk Assessment – Dermal absorption	
Value(s	KMPS: not relevant, breakdown to K^+ and SO_4^{2-} K^+: not relevant (ionic form) SO_4^{2-}: not relevant (ionic form)
Justification for the selected value(s)	No value for the dermal absorption of KMPS was determined. Due to the high reactivity of KMPS and its immediate dissociation into potassium and sulphate ions when in contact with wet tissues, dermal absorption of KMPS itself is not considered relevant. Regarding the breakdown products, i.e. potassium and sulphate ions, dermal absorption is not considered relevant as ions are unlikely to penetrate the dermal barrier. Moreover, both breakdown products are physiologically relevant metabolites and not toxic *per se* (as detailed above) even when becoming systemically available. KMPS exerts only local effects (i.e. corrosion) at the site of first contact due to direct chemical reactivity. Any potential systemic effects are considered secondary to this local mode of action. Consequently, only a local risk assessment needs to be performed and values relevant for a systemic risk assessment such as dermal absorption are not deemed necessary.

Value(s) used in the Risk Assessment – Inhalatory absorption	
Value(s)	KMPS: not relevant, breakdown to K^+ and SO_4^{2-} K^+: not relevant (not volatile) SO_4^{2-}: not relevant (not volatile)
Justification for the selected	No value for the inhalatory absorption of KMPS was determined. Due to the high reactivity of KMPS and its immediate dissociation into potassium and

value(s)	sulphate ions when in contact with wet tissues, inhalatory absorption of KMPS itself is not considered relevant. Regarding the breakdown products, i.e. potassium and sulphate ions, no data is available for inhalatory absorption. Both breakdown products are ions and are not considered volatile when present in aqueous solutions. Moreover, both breakdown products are physiologically relevant metabolites and not toxic *per se* (as detailed above) even when becoming systemically available. KMPS exerts only local effects (i.e. corrosion) at the site of first contact due to direct chemical reactivity. Any potential systemic effects are considered secondary to this local mode of action. Consequently, only a local risk assessment needs to be performed and values relevant for a systemic risk assessment such as inhalatory absorption are not deemed necessary.

Conclusion(s) used in the Risk Assessment – Distribution	
Conclusion	KMPS: not relevant, breakdown to K^+ and SO_4^{2-} K^+: widely distributed in the body, important physiological functions SO_4^{2-}: widely distributed in the body, important physiological functions
Justification for the conclusion	Due to the high reactivity of KMPS and its immediate dissociation into potassium and sulphate ions when in contact with wet tissues, no ADME study has been performed nor is it considered feasible or relevant. KMPS dissociates into potassium and sulphate ions in aqueous environment. Data is available for the distribution of these breakdown products, which constitute physiological relevant metabolites.

Conclusion(s) used in the Risk Assessment – Metabolism	
Conclusion	KMPS: not relevant, breakdown to K^+ and SO_4^{2-} K^+: no metabolism SO_4^{2-}: used in protein turn-over
Justification for the conclusion	Due to the high reactivity of KMPS and its immediate dissociation into potassium and sulphate ions when in contact with wet tissues, no ADME study has been performed nor is it considered feasible or relevant. KMPS dissociates into potassium and sulphate ions in aqueous environment. Both ions are simple inorganic compounds, which cannot be further degraded neither chemically nor biologically.

Conclusion(s) used in Risk Assessment – Elimination	
Conclusion	KMPS: not relevant, breakdown to K^+ and SO_4^{2-} K^+: eliminated mostly by urine, minor excretion by sweat or faeces SO_4^{2-}: eliminated mostly by urine
Justification for the conclusion	Due to the high reactivity of KMPS and its immediate dissociation into potassium and sulphate ions when in contact with wet tissues, no ADME study has been performed nor is it considered feasible or relevant. KMPS dissociates into potassium and sulphate ions in aqueous environment. Data is available for the elimination of these breakdown products, which constitute physiological relevant metabolites.

Data waiving	
Information requirement	TNsG on Data Requirements, Chapter 1.4.3: Study can be waived if it is not scientifically necessary due to the intrinsic properties of the chemical or if other existing data can be used instead of the required data.
Justification	After contact with wet tissues KMPS rapidly dissociates to form potassium and sulphate ions. Due to the rapid breakdown of KMPS, ADME studies with this substance are not technically feasible. The breakdown products (i.e. K^+ and

	SO_4^{2-}) are simple inorganic compounds, which cannot be either chemically or biologically further degraded. Moreover, these ions are physiologically essential elements of all living organisms. Data is available for ADME of both, potassium and sulphate ions. KMPS exerts only local effects (i.e. corrosion) at the site of first contact due to direct chemical reactivity. Any potential systemic effects are considered secondary to this local mode of action. Consequently, only a local risk assessment needs to be performed and values relevant for a systemic risk assessment of KMPS such as oral, dermal and inhalatory absorption are not deemed necessary.

3.2 ACUTE TOXICITY

3.2.1 Acute oral toxicity

Summary table of animal studies on acute oral toxicity						
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels, Type of administration**	**Signs of toxicity**	**Value LD_{50}**	**Remarks**	**Reference**
Acute oral toxicity- Acute toxic class method OECD 423 GLP: Yes Reliability: 1	Rat Sprague-Dawley (CD) M/F 3M + 3F/ 200 mg/kg bw 3 F/2000 mg/kg bw	Oxone® Monopersulphate Compound (=KMPS) 200 mg/kg bw/day (concentration of 20 mg/mL) 2000 mg/kg bw/day (concentration of 200 mg/mL) Gavage	Mortality: 3/3 F at 2000 mg/kg bw Clinical signs: - both doses: piloerection 1 h after treatment - 2000 mg/kg bw: hunched posture, lethargy, abnormal gait, reduced body temperature, body tremors, shallow respiration and pallor of skin with dull eyes in two females and partially closed eyelids and red staining around the uro/genital area in one female. Necropsy: - In deceased animals, congestion was noted in the subcutaneous tissue, brain, heart, lungs and spleen with pallor of the kidneys and pale patches on the liver and red fluid contents of the urinary bladder. Congestion and fluid contents were noted in the stomach and along the alimentary tract and in the urinary tract with enlarged, swollen or thickened tissues and dark and pale discolouration of the lining also in the stomach of all animals. Body weight: bw loss in 2/3 F treated with 2000 mg/kg bw	LD_{50} = 500 mg/kg bw KMPS	None	6.1.1/01 [redacted], 2001a (Doc. No. 521-003)

Acute oral toxicity was studied in rats. Clinical signs observed in treated animals included hunched posture, lethargy, abnormal gait, reduced body temperature, tremors, shallow respiration, pale skin and dull eyes (in two rats), partially closed eyelids and redness around urogenital area (in one rat). The observed clinical signs are, along with piloerection (1 h after treatment at both doses), attributed to severe pain and inflammatory response at the point of contact (non-glandular stomach after dosing via gavage). Necropsies in deceased animals revealed

congestion in subcutaneous tissue, brain, heart, lungs and spleen and pale liver and kidneys, red fluid in urinary bladder (in one or more animals). Congestion and fluid retention was found in gastrointestinal and urogenital tract. The wall of the two organ systems was thick, with dark or pale discolorations of the epithelia. The effects seen are resulting from primary local effects. No signs of toxicity (except piloerection) were observed in animals who received 200 mg of Oxone® Monopersulphate Compound (KMPS)/kg bw. Recovery of survived animals, judged by external appearance and behaviour, was completed by the day 3. No abnormalities were revealed for surviving animals.

Acute oral LD_{50} was calculated to 500 mg/kg bw KMPS, according to OECD 423 Annex 2c.

No human data on acute oral toxicity of KMPS is available.

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} = 500 mg/kg bw
Justification for the selected value	Since no deaths occurred at a dose level of 200 mg/kg bw KMPS and all animals died after the administration of 2000 mg/kg bw the LD_{50} (oral) was determined to be 500 mg/kg bw according to OECD 423 Annex 2c. Therefore the classification as Acute Tox. 4, H302 (Harmful if swallowed) is proposed for KMPS according to criteria of Regulation 1272/2008.

3.2.2 Acute dermal toxicity

	Summary table of animal studies on acute dermal toxicity					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area,**	**Signs of toxicity**	**Value LD_{50}**	**Remarks**	**Reference**
Acute dermal toxicity OECD 402 GLP: Yes Reliability: 1	Rat Sprague-Dawley (CD) M/F 5/sex/dose	Oxone® Monopersulphate Compound (=KMPS) 2000 mg/kg bw/day (concentration of 1667 mg/mL) covered area approx. 10% of the total body surface occlusive dressing 24 h exposure	Mortality: none Clinical signs: None. Dermal effects: Severe dermal irritation was seen in 3 animals following removal of the dressings persisting until study termination. Slight to well-defined dermal irritation was observed in 6 animals following removal of dressings. These reactions had resolved completely by day 3 in 1 animal, day 5 in 1 animal and day 8 in 4 animals. In addition, localised necrosis, localised spots and/or scabbing, spots and/or scabbing over the majority of the treatment site, blanching over the majority of the treatment site, cracking of the skin at the edge of the blanched area and wet ulceration on the dose site were noted in a number of animals during the study. Necropsy: Macroscopic examination revealed necrotic area on the dose site of three animals and scabbing on the dose site of two animals. Body weight: Loss of body weight was recorded for 1 female and low body weight gains were recorded for 2 females on day 8.	LD_{50} > 2000 mg/kg bw	None	6.1.2/01 [redacted] 2001b (Doc. No. 522-002)

Acute dermal toxicity was studied in rats. There were no deaths and no systemic clinical signs observed. The treated animals showed significant dermal irritation, that persisted in three animals until study was terminated; slight to well defined dermal irritation was seen in 6 animals, but it resolved by day 3, 5, and 8, respectively. The skin damage included: localized necrosis, localized spots and/or scabbing, spots and/or scabbing over the majority of treatment site, blanching over the majority of treatment site, cracking of the skin of the blanched area and wet ulcerations. Loss of weight was observed in 1 female animal and low body weight gain in another two female rats.

Acute dermal LD_{50} was calculated to > 2000 mg/kg bw of Oxone® Monopersulphate Compound (KMPS). The study indicated that Oxone® Monopersulphate Compound causes local irritation of the skin.

No human data on acute dermal toxicity of KMPS is available.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50} > 2000 mg/kg bw
Justification for the selected value	No mortalities were observed in rats dermally exposed to Oxone® at 2000 mg/kg bw. No classification and labelling with respect to acute dermal toxicity is required for KMPS according to Regulation (EC) 1272/2008.

3.2.3 Acute inhalation toxicity

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, form and particle size, Actual and nominal concentration, Type of administration**	**Signs of toxicity**	**Value LC_{50}**	**Remarks**	**Reference**
Acute Inhalation Toxicity OECD 403 GLP was not compulsory at the time of study conduct Reliability: 1	Rat Crl:CD M 10/dose	Oxone® Monopersulphate Compound (approximately 100% KMPS) dust aerosol MMAD: 1.7 to 4.0 µm Actual concentration: 1.5, 3.9, 4.2 and 5.0 mg/L (higher atmospheric concentrations could not be generated under the conditions used in the study) Head-only exposure (4 h) 14 day post-observation period	Mortality: No animal died during the study duration. Clinical signs: During exposure: Reduced response to sound, ocular and nasal discharge increasing with concentration were observed. Rats exposed at 1.5 mg/L exhibited moderate lung noise immediately post exposure. Post-exposure: Rats exposed to 3.9, 4.2 and 5.0 mg/L exhibited alopecia around the eyes, cloudy eyes (some eventually turning black in colour), and severe discharge from eyes and nose. At 1.5 mg/L, only 1 cloudy eye (that turned black in colour) was noted. One rat exposed at 3.9 mg/L became hypersensitive to touch. Necropsy: No pathological findings reported. Body weight: Slight to severe weight loss was noted lasting 24-96 hours post-exposure. This was followed by a normal rate of weight gain.	LC_{50} > 5.0 mg/L	Only male rats were used in the investigation. In a comparable investigation performed with the KMPS containing product Virkon S in male and female rats of the same strain and source, male rats were demonstrated to be slightly more sensitive towards Virkon S dust than female rats (please refer to Document IIIA, Section A6.1.3/02 – read across study). Thus, the inhalation study reliably reflects and does not under-estimate the acute inhalation toxicity potential of Oxone® dust.	6.1.3/01 [redacted] (1980) (Doc. No. 523-001)

Acute Inhalation Toxicity OECD 403 GLP: Yes Reliability: 1	Rat Crl:CD®BR M and F 5/sex/group	Virkon S (dust aerosol), containing 49.8% Oxone monopersulfate compound (= KMPS) MMAD: 3.1 - 3.8 µm Actual concentrations: 2.5, 3.1, 4.8 mg/L Nose-only exposure (4h) 14 day post-observation period	Mortality: No deaths in the 2.5 mg/L group, 3/5 of male rats and 1/5 of female rats died in the 3.1 mg/L group, all male rats and 3/5 of the females of the 4.8 mg/L group died. Clinical signs: Clinical signs immediately following exposure: wet underbody, gasping, nasal and ocular discharges, hunched posture, lethargy, weakness, diarrhea, enophthalmus, and irregular respiration. Clinical signs during recovery period: nasal and ocular discharges, hunched posture, irregular respiration, lethargy, lung noise, weakness, enophthalmus, ruffled fur, gasping and diarrhea (corneal opacity of one female of the 4.8 mg/L group). Necropsy: No pathological findings reported. Body weight: All surviving rats experienced severe body weight losses up to five days following exposure. All males and most females had an overall weight gain by the end of the 14-day recovery period.	LC_{50} = 3.7 mg/L	Supportive study	6.1.3/02 [redacted] (1995) (Doc. No. 528-002)

In an acute inhalation study performed with Oxone® Monopersulphate Compound (KMPS), male rats were exposed for 4 hours to a dust aerosol consisting of particles in the respirable range (MMADs < 4 µm). The results obtained showed that KMPS did not reveal an inhalation hazard up to and including the highest exposure level of 5 mg/L tested. Thus, no classification and labelling with respect to acute inhalation toxicity is required for KMPS.

The LC50 value was calculated based on the study that used Oxone® Monopersulphate Compound (KMPS). Because only male rats were used in this study, the second study is presented as a supporting study to show that female rats are not more sensitive to KMPS. In the second study, animals were exposed to product Virkon S that contains 49.8% Oxone monopersulfate compound (KMPS) and other co-formulants (that are expected to cause more severe effects in animals than KMPS alone). In a comparable investigation performed with the KMPS containing product Virkon S in male and female rats of the same strain and source, male rats were demonstrated to be slightly more sensitive towards Virkon S dust than female rats. Thus, the inhalation study with Oxone® in male rats reliably reflects and does not underestimate the acute inhalation toxicity potential of Oxone® dust.

No human data on acute inhalation toxicity of KMPS is available.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LC_{50} > 5 mg/L (4-hour inhalation)
Justification for the selected value	When male Crl:CD® rats were exposed head-only for a single 4-hour exposure period towards Oxone® (KMPS) dust at particle sizes lying well within the respirable range for rats, no deaths occurred up to and including the highest exposure level of 5.0 mg/L tested. No classification and labelling with respect to acute inhalation toxicity is required for KMPS according to Regulation (EC) 1272/2008.

3.2.4 Overall conclusion on acute toxicity

Value used in the Risk Assessment – Acute systemic toxicity	
Value	KMPS exerts only local effects (i.e. corrosion) at the site of first contact due to direct chemical reactivity. Any potential systemic effects are considered secondary to this local mode of action. Anyway, the following (systemic) LD/LC_{50} values have been derived from the acute toxicity studies: Acute oral $LD_{50, rat}$ = 500 mg/kg bw Acute dermal $LD_{50, rat}$ > 2000 mg/kg bw Acute inhalation $LC_{50, rat}$ > 5.0 mg/L
Justification for the selected value	Acute oral effects: Since no deaths occurred at 200 mg/kg bw and all animals died after the administration of 2000 mg/kg bw, the LD_{50} (oral) was determined to be 500 mg/kg bw according to OECD 423 Annex 2c. Acute dermal effects: No mortalities were observed in rats dermally exposed to 2000 mg/kg bw KMPS. Acute inhalation effects: No mortalities were reported in rats exposed head-only to 5.0 mg/L KMPS for 4 hours.
Classification according to CLP	The following classification is proposed for KMPS: According to Regulation (EC) 1272/2008, KMPS should be assigned the classification and labelling as Acute Tox. 4, H302 "Harmful if swallowed". According to Regulation (EC) 1272/2008, KMPS does not warrant classification for acute toxicity regarding the dermal and inhalation route of exposure.

Value/conclusion used in the Risk Assessment – Acute local effects	
Value/conclusion	Acute $NOAEC_{oral}$: / Acute $NOAEC_{dermal}$: / Acute $NOAEC_{inhalation}$: /
Justification for the selected	Acute oral, dermal and inhalation toxicity studies were not performed in a way that would allow setting of NOAEC values for acute local effects of KMPS.

value/conclusion	

3.3 IRRITATION AND CORROSION

3.3.1 Skin corrosion and irritation

No *in vitro* study on skin corrosion and irritation was performed for KMPS.

Summary table of animal studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results**	**Remarks**	**Reference**
Acute dermal irritation/corrosion Comparable to OECD 404 GLP: No Reliability: 1	Albino rabbit White Russian F 3/group	Caroat® (KMPS) 0.5 g test substance were moistened with 0.15 mL demineralised water occlusive dressing exposure duration: 4 h post-exposure period: 14 days examination time points 1 h, 24 h, 48 h, 72 h after removal of the test patches	Skin irritation index per animal (average of skin irritation scores at 24, 48, 72 h after exposure): -Erythema: 4.00, 4.00, 4.00 -Oedema: 0.67, 0.33, 0.67 Erythema was not reversible within 14 day of study duration. Oedema resolved completely by day 2. Coloration: The treated skin was white. Corrosion: Irreversible skin destruction of the treated skin was observed. Clinical signs: No systemic toxicity was stated and no mortalities occurred.	Deviations: - skin was not flushed with water after exposure; - no further information on the test substance (stability; purity) Study results indicate that KMPS should be classified as Skin Corrosive, due to skin discolouration and persisting erythema around the treated area for 14 days. However, because no washing of treated site was performed, duration of exposure could have been longer than 4 hrs and thereafter the proposed classification could be over conservative. According to criteria for classification in Regulation 1272/2008 the classification Skin Corr. 1 is proposed for KMPS regarding study results, while a subcategory cannot be proposed.	6.1.4/01 [redacted] (1983) (Doc. No. 565-001)

KMPS was tested for skin irritation in rabbits. After 4 h occlusive application of the substance, severe erythema of the treated skin was observed, which persisted for 72 h after exposure. For erythema, the mean score 24-72h after exposure in all three animals was 4.0. These erythemas were irreversible within the post-exposure period of 14 days. Oedema was less severe (very slight to slight). The mean scores 24-72 hrs were 0.67 in two animals and 0.33 in one animal. Oedema completely resolved within 2 days.
KMPS was found to be corrosive to the skin of rabbits. Irreversible destruction of the treated skin was observed.
However, the test substance was not washed from the skin after 4 hours of exposure. Therefore the skin irritating potential of KMPS could be overestimated in this study.
Based on the available information, the subcategory cannot be proposed, and classification as Skin Corr. 1 is appropriate in line with the Guidance on the CLP Criteria, section 3.2.2.4.

Summary table of human data on skin corrosion/irritation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**

<table>
<tr>
<td>Direct observations (Product investigations)
no guideline available
GLP: no
Reliability: 2 (for skin irritating effects)</td>
<td>Impact® (91% KMPS triple salt)</td>
<td>A number of 109 adult human volunteers participated in an intensified version of the Shelanski and Shelanski Repeated insult patch test (one subject dropped out after first postapplication). Three different substances including KMPS were tested in parallel in the same individuals on different sites on the back.

The study was designed to evaluate the skin sensitising potential of Impact®, but participants showed signs of skin irritation rather than skin sensitisation. Only effects related to skin irritation during the induction phase are reported here.

During the induction phase, the patches were applied under occlusive conditions to the test persons for 24 h on 4 consecutive days/week for a total of 3 weeks.
Test substance was applied as aqueous solution containing 7100 ppm (0.71 %) KMPS.
No negative control group (occlusive patch without test substance) was included in the study.

Scoring system:
<table>
<tr><th>Response</th><th>Visible Change</th><th>Grading PII</th></tr>
<tr><td>Absent Inflammation</td><td>None</td><td>0</td></tr>
<tr><td>Stage I</td><td>Faint redness</td><td>1</td></tr>
<tr><td></td><td>Moderate redness</td><td>2</td></tr>
<tr><td></td><td>Intense redness</td><td>3</td></tr>
<tr><td>Stage II</td><td>Redness plus induration, edema, papules, and/or vesicules</td><td>4</td></tr>
<tr><td>Stage III</td><td>Weeping vesicles, blisters, or bullae</td><td>5</td></tr>
<tr><td>Stage IV</td><td>Extension of damage beyond margin of contact site</td><td>6</td></tr>
<tr><td>Corrosion</td><td>Destruction, necrosis, and/or sloughing of skin</td><td>7</td></tr>
</table>
</td>
<td>In induction phase no adverse effects were detected on 17 out of 109 subjects on whom one or more post application examinations were conducted during this phase. Adverse skin changes were detected on 92 subjects: 5 faint (Grade 1) erythema, 15 moderate (Grade 2) erythema, 8 intense (Grade 3 erythema), 64 intense erythema with induration and/or vesicles (Grade 4).

Only few visible skin changes of minor degree (grade 1-4) occurred during the first week of the study regimen (induction phase).

24 h exposure (scoring day 1):
1/109 subjects with skin changes grade 4
108/109 subjects scored with grade 0

48 h exposure (scoring day 2):
4/108 subjects with skin changes grade 1
1/108 subjects with skin changes grade 2
103/108 subjects scored with grade 0

72 h exposure (scoring day 3):
9/108 subjects with skin changes grade 1
2/108 subjects with skin changes grade 2
1/108 subjects with skin changes grade 3
1/108 subjects with skin changes grade 4
95/108 subjects scored with grade 0

96 h exposure (scoring day 4):
8/108 subjects with skin changes grade 1
5/108 subjects with skin changes grade 2
1/108 subjects with skin changes grade 3
2/108 subjects with skin changes grade 4
92/108 subjects scored with grade 0

<table>
<tr><th>Week</th><th colspan="5">Volunteers with grade of skin reactions observed</th><th>Nr. affected</th></tr>
<tr><td></td><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td><td></td></tr>
<tr><td>1</td><td>81</td><td>17</td><td>6</td><td>1</td><td>4</td><td>28</td></tr>
<tr><td>2</td><td>63</td><td>2</td><td>14</td><td>7</td><td>22</td><td>46</td></tr>
<tr><td>3</td><td>31</td><td>2</td><td>19</td><td>6</td><td>45</td><td>78</td></tr>
</table>
During week 2 and 3, the number of visible skin changes increased over time. Thus, after repeated 24 h exposure under occlusive conditions, KMPS shows increasing skin irritating potential.</td>
<td>6.12.2/01 [redacted] (1992) (Doc. No. 572-001)</td>
</tr>
</table>

Direct observations (Product investigations) no guideline available GLP: no Reliability: 2 (for skin irritating effects)	Impact® (91% KMPS triple salt)	A number of 25 adult human volunteers participated in a patch test. All test subjects gave their prior informed consent for participation in this study. The study utilised a double-blind, non-placebo controlled, single-cell design to determine the adverse potentialities of the samples investigated on the skin of adult humans. Study subjects had already been participating for one week in a patch study regiment involving samples from other sponsors. The study was designed to evaluate the skin sensitising potential of Impact®, but participants showed signs of skin irritation rather than skin sensitisation. Only effects related to skin irritation during the induction phase are reported here. During the induction phase, the patches were applied under occlusive conditions to the test persons for 24 h on 4 consecutive days/week for a total of 3 weeks. Test substance was applied as aqueous solution containing 12 ppm, 150 ppm or 7000 ppm KMPS. Subjects receiving 7000 ppm were split during week 3 with 13 subjects continued on 7000 ppm and 11 subjects receiving 150 ppm on naïve sites. No negative control group (occlusive patch without test substance) was included in the study. Scoring system: **Response** / **Visible Change** / **Grading PII** **Absent** / None / 0 **Inflammation** **Stage I** / Faint redness / 1 Moderate redness / 2 Intense redness / 3 **Stage II** / Redness plus induration, edema, papules, and/or vesicules / 4 **Stage III** / Weeping vesicles, blisters, or bullae / 5 **Stage IV** / Extension of damage beyond margin of contact site / 6 **Corrosion** / Destruction, necrosis, and/or sloughing of skin / 7	The following skin changes occurred during the first week of the study regimen (induction phase). 12 ppm group: No adverse skin reactions were visible during the induction phase in the subjects. 150 ppm group: No adverse skin reactions were visible during induction phase in the subjects. Faint erythema (score 1) were seen in one subject after 96 h of exposure. 7000 ppm group: 24 h exposure (scoring day 2): 25/25 subjects with skin changes grade 0 48 h exposure (scoring day 3): 1/25 subjects with skin changes grade 4 24/25 subjects with skin changes grade 0 72 h exposure (scoring day 4): 1/24 subjects with skin changes grade 1 1/24 subjects with skin changes grade 2 2/24 subjects with skin changes grade 4 20/24 subjects with skin changes grade 0 96 h exposure (scoring day 5): 5/22 subjects with skin changes grade 1 2/22 subjects with skin changes grade 2 1/22 subjects with skin changes grade 4 14/22 subjects with skin changes grade 0 At the beginning of week 2, grade 4 skin reactions were seen in 10 individuals and grade 6 in one. During week 2 and 3, the number of visible skin changes increased over time. Notably, in 2 subjects, no skin changes at all were observed over the 3 weeks of repeated application of Impact® under occlusive conditions.	6.12.2/02 [redacted] (1992) (Doc. No. 572-002)

KMPS was used in two skin sensitisation/irritation human volunteer studies. In both studies aqueous solutions containing 7000 or 7100 ppm of KMPS have been demonstrated to be not irritating to human skin when applied for 24 h under occlusive conditions: Signs of skin irritation (grade 4) were seen in a single individual out of 109 volunteers treated with 7100 ppm and in none of the 25 volunteers exposed to 7000

ppm. However, with prolonged and repeated 24 h-exposure to KMPS at 0.71 or 0.70 % under occlusive conditions, incidence and severity of skin reactions was increasing. However, this exposure pattern represents a very worst-case scenario for the real-life dermal contact with KMPS. In addition, occlusion itself was reported to increase irritating potential of irritant chemicals.
In the second study, three concentrations of KMPS were tested (12, 150 and 7000 ppm). At 150 ppm only transient mild erythema was seen in three individuals, while at 12 ppm no signs of skin irritation were reported.

Conclusion used in the Risk Assessment – Skin irritation and corrosivity	
Value/conclusion	KMPS is corrosive to animal skin (rabbit). Based on the results obtained for an exposure duration of 4 h and taking into account the provisions of Regulation (EC) 1272/2008, KMPS is proposed to be classified and labelled as Skin Corr. 1 with the hazard statement H314: "Causes severe skin burns and eye damage". In two studies human volunteers were treated dermally with KMPS for 24 hrs under occlusive conditions for 4 days per week for 3 consecutive weeks. Aqueous solutions of KMPS at 7000/7100 ppm were not irritating to human skin after 24 hrs except in one single individual (of 109 treated with 7100 ppm and 25 treated with 7000 ppm) where mild skin irritation (grade 4) was seen. The incidence and severity of skin irritation increased with study duration. The exposure pattern of individuals in the study (repeated exposure for 24 h under occlusive conditions) is considered unrealistic since professionals and non-professionals are considered to wash their hands after contact with KMPS, at least after shift, and not to occlude the exposed site for 24 hrs. The derivation of a dermal NOAEC value was considered unnecessary due to the risk management measures that will be applied due to the classification of KMPS for corrosive properties.
Justification for the value/conclusion	In a skin corrosion/irritation study in rabbits, irreversible erythema of grade 4 was observed in animals exposed to KMPS for 4 hours under occluded conditions.

3.3.2 Eye irritation

No *in vitro* study on eye irritation of KMPS was performed.

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance** **Dose levels, Duration of exposure**	**Results**	**Remarks**	**Reference**
Acute eye irritation study OECD 405 GLP: No, but several quality assurance inspections were carried out Reliability: 2	Rabbit New Zealand White (outbred) Sex not stated 3 animals	RD/1/58 (KMPS) 0.1 g in conjunctival sac of right eye left eye remained untreated and served as control	Instillation of the test material caused practically no initial pain responses in all animals. Instillation of test material into the conjunctival sac of three rabbits caused severe ocular lesions within 1 h. Animals were sacrificed 24 h after instillation of test substance due to ocular damage indicating necrosis. Scores per animal at 24 h: - Corneal opacity: 3, 3, 3 - Conjunctival redness: 3, 3, 3 - Chemosis: 3, 3, 2 - Iris: 0, 0, 0 - Necrosis of conjunctival and nictitating membrane.	No further information on the test substance (stability, purity) is available.	A6.1.4/02, [redacted] (1985) (Doc. No. 566-002)

Compound RD/1/85 containing KMPS was tested for eye irritation in rabbits. Instillation of 0.1 g into the conjunctival sac of three rabbits caused severe ocular lesions which were apparent in all animals within 1 h and justified the termination of the test on humane ground, 24 h after treatment.

Principal lesions include: opacity of cornea, beefy-red conjunctiva, chemosis and ocular discharge, necrosis of lower conjunctiva and nictitating membrane. These results indicate serious eye damage.

No human study on eye irritating potential of KMPS is available.

Conclusion used in Risk Assessment – Eye irritation and corrosivity	
Value/conclusion	KMPS is corrosive to animal eyes (rabbit). Based on the results of the eye damage and irritation study in rabbits, KMPS warrants classification as Eye Dam. 1, H318 "Causes serious eye damage" according to Regulation (EC) 1272/2008. However, since KMPS has to be classified as Skin Corr. 1 and assigned H314 ("Causes severe skin burns and eye damage"), the risk of severe damage to eyes is considered implicit and H318 does not need to be indicated on the label due to redundancy in accordance with Regulation (EC) 1272/2008 Article 27.
Justification for the value/conclusion	Observations from an animal study (rabbit) indicate that KMPS is corrosive and causes severe and irreversible eye damage.

3.3.3 Respiratory tract irritation

No animal study or human data investigating the irritation potential of KMPS to the respiratory tract is available.

According to Section 3.1.2.3.3 and Note 1 of Table 3.1.3 in Annex I to CLP, in addition to classification for inhalation toxicity, if data are available that indicate that the mechanism of toxicity was corrosivity, the substance or mixture shall also be labelled as 'corrosive to the respiratory tract' (see note 1 in 3.1.4.1). Corrosion of the respiratory tract is defined by destruction of the respiratory tract tissue after a single, limited period of exposure analogous to skin corrosion; this includes destruction of the mucosa. According to Section 1.2.6. in Annex II of CLP, EUH071 can also be applied to inhaled corrosive substances not tested for acute inhalation toxicity in addition to classification for skin corrosivity.

KMPS is not acutely toxic via inhalation route, but it is corrosive to skin. KMPS can be inhaled (aerosols of dust or mist). Effects on respiratory tract considered relevant for classification purposes were observed in inhalation toxicity studies:
- Acute inhalation toxicity study (please refer to Section A.3.2.3.): Reduced response to sound, ocular and nasal discharge increasing with concentration were observed. Rats exposed at 1.5 mg/L exhibited moderate lung noise immediately post exposure. No pathological findings were reported at the necropsy.
- Sub-acute inhalation toxicity study (please refer to Section A.3.5.3.): The respiratory effects described were as follows: Slight lung noise at highest test-level 0.0431 mg/L. A preliminary experiment was conducted with doses of 100, 500, and 1000 mg/m^3, corresponding to 0.1, 0.5, and 1 mg/L/6h/day. These doses proved to be toxic after a few repeated exposures. After 3 exposures at 1 mg/L, 1 death had occurred, and most of the other high level dosage rats were in extremis condition. After 5 exposures at 0.5 mg/L, all rats were in extremis. Based on these observations, the high dosage levels were terminated and only 0.1 mg/L was continued through 10 exposures with definitive visible effects. The decision was made to continue this project using the lower dose levels of 0, 0.001, 0.01, and 0.05 mg/L, 6 hrs/day, 5 days/week, for two weeks. There are no additional data available on the nature and severity of the effects observed in the preliminary experiment.

Based on the available data, the corrosive effect of KMPS on the respiratory system cannot be excluded. Lack of pathological findings at

the end of the post-exposure period in acute inhalation toxicity study could be due to reparative capacity of respiratory tract (Horiba and Fukuda, Virchows Arch. 1994;425(4):425-34; Basil et al., Cell Stem Cell. 2020;26(4):482-502). Injuries caused by corrosive effects could be repaired by the time of necropsy, which was done 14 days after exposure. Supplementary labelling with EUH071 "Corrosive to the respiratory tract" is therefore proposed.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Conclusion	KMPS is corrosive to the respiratory tract .
Justification for the conclusion	Based on the chemical mode of action of KMPS and on the results obtained in a skin corrosion/irritation study (please refer to chapter 3.3.1), KMPS can be expected to have respiratory tract irritation/corrosion potential. In an acute inhalation study performed with KMPS (please refer to chapter 3.2.3), signs of respiratory tract irritation were perceived in treated rats. During exposure, ocular and nasal discharge was observed in all animals, which increased with concentration of KMPS. During the 14-day post-observation period, discharge from eyes and nose was noted in rats exposed at the 3 highest concentrations. These findings are indicative of a respiratory tract irritation potential of KMPS. In preliminary experiment in sub-acute inhalation toxicity study animals died at higher doses after few repeated exposures. Supplementary labelling with EUH071 "Corrosive to the respiratory tract" is proposed, based on the fact that the substance is corrosive and based on the possibility of the exposure to aerosols.

3.3.4 Overall conclusion on corrosion and irritation

Conclusion used in the Risk Assessment – Corrosion and irritation	
Value	KMPS is corrosive to skin. KMPS is corrosive to eyes. KMPS is corrosive to respiratory tract
Justification for the selected value	**Skin corrosion/irritation:** In rabbits, KMPS caused signs of skin irritation/corrosion after 4 h of exposure under occlusive conditions. In two human volunteer studies, aqueous solutions containing 7000 or 7100 ppm of KMPS have been demonstrated to irritate skin, but only when applied for 3 to 4 consecutive days under occlusive conditions for 24 hrs. **Eye irritation/eye damage:** In rabbits, KMPS caused severe eye damage within 1 h. As effects were irreversible within 24 h, the study was terminated. **Respiratory tract irritation/corrosion:** Although KMPS was not tested for respiratory tract irritation, data from an acute inhalation study indicate respiratory tract irritation potential: rats exposed to KMPS dust aerosol showed ocular and nasal discharge, which increased with increasing KMPS concentrations. In a sub-acute inhalation toxicity study KMPS caused dead of animals after few repeated exposures. As KMPS is corrosive to the skin according to the results of a skin irritation/corrosion study in rat, it is likely that KMPS also exhibits respiratory tract irritation/corrosion potential.

Classification according to CLP	The following classification is proposed for KMPS: According to Regulation (EC) 1272/2008, KMPS warrants classification and labelling as Skin Corr. 1, H314 "Causes severe skin burns and eye damage". According to Regulation (EC) 1272/2008, KMPS warrants classification as Eye Dam. 1, H318 "Causes serious eye damage". However, since KMPS has to be classified as Skin Corr. 1 and assigned H314 ("Causes severe skin burns and eye damage"), the risk of severe damage to eyes is considered implicit and H318 does not need to be indicated on the label due to redundancy in accordance with Regulation (EC) 1272/2008 Article 27. Supplementary labelling with EUH071 "Corrosive to the respiratory tract" is proposed, based on the fact that the substance is corrosive and based on the possibility of the exposure to aerosols.

3.4 SENSITISATION

3.4.1 Skin sensitisation

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Route of exposure, Duration of exposure**	**Results**	**Remarks**	**Reference**
Skin sensitisation study, Magnusson-Klingmann method OECD 406 GLP: Yes Reliability: 1	Albino Guinea pig Dunkin-Hartley Males 5/control 10/test dose group	Oxone® Monopersulphate Compound (KMPS) in sterile water Intradermal induction (day 1): 0.1 mL of 0.25 % (w/v) Oxone® Monopersulphate Compound dilution in water, 1:1 mixture of FCA/water and 0.25% (w/v) test item in a 1:1 mixture of FCA/water Topical induction (day 8): 20% (w/v) Oxone® Monopersulphate Compound in water Topical challenge (day 22): 5 % (w/v) and 2.5 % (w/v) of Oxone® Monopersulphate Compound in water Positive control: Hexyl cinnamic aldehyde (HCA)	Intradermal injections: Necrosis was recorded at sites receiving FCA in test and control animals. No irritation was seen in the test animals at sites receiving Oxone® Monopersulphate Compound, 0.25 % (w/v) in water for irrigation and no irritation was observed in control animals. Topical application: Well defined to moderate erythema, accompanied by blanching of the dose site, was observed in all test animals following topical application with Oxone® Monopersulphate Compound, 20 % (w/v) in water for irrigation. No erythema was seen in the control group. Challenge: There were no dermal reactions seen in any of the test or control animals. None of the animals of the control or test group showed clinical signs of toxicity and no mortalities were observed. There were no effects on body weight of animals in the main study. None of the animals demonstrated any evidence for an allergic reaction. Oxone® Monopersulphate Compound is therefore not considered to be a potential skin sensitiser.	None	A6.1.5/01, [redacted] (2001) (Doc. No. 567-007)

Summary table of human data on skin sensitisation				
Type of data/report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
Direct observations (Product investigations) no guideline available GLP: no Reliability: 3 (for skin sensitising effects)	Impact® (91% KMPS triple salt)	A number of 109 adult human volunteers participated in an intensified version of the Shelanski and Shelanski Repeated insult patch test. Three different substances including KMPS were tested in parallel in the same individuals on different sites on the back. The study was designed to evaluate the skin sensitising potential of Impact®, but participants showed signs of skin irritation rather than skin sensitisation. Only effects related to skin sensitisation are reported here. During the induction phase, the patches were applied under occlusive conditions to the test persons for 24 h on 4 consecutive days/week for a total of 3 weeks. Test substance was applied as aqueous solution containing 7100 ppm KMPS. During the challenge phase, the patches were applied under occlusive conditions to the test persons for 24 h on 4 consecutive days/week for one week. Test substance was applied as aqueous solution containing 7100 ppm KMPS. No negative control group (occlusive patch without test substance) was included in the study. Scoring system: **Response** / **Visible Change** / **Grading PII** **Absent** / None / 0 **Inflammation** **Stage I** / Faint redness / 1 Moderate redness / 2 Intense redness / 3 **Stage II** / Redness plus induration, edema, papules, and/or vesicules / 4 **Stage III** / Weeping vesicles, blisters, or bullae / 5 **Stage IV** / Extension of damage beyond margin of contact site / 6 **Corrosion** / Destruction, necrosis, and/or sloughing of skin / 7	Distinct skin reactions were observed after induction and challenge phase in some individuals. The challenge applications at naïve sites induced skin reactions in 42 % of the participants following application of Impact, respectively. However, from a scientific point of view the study has several limitations which distinctly influence the reliability and significance of the results: - Sensitisation is an immune response to the application of a test substance and sensitisation can generally only be observed at low, non-irritating concentrations. - As the concentrations used for the induction and challenge phase were identical and have been shown to be irritating in some individuals after repeated 24 h-exposures under occlusive conditions, it is not possible to distinguish between an irritant and a sensitisation skin response in the study. - All three test substances were concurrently tested in the same individuals; therefore, no conclusion can be drawn for the sensitising properties of the individual substances, especially when considering that one tested substance is classified as respiratory and skin sensitizer. The results obtained in this study are not scientifically robust enough to derive any conclusions on the sensitising properties of either substance tested.	6.12.2/01 [redacted] (1992) (Doc. No. 572-001)

Direct observations (Product investigations) no guideline available GLP: no Reliability: 3 (for skin sensitising effects)	Impact® (91% KMPS triple salt)	A number of 25 adult human volunteers participated in a patch test. All test subjects gave their prior informed consent for participation in this study. The study utilised a double-blind, non-placebo controlled, single-cell design to determine the adverse potentialities of the samples investigated on the skin of adult humans. Study subjects participated in a patch study regiment involving samples from other sponsors during the course of the study. The study was designed to evaluate the skin sensitising potential of Impact®, but participants showed signs of skin irritation rather than skin sensitisation. Only effects related to skin irritation during the induction phase are reported here. During the induction phase, the patches were applied under occlusive conditions to the test persons for 24 h on 4 consecutive days/week for a total of 3 weeks. Test substance was applied as aqueous solution containing 12 ppm, 150 ppm or 7000 ppm KMPS. Subjects receiving 7000 ppm were split during week 3 with 13 subjects continued on 7000 ppm and 11 subjects receiving 150 ppm on naïve sites. During the challenge phase, the patches were applied under occlusive conditions to the test persons for 24 h on 4 consecutive days/week for one week. For challenge, the same concentrations as used for the induction phase were used for subjects receiving 12 ppm and 150 ppm; subjects induced with 7000 ppm received 150 ppm during challenge. No negative control group (occlusive patch without test substance) was included in the study. Scoring system: **Response** / **Visible Change** / **Grading PII** **Absent** / None / 0 **Inflammation** **Stage I** / Faint redness / 1 Moderate redness / 2 Intense redness / 3 **Stage II** / Redness plus induration, edema, papules, and/or vesicules / 4 **Stage III** / Weeping vesicles, blisters, or bullae / 5 **Stage IV** / Extension of damage beyond margin of contact site / 6 **Corrosion** / Destruction, necrosis, and/or sloughing of skin / 7	Minor degrees of erythema were seen in one to two subjects during both the primary/activation and challenge phase with 12 ppm. Faint erythema were seen in one subject during the primary/activation phase (150 ppm) and transient erythema in another subject during the challenge phase (150 ppm) disappearing within 24 hours. Signs of skin irritation were observed in individuals exposed to 7000 ppm during induction phase. During challenge with 150 ppm, no adverse effects were detected in any of the 24 subjects of the 7000 ppm group. During the additional challenge procedure with 22 subjects receiving 3500 and 7000 ppm Impact® for 24 or 48 h respectively, 9 subjects were scored for skin changes, with 3 subjects showing skin changes only on sites where Impact® was applied for 48 h. Grade 4 skin changes were visible only in 4 of these subjects. The skin reactions noted at 7000 ppm or 150 ppm cannot unequivocally be attributed to a skin sensitising response since, from a scientific point of view, the study has several limitations which distinctly influence the reliability and significance of the results: - Sensitisation is an immune response to the application of a test substance and sensitisation can generally only be observed at low, non-irritating concentrations.	6.12.2/02 [redacted] (1992) (Doc. No. 572-002)

			- The concentrations used for the induction and challenge phase was identical for the 12 ppm, and 150 ppm group. For the 7000 ppm group, the concentration has been shown to be irritating in some individuals after repeated 24 h-exposures under occlusive conditions. Thus, it is not possible to distinguish between an irritant and a sensitisation skin response in the study. - Other test substances which were not specified in the study report were concurrently tested in the same individuals during the course of the study. Therefore, no firm conclusion can be drawn on the sensitising potential of KMPS. Based on the results obtained in this study and taking into account the limitations of this test as well as the study design, a skin sensitising effect of KMPS could not be proven and the skin reactions noted suggest a concentration-dependent irritating effect to the skin rather than a skin sensitising potential of the test substance.	

The skin sensitisation potential of Oxone® Monopersulphate Compound (KMPS) was investigated in a guinea pig maximization test. In the range finding study, after topical application of KMPS, the following effects were observed: 25% (w/v) to 100% (w/v): necrosis; 20% (w/v): slight to moderate erythema with slight oedema; 10% (w/v): slight to well-defined erythema with slight oedema; 5% (w/v), 1% (w/v), 0.1% (w/v), 0.05% (w/v), 0.01% (w/v): no erythema, no oedema. OECD TG 406 recommends: "The concentration of test chemical used for each induction exposure should be well tolerated systemically and should be the highest to cause mild-to-moderate skin irritation. The concentration used for the challenge exposure should be the highest non-irritant dose." 20% (w/v) was used for induction topical application as this was the highest concentration that produced some irritation but did not adversely affect the animals. 5% (w/v) and 2.5% (w/v) were used for topical challenge as 5% (w/v) was the highest concentration not giving rise to irritating effects.
Following intradermal injection necrosis was recorded at sites receiving FCA in test and control animals. No irritation was seen in the test animals at sites receiving Oxone® Monopersulphate Compound 0.25 % (w/v) in water for irrigation and no irritation was observed in control animals receiving water for irrigation.
Well defined to moderate erythema, accompanied by blanching of the dose site, was observed in all test animals receiving Oxone® Monopersulphate Compound 20 % (w/v) in water for irrigation. No erythema was seen in the control group.
Following challenge application, no dermal reactions were seen in any of the test or control animals. Consequently, all ten test animals gave negative responses leading to the conclusion that KMPS is not considered to be a potential skin sensitiser.

In two human volunteer studies, distinct skin reactions were observed after induction at 7100 ppm and challenge at 7100 ppm or induction

at 7000 ppm and challenge at 150 ppm in some individuals. However, no firm conclusions on skin sensitisation potential of KMPS can be drawn due to limitations in the study design (same concentration used for induction and challenge, irritating effects after repeated 24-h exposures under occlusive conditions, concurrent application of other (sensitising) test substances). However, at 150 ppm and 12 ppm only mild skin reactions were seen after exposure to KMPS in a small number of individuals. The skin reactions noted at 7000 or 7100 ppm suggest a concentration-dependent irritating effect to the skin after repeated exposure rather than a skin sensitising potential of KMPS.

KMPS contains the impurity dipotassium peroxodisulphate ($K_2S_2O_8$) which has a harmonised classification as Skin sens. 1, H317 and Respiratory sesitiser 1, H334. The content of potassium persulphate is higher than the trigger value for classification for Skin sens. 1 and Respir. sens. 1. However, a guinea pig skin sensitisation study (Magnusson-Klingman method) was performed with KMPS and thereafter no classification is required regarding skin sensitising potential according to criteria of Regulation 1272/2008.

The applicant has submitted an overview of the sensitisation data on KMPS in which it is explained that KMPS does not need to be classified as a skin or respiratory sensitiser ([redacted] 2016). The overview includes a brief summary of the risk assessment for Oxone which is actually based on the risk assessment for Virkon S. The exposure scenario includes application of Virkon S by fogging. Virkon S contains 50 % Oxone. It is reported that exposure levels are below DNEL and AEL demonstrating low risk to operators, but reference values are not stated in the brief summary. This risk assessment demonstrates that a high exposure to Oxone is not expected to present a sensitising risk because of the presence of $K_2S_2O_8$ as an impurity.
Skin sensitisation studies were performed with KMPS containing potassium persulphate as impurity. A Guinea pig Maximisation test by [redacted] in 2001 was conducted with Oxone and it did not induce skin sensitisation in exposed animals.
In the KMPS REACH dossier another skin sensitisation study is presented with Caroat. No skin sensitising properties were observed on epidermal challenge with 3 % concentration following intradermal injection of 0.05 % and epidermal application of 10 % test substance. This study has a reliability score 2 in the REACH registration dossier since identity and purity of the test substance was not fully specified. Additionally, the concentration of potassium persulphate in Caroat tested in the skin sensitisation study is not reported.
Three more skin sensitisation studies with KMPS are summarised in the REACH dossier. All studies were interpreted by applicant as negative but have low reliability scores (3) due to insufficient reporting of the identity of test substance and, not being performed according to principles of the GLP, which was not required at the time and two of them were performed according to Buehler method of the Guinea pig maximisation test with 3 inductions what is considered not to be sensitive enough. The applicant also reports three skin sensitisation studies performed with Virkon S that contains 50 % Oxone. In two Guinea pig Maximisation tests it did not elicit skin sensitising reactions in exposed animals. Additional test was performed according to the Buehler method which also gave negative result. But also for these studies there is no information on the content of potassium persulphate impurity.

Medical surveillance data on workers in manufacturing and packaging of Oxone was submitted. It did not indicate any cases of skin or respiratory sensitivity of workers being in contact with KMPS. Incidence reports from a previous and current manufacturing periods were searched for reports that could be related to skin or respiratory sensitisation. In the period of 2002-2016 six entries only were referring to

sensitisation or allergy. The claims were unsubstantiated or unclear, with various products cited or misuse was involved, and any reported effects do not appear to be characteristic of dermal sensitisation rather than other effects such as irritation. It is also not clear whether effects observed were due to Oxone or other components of Virkon S.

A case of a 55-year old man using a hot tub (containing potassium peroxymonosulfate, KMPS) is reported (Kagen et al., 2004). The man experienced skin eruption and wheezing related to the recent use of a hot tub treated with potassium peroxymonosulfate, an active ingredient of Oxone™, for disinfection. These symptoms cleared after avoidance of the disinfectant product. The authors conclude that KMPS was the case of the rush and pulmonary symptoms. The patient had positive patch test result for potassium peroxymonosulfate KMPS at 5% *in pet* (*in petrolatum*; Vaseline), and also a questionable reaction to potassium dichromate from the patch test. Potassium dichromate may cause allergic respiratory reaction (NIOSH 2016). In addition, KMPS at 5% is clearly corrosive to skin, reason why KMPS is classified as Skin Corr. 1 according to the CLP. Consequently, the effects of 5% KMPS as observed in the human patch test are rather considered as irritant (irritant contact dermatitis) and not as allergen (allergic contact dermatitis) reactions. Quantification of exposure concentrations for potassium peroxymonosulfate was absent, and exposure to other potential sensitizing agents were not documented in this case report ([redacted] 2016).

Oxone is also widely used as a denture cleaner and as oxidant in swimming and spa pools. The denture cleaner is usually a tablet, containing 10 % Oxone, which should be dissolved in a glass of tap water. People using such tablets are in skin contact with the tablet first and later with the solution. According to manufacturers and suppliers of dissolving tablets for denture cleaning 10 millions of users are annually exposed to Oxone on a daily bases. Regarding such a widespread use of Oxone numerous reports of sensitising reactions would be expected if KMPS induced sensitising reactions in exposed individuals.
Considering all the available information we conclude that KMPS is not a skin sensitiser.

As KMPS contains impurity dipotassium peroxodisulphate ($K_2S_20_8$) which has a harmonised classification as Skin Sensitiser 1, H317 and Respiratory Sensitiser 1, H334 and is present in a concentration greater than that specified in Table 3.4.6 of Annex I of Regulation (EC) 1272/2008 the active substance KMPS shall be labelled with EUH208 "Contains dipotassium peroxodisulphate (CAS 7727-21-1). May produce an allergic reaction."

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	KMPS is not a skin sensitiser. The active substance KMPS warrants labelling EUH208 "Contains dipotassium peroxodisulphate (CAS 7727-21-1). May produce allergic reaction", according to Regulation (EC) 1272/2008.
Justification for the value/conclusion	In a guinea pig maximisation test none of test animals responded with signs of skin sensitisation. In two human volunteer studies, skin irritation after repeated occluded exposure rather than firm signs of skin sensitisation were noted. Thus, KMPS is expected to have no skin sensitising potential in humans. As KMPS contains impurity dipotassium peroxodisulphate ($K_2S_20_8$) which has a harmonised classification as Skin Sensitiser 1, H317 and Respiratory Sensitiser 1, H334 and is present in a concentration greater than that specified in Table 3.4.6 of Annex

	I of Regulation (EC) 1272/2008 the active substance KMPS shall be labelled with EUH208 "Contains dipotassium peroxodisulphate (CAS 7727-21-1). May produce an allergic reaction."

3.4.2 Respiratory sensitisation

No animal or human data is available on respiratory sensitisation potential of KMPS.

KMPS contains impurity dipotassium peroxodisulphate ($K_2S_2O_8$) which has a harmonised classification as Skin Sensitiser 1, H317 and Respiratory Sensitiser 1, H334. The concentration of the impurity in KMPS is above the generic concentration limit of 1 % triggering classification as Skin Sens. 1 or Resp. Sens. 1.

Currently no testing method is available for respiratory sensitisation and therefore this classification is based only on human data. As summarised by the applicant, medical surveillance data on workers involved in KMPS manufacture and packaging did not indicate any cases of respiratory sensitivity after exposure to KMPS.
Applicant also reports further detailed review of health records for personnel (33) involved in Oxone manufacture. Results obtained from occupational health surveillance questionnaires and pulmonary function tests indicate that there are no pulmonary symptoms reported and no chronic obstructive pulmonary disease observed amongst these employees during 2013 and 2016. Workers in the production of KMPS are considered to have the highest potential exposure to KMPS, even though RMM are used. These data further indicate that KMPS, including its impurities, is not a respiratory sensitiser.

Additionally, KMPS is widely used in swimming and spa pools and as denture cleaners. Due to use of denture cleaning tablets alone 10 million of people in Europe are estimated to be in contact with KMPS on daily bases. Regarding daily exposure of so many people numerous reports of sensitising reactions would be expected if KMPS would exert respiratory sensitising potential. However in open literature we did not find any publication regarding respiratory sensitisation related to KMPS exposure.

Conclusion used in the Risk Assessment – Respiratory sensitisation	
Value/conclusion	KMPS is not considered to be a respiratory sensitiser.
Justification for the value/conclusion	See the following justification for waiving the respiratory sensitisation endpoint.

Data waiving

Information requirement	Respiratory sensitisation
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. KMPS is not a skin sensitiser, and thus is not considered to have respiratory sensitisation potential. This conclusion is supported by data from medical surveillance of workers at their KMPS manufacturing sites where no evidence for respiratory hypersensitivity was seen (see chapter 3.14). Additionally, case reports would be expected in the open literature due to widespread use of KMPS also among general public (e.g. in disinfection of swimming and spa pools and denture cleaners).

3.4.3 Overall conclusion on sensitisation

Conclusion used in the Risk Assessment – Sensitisation	
Value	KMPS is not a skin sensitiser. KMPS is not expected to be a respiratory sensitiser.
Justification for the selected value	In a guinea pig maximisation test, none of test animals responded with signs of skin sensitisation. In two human volunteer studies, skin irritation after repeated occlusive exposure rather than firm signs of skin sensitisation were noted. Thus, KMPS is expected to have no skin sensitising potential in humans. Based on the lacking skin sensitisation potential of KMPS and based on medical surveillance data of workers in contact with KMPS, KMPS is not expected to be a respiratory sensitiser. As KMPS contains impurity dipotassium peroxodisulphate ($K_2S_20_8$) which has a harmonised classification as Skin Sensitiser 1, H317 and Respiratory Sensitiser 1, H334 and is present in a concentration greater than that specified in Table 3.4.6 of Annex I of Regulation (EC) 1272/2008 the active substance KMPS shall be labelled with EUH208 "Contains dipotassium peroxodisulphate (CAS 7727-21-1). May produce an allergic reaction."
Classification according to CLP	According to the criteria of Regulation (EC) 1272/2008, KMPS does not warrant classification as skin sensitiser or respiratory sensitiser. KMPS should be labelled with EUH208 "Contains dipotassium peroxodisulphate (CAS 7727-21-1). May produce an allergic reaction."

3.5 SHORT TERM REPEATED DOSE TOXICITY

3.5.1 Short-term oral toxicity

Summary table of oral short-term animal studies (usually 28-day studies)						
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels, Route of exposure, Duration of exposure**	**NOAEL, LOAEL**	**Results**	**Remarks**	**Reference**
14-days oral toxicity study Study similar and in accordance with OECD 407 GLP: Yes Reliability: 2	Rat CD (Crl: CD (SD) IGS BR) Males and females 3/dose/sex	Oxone® Monopersulphate Compound (KMPS) 0, 50, 400 and 1000 mg/kg bw (corresponding to 0, 5, 40, 100 mg/mL) Gavage 14 days	NOAEL > 1000 mg/kg bw/day (corresponding toNOAEC > 100 mg/mL) LOAEL was not determined in the study.	Clinical signs: There were no clinical signs indicative of systemic toxicity noted. No deaths occurred. At 40 mg/mL (400 mg/kg bw), salivation was noted for 2/3 males and for all animals at 100 mg/L (1000 mg/kg bw). This effect is assumed to result from the taste of test substance. Food consumption: Transient higher food consumption in both sexes considered not toxicologically relevant. Body weight: There was no toxicologically relevant effect; test group animals actually gained more weight and had a higher terminal body weight than control animals. Macroscopic examination: Cysts in the kidneys were noted in 1/3 females at 100 mg/mL (1000 mg/kg bw/day) and 2/3 males and 2/3 females at 40 mg/mL (400 mg/kg bw/day) compared with none in the controls. These cysts were spontaneous lesions and were not considered to be related to treatment.	Only 3 instead of 5 animals/dose were used in the study (dose-range finding study), no histopathological, haematological or clinical chemistry examination was performed and no urinalysis. Study is considered supportive.	A6.3.1/01 [redacted] (2001) (Doc. No. 531-002)

Oral gavage with Oxone® Monopersulphate Compound (KMPS) at doses of up to 1000 mg/kg bw/day for 14 days were well tolerated by rats of both sexes.

Oxone® Monopersulphate Compound was administered to rats by gavage for 14 consecutive days at doses of 0, 50, 400 and 1000 mg/kg bw/day (corresponding to 0, 5, 40, 100 mg/mL) according to the OECD Guidance 407 and GLP. Animals were observed once daily and clinically checked on weekly basis until sacrificed on day 15.

No deaths occurred. There were no clinical signs of systemic toxicity in this study. Transiently higher food consumption and increased body weight gain compared to controls was seen in all groups of treated animals, but was not dose dependent and therefore considered to be not test substance related. Salivation was observed in 2/3 males receiving KMPS at doses of400 mg/kg bw/day and all animals receiving KMPS at 1000 mg/kg bw/day, but this might be due to the unpleasant taste of the compound. Kidney cysts were found in 1/3 females receiving KMPS at 1000 mg/kg bw /day and 2/3 males and 2/3 females receiving 400 mg/kg/bw/day. Since increased incidence of kidney cysts was not dose related and also not reported in 90-days rat study the cysts were considered to be spontaneous lesions and not induced by Oxone® Monopersulphate Compound.

The NOAEL for Oxone® Monopersulphate Compound in this study is >1000 mg/kg/bw/day.

No human data on short-term oral toxicity is available for KMPS.

Value used in the Risk Assessment – Short-term oral toxicity	
Value/conclusion	NOAEL > 1000 mg/kg bw/day
Justification for the value/conclusion	In a 14-days oral toxicity study in rats, no relevant signs of toxicity were observed in treated animals at doses to up to 1000 mg/kg bw/day.

3.5.2 Short-term dermal toxicity

No animal or human data on short-term dermal toxicity is available for KMPS.

Value used in the Risk Assessment – Short-term dermal toxicity	
Value/conclusion	KMPS is not considered to cause adverse systemic effects after short-term dermal exposure.
Justification for the value/conclusion	Based on the chemical mode of action, KMPS is expected to induce skin corrosion or irritation at site of first contact with skin. This is substantiated by acute dermal toxicity studies and studies on skin irritation/corrosion (please refer to chapters 3.2.2 and 3.3.1). Please see the following justification on data waiving for more information.

	A semi-quantitative risk assessment for KMPS needs to be performed for the local dermal effects taking into account the classification of the product.

Data waiving	
Information requirement	Short-term dermal toxicity
Justification	No dermal sub-acute toxicity study has been performed with KMPS. The conduct of a dermal sub-acute toxicity study is considered to be not necessary for the following reasons: According to the TNsG on Data Requirements, chapter 1.4.3, a study can be waived if the outcome can be reliably predicted. Moreover, the Guidance on the BPR, Volume III, Part A Section 8.9.1 states that dermal repeated dose toxicity studies should be avoided, "if the substance is a severe irritant or corrosive, testing by the dermal route should be avoided unless it can be performed at doses that do not cause irritation or corrosion and such doses are still toxicologically relevant". Due to its oxidative and corrosive/irritative properties, KMPS will cause skin destructions when applied topically. These effects are considered to be of local nature due to the reaction of the substance with the surrounding tissue. Systemic toxicity would therefore occur only secondary to locally irritating effects at the site of first contact. In the available studies there are no indications for any other mechanism of toxicity than the local corrosion/irritation. Since this mode of action is chemically driven, it is not species specific. Moreover, breakdown products of KMPS are potassium and sulphate ions, which are both essential metabolites. Application of KMPS in concentrations which do not cause irritation/corrosion, results in physiological concentrations of potassium and sulphate ions. Thus, no adverse effects besides the local corrosion/irritation are expected. The skin irritating potential of KMPS was investigated *in vivo* (please refer to section 3.3.1). Severe erythema as well as irreversible skin destruction was observed around the white coloured treated skin. Erythema were irreversible within the post-exposure period of 14 days. Moreover, no systemic effects were observed neither in the dermal irritation study nor in the acute dermal toxicity study (please refer to section 3.3.1 and 3.2.2). In the acute dermal irritation study, skin destruction was immediately visible after an exposure time of 4 h, as it can be expected for a corrosive substance. Systemic toxicity after dermal exposure towards KMPS would therefore occur only secondary to local irritating effects. Taken together: the outcome of a repeated dose/sub-acute dermal study is predictable due to the local mode of action of KMPS, namely local corrosion/skin irritation at the site of first contact. Since these local effects are rather concentration than time dependent, it can be assumed that the effects seen in acute studies (such as acute dermal toxicity and skin irritation studies) would also be observed in repeated/sub-acute dermal studies. In other words: an extension of the study duration would not lead to additional information. Consequently, and taking into account the predictability of the study results, a repeated/sub-acute dermal toxicity study would not provide any additional information for the assessment of KMPS, and should therefore not be conducted due to animal welfare reasons.

3.5.3 Short-term inhalation toxicity

Summary table of inhalatory short-term animal studies (usually 28-day studies)						
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/ group**	**Test substance, form and particle size, Actual and nominal concentration, Type of administration, Duration of exposure**	**NOAEL, LOAEL**	**Results**	**Remarks**	**Reference**
Sub-acute Inhalation Toxicity (14 days) Study performed comparably with OECD 412 GLP: No, was not compulsory at the time of study conduct Reliability: 2	Rat Crl:CD Males 10/dose	Oxone® Monopersulphate Compound (approximately 100% KMPS) (dust aerosol) MMDA not stated Target concentration: 0, 0.001, 0.01, 0.05 mg/L Analytical concentration: 0, 0.0014, 0.0101, 0.0431 mg/L Head-only exposure 6 h/day 5 days/week 14-days exposure 13 days post-exposure period	Local effects: LOAEC: 0.0101 mg/L (10.1 mg/m³) NOAEC: 0.0014 mg/L (1.4 mg/m³)	Clinical signs: Eye irritation (alopecia around the eye, conjunctival swelling, severe opacity, corneal ulceration and haemorrhage, corneal vascularisation, discharge and crusty scab around the eyes) at mid and high test-level; slight lung noise (at high test-level). The 13-day observation period allowed only partial recovery from ocular effects. Body weight: Decreased body weight gain was noted at the high test-level on days 10-16 and at mid test-level on day 12. Gross findings: Ocular discharge, swollen eyelids with hair loss, cloudy appearance of the cornea were noted at mid and high test-level. Microscopic lesions: Eye lesions (blepharitis, keratitis, corneal vascularisation, iritis, degeneration of the lens) were noted at mid and high test-level. The 13-day observation period allowed only partial recovery from ocular effects. Organ weights: No effects. Clinical chemistry: No toxicologically relevant effects.	Only male rats were used (not considered to have compromised the study results as male rats were shown to be the more sensitive sex in the acute inhalation toxicity study). Particle size not analysed. Food/water consumption not investigated.	[redacted] (1981) (Doc. No. 531-001)

In a sub-acute inhalation toxicity study, rats received Oxone® Monopersulphate Compound (KMPS) as dust aerosol at actual (measured) concentrations of 0, 0.0014, 0.0101 and 0.0431 mg/L. No deaths occurred. Transient decrease in body weight was observed at 0.0431

mg/L on days 10-16 and at 0.0101 mg/L on day 12.

Mid and high test-levels of KMPS caused alopecia around the eye, conjunctival swelling, severe opacity, corneal ulceration and haemorrhage, corneal vascularisation, and clear discharge. In general, a dry, crusty scab was formed around the eyes, keeping them closed unless forced open. One control rat had a cloudy, glazed right eye. A slight lung noise in high test-level rats was observed during exposure.

Individual pathology data from gross and histopathological examinations were recorded after the 10th exposure when 5 rats from each level were selected at random and sacrificed for gross and histopathological examination. Remaining rats were sacrificed on the 13th observation day for an identical examination. The organs and tissues examined included: ear pinna, skin, thymus, mediastinal tissue, spleen, bone marrow (sternum), heart, trachea, lungs, esophagus, stomach, small intestines (duodenum, jejunum, and ileum), large intestines (cecum and colon), liver, kidneys, testes, epididymides, thyroids, adrenals, brain, eyes, and any other tissues observed to be abnormal at necropsy.

Based on this, one can assume that the tissues and organs not examined at necropsy were normal, but there is no clear indication of this and it could only be concluded that there is no histopathological data available for the nasal cavity and possible deposition of KMPS particles therein.

At necropsy, no gross findings were observed in control or low level rats. Intermediate and high level rats generally had ocular discharge, swollen eyelids with hair loss, and a cloudy appearance of the cornea. Microscopic lesions attributable to the test compound were limited to the eyes and eyelids of rats exposed at the 2 highest exposure levels. These changes included: blepharitis, keratitis, corneal vascularisation, iritis, inflammatory exudate in the anterior and posterior chambers of the eye, haemorrhage mainly in the vitreous body of the eye and degeneration of the lens (cataract). These findings were equal in severity in the mid and high test groups but higher in incidence in the high test group. The 13-day observation period allowed only slight recovery of these lesions (irreversible damage). No eye damage occurred at the low test-level.

In rats receiving the highest concentration, 3/10 leukocytosis was reported, that could be due to inflammation of damaged eyes.

At the high test-level, increased serum glutamic-oxalacetic acid, glutamic-pyruvic transaminase and urea nitrogen activities and depressed levels in alkaline phosphatase, and serum creatinine were measured. After 13 days of recovery, glutamic-pyruvic transaminase, glutamic-oxalacetic acid, creatinine levels and total protein levels were statistically lower than controls. This effect is not considered to be treatment related. The decrease in the creatinine level was not dose-dependent and was not considered to be toxicologically relevant. Changes seen on the alkaline phosphatase level were shown to be completely reversible during the recovery period.

Rats receiving the highest concentration had an elevated blood urea nitrogen, which was no longer observed after recovery period. Urinary pH was depressed in rats at treated with the high dose. Following the recovery period slight decrease in urinary pH was still seen, but not was not considered to be adverse.

The critical effect observed in the sub-acute inhalation study was severe eye damage of exposed animals. No true systemic toxicity observations were reported in this study. The NOAEC of 0.0014 mg/L (1.4 mg/m^3) is based on clinical signs of the eyes and histological eye findings observed at the next higher test concentration (LOAEC of 0.0101 mg/L (10.1 mg/m^3)).

According to Regulation (EC) 1272/2008 (Annex 3.9.1), substances can be classified for STOT RE in Category 1 based on observations from appropriate studies in experimental animals in which significant and/or severe toxic effects, of relevance to human health, were produced

at generally low exposure concentrations. Guidance dose/concentration for inhalation exposure considered applicable for subacute inhalation study is C ≤ 0.06 mg/litre/6h/day. The eye effects in this study can be considered severe and relevant to human health. Exposure concentrations where effects occurred were 0.0101 and 0.0431 mg/L/6h/day which are below the guidance concentration of 0.06 mg/litre/6h/day.

Additional considerations are set out in CLP Guidance (Section 3.9.2.5.1, p. 470):

"Substances (or mixtures) classified as corrosive may cause severe toxicological effects following repeated exposure, especially in the lungs following inhalation exposure. In such cases, it has to be evaluated whether the severe effect is a reflection of true repeated exposure toxicity or whether it is in fact just acute toxicity (i.e. corrosivity). One way to distinguish between these possibilities is to consider the dose level which causes the toxicity. If the dose is more than half an order of magnitude lower than that mediating the evident acute toxicity (corrosivity) then it could be considered to be a repeated-dose effect distinct from the acute toxicity. In this case, classification as specific target organ toxicant (repeated exposure) would be warranted even if the substance (or mixture) is also classified as acutely toxic and/or corrosive.

In assessing non systemic effects caused by irritating/corrosive substances it should be kept in mind, that the guidance values /criteria for STOT-RE of the CLP were derived from acute toxicity criteria (lethality based) assuming that systemic effects show a time dependent increase of severity due to accumulation of toxicity and taking also adaptive and detoxification processes into account. The effect considered in this context was lethality. This indicates that classification was intended for the presence of severe health damage, only. (see ECBI/67/00, (2000) in EU Commission Summary Record of Meeting of the Commission Working Group on C&L of Dangerous Substances ECBI/44/01)."

The effects in subacute inhalation study were seen at concentration that is 150 lower than the lowest concentration tested in the acute inhalation toxicity study and orders of magnitude lower than the basis for Eye Dam. 1 classification (0.1 g pure substance). Therefore, the classification is warranted also when considering additional considerations set out in CLP Guidance.

Classification STOT RE 1, H372 for local ocular effects is therefore proposed.

No human data on short-term inhalation toxicity of KMPS is available.

Value used in Risk Assessment – Short-term inhalation toxicity	
Value/conclusion	NOAEC: 0.0014 mg/L (1.4 mg/m³) LOAEC: 0.0101 mg/L (10.1 mg/m³) Causes damage to organs (eyes) trough prolonged or repeated exposure.
Justification for the value/conclusion	A valid sub-acute 14-day inhalation study in rats is available. No signs of systemic toxicity were observed up to and including the highest test concentration (0.0431 mg/L). Local effects occurred at the mid and high test concentration (0.0101 and 0.0431 mg/L). No effects – neither systemic nor local – were observed at the lowest test concentration of 0.0014 mg/L (1.4 mg/m³), which is thus considered a NOAEC for the inhalation route.

3.5.4 Overall conclusion on short-term repeated dose toxicity

Value used in the Risk Assessment – Short-term repeated dose systemic toxicity	
Value	Not relevant.
Justification for the selected value	KMPS does not exert primary systemic effects.
Classification according to CLP	

Value/conclusion used in the Risk Assessment – Short-term repeated dose local effects	
Value/conclusion	short-term repeated dose oral toxicity: NOAEL > 1000 mg/kg bw/day short-term repeated dose dermal toxicity: no data available, waiving short-term repeated dose inhalation toxicity: NOAEC 0.0014 mg/L (1.4 mg/m³) Causes damage to organs (eyes) trough prolonged or repeated exposure.
Justification for the selected value/conclusion	**Short-term repeated dose oral toxicity:** In a short-term repeated dose oral toxicity study in rats performed with KMPS, no signs of systemic toxicity were observed. A short-term oral NOAEL > 1000 mg/kg bw/day **Short-term repeated dose dermal toxicity:** No data is available. Due to the local mode of action of KMPS which is mainly concentration-dependent no additional study to the available human volunteer studies was considered necessary (please refer to the information on data waiving provided above). KMPS is expected to induce skin corrosion or irritation at the site of first contact with skin. This is substantiated by acute dermal toxicity studies and studies on skin irritation/corrosion (please refer to chapters 3.2.2 and 3.3.1). No systemic effects are expected due to the high chemical reactivity of KMPS. **Short-term repeated dose inhalation toxicity:** In a short-term repeated dose inhalation toxicity study in rats performed with KMPS, a NOAEC of 1.4 mg/m³ was derived for local effects based on clinical signs of the eyes and histological eye findings observed at the next higher test concentration (LOAEC of 0.0101 mg/L (10.1 mg/m³)).
Classification according to CLP	KMPS warrants classification STOT RE Category 1, H372 "Causes damage to eyes trough prolonged or repeated exposure" according to Regulation (EC) 1272/2008.

3.6 SUB-CHRONIC REPEATED DOSE TOXICITY

3.6.1 Sub-chronic oral toxicity

Summary table of oral sub-chronic animal studies (usually 90-day studies)						
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/ group**	**Test substance Dose levels, Route of exposure, Duration of exposure**	**NOAEL, LOAEL**	**Results**	**Remarks**	**Reference**
Sub-chronic oral toxicity study OECD 408 GLP: Yes Reliability: 1	Rat Crl:CD®(SD) IGS BR M/F 10/sex/ group	Oxone® Monopersulphate Compound (KMPS) 0, 25, 200, and 600/1000 mg/kg bw (0, 2.5, 20, 60/100 mg/mL) Gavage 7d/week 13 weeks Functional and observational battery and motor activity assessments were performed during the study before initiation of treatment and during the 12th week of treatment. A shortened battery was performed during weeks 1-11 and week 13.	NOAEL 200 mg/kg bw/day (20 mg/mL) LOAEL: 600 mg/kg bw/day (60 mg/mL)	Clinical signs: Salivation, piloerection, abnormal gait, gasping, hunched posture, noisy respiration, wet coat, and paddling of forepaws were mostly noted at the highest concentration. Mortality: At 1000 mg/kg bw/day, 3 males and 1 female were humanely sacrificed in weeks 3 and 4. Body weight: Decreased body weight was noted in males for all test concentrations. Food consumption: Reduced food consumption was noted in males at the highest test concentration. Food conversion efficiency: Lower food conversion efficiency was noted for animals at the highest test concentration. Water consumption: No changes were observed. Haematology and clinical chemistry: No adverse treatment related changes were noted. Organ weights (bw adjusted): Higher group mean liver (males and female) and adrenal weights (males) were noted but either not considered adverse or related to treatment. Macroscopic/microscopic examination: Decedents: Congested GIT and necrotic and inflammatory lesion of the stomach and the small intestine were considered factors contributing to death. Survivors: Thickening of the forestomach and inflammation, oedema, haemorrhage in the mucosal and submucosal areas, epithelial necrosis, ulceration and hyperplasia were noted at the highest test concentration. The effects observed can be attributed to local oxidative reaction at the site of first contact. No signs of true systemic toxicity were observed in the study. No behavioural changes were noted which are considered to be indicative for neurotoxicity.	Due to 4 unscheduled deaths, the highest test dose of 1000 mg/kg bw was reduced to 600 mg/kg bw after 4 weeks of treatment	A6.4.1/01 [redacted] (2002) (Doc. No. 533-001)

In a sub-chronic oral toxicity study, rats received 0, 25, 200 and 1000 mg/kg bw/day Oxone® Monopersulphate Compound/mL (concentrations 0, 2.5, 20 and 200 mg/mL) 7 days per week for 13 weeks. Due to 4 unscheduled deaths in weeks 3 and 4, the highest dose was reduced to 600 mg/kg bw/day at the end of week 4.

In all 4 decedent animals, necrotic and inflammatory lesions of the stomach and the small intestine were considered factors contributing to death.

Histopathological changes were evident in surviving animals receiving Oxone® Monopersulphate Compound (KMPS) at concentrations of 1000/600 mg/kg bw/day for 13 weeks. The target organ was identified as the stomach with inflammatory, degenerative and hyperplastic changes mainly in the forestomach (findings including inflammation, oedema, haemorrhage in the mucosal and submucosal areas, epithelial necrosis and ulceration, and epithelial hyperplasia). Related macropathological changes such as thickening of the forestomach were also apparent. No histopathological changes were noted at 25 or 200 mg/kg bw/day.

The pathological findings seen in the stomach are considered to be a direct local effect following bolus administration and the oxidative reaction mechanisms of KMPS at the site of first contact, and are as such not considered to be associated with systemic toxicity.

Post-dosing salivation was noted for all animals at 1000 mg/kg bw/day and also noted among animals receiving 200 mg/kg bw/day. During the 4th week of treatment with 1000 mg/kg bw/day in some rats a transient piloerection, abnormal gait, gasping and hunched posture were noticed 1-2 h after intake. During the first 4 weeks of treatment, some animals showed pronounced lung sounds. Incidences of wet coat, paddling of forepaws and piloerection were noted among animals receiving 600 mg/kg bw/day during week 12 and 13. The signs (except pronounced lung sounds) are behavioural signs attributed to severe pain and inflammatory response at the point of contact (nonglandular stomach when dosed via gavage).

Higher body weight adjusted group mean liver (males and female) and adrenal (males) weights were noted but either not considered adverse or related to treatment.

There were no adverse treatment related changes in clinical chemistry parameters or haematology.

Rats receiving Oxone® Monopersulphate Compound up to and including the highest concentration of 1000/600 mg/kg bw/day showed no signs of systemic toxicity. The effects observed at doses of 1000/600 mg/kg bw/day (LOAEL) were lesions of the stomach, which are a consequence of the direct local effect following bolus administration of Oxone® Monopersulphate Compound. Thus, the NOAEL is considered to be 200 mg/kg bw/day.

Systemic effects noted at 600 mg/kg bw/day including decreased body weights, food consumption, and food conversion efficiency are considered to be secondary to corrosive/irritative effects at the site of entry into organism and not related to primary toxicity. This is plausible based on the mode of action of KMPS.

Functional and observational battery and motor activity assessments were performed during the study before initiation of treatment and during the 12th week of treatment.

A shortened battery was performed during weeks 1-11 and week 13. No behavioural changes were noted which are considered to be indicative for neurotoxicity.

No data on human sub-chronic oral toxicity of KMPS is available.

Value used in Risk Assessment – Sub-chronic oral toxicity	
Value/conclusion	Local effects: NOAEL: 200 mg/kg bw/day (20 mg/mL) LOAEL: 600 mg/kg bw/day (60 mg/mL)
Justification for the value/conclusion	In a 13-week oral toxicity study in rats, no systemic toxicity was observed in treated animals at doses of up to 1000/600 mg/kg bw/day Oxone®. Primary toxicity was noted at the site of first contact in the organism (gastrointestinal tract) characterised by inflammation and necrosis of the stomach. Systemic effects are considered secondary to these primary irritating effects which are triggered by the direct chemical reactivity of KMPS.

Data waiving	
Information requirement	Sub-chronic oral toxicity in 2nd species
Justification	No sub-chronic oral toxicity study in a 2nd species has been performed with KMPS. The conduct of a sub-chronic oral toxicity study in a 2nd species is considered to be not necessary for the following reasons: In chapter 1.4.4.2 of the TNsG on Data Requirements it is stated that the sub-chronic toxicity study in the second animal species may be waived "if the mechanism of the toxicity is known and it is justified that the toxicological effect is not specific to the first species […]". Due to its oxidative and corrosive/irritative properties, KMPS will cause destruction of mucous membranes of the gastrointestinal tract when ingested. These effects are considered to be of local nature due to the reaction of the substance with the surrounding tissue. Systemic toxicity would therefore occur only secondary to locally irritating effects at the site of first contact. In the available studies there are no indications for any other mechanism of toxicity than the local corrosion/irritation. Since this mode of action is chemically driven, it is not species specific. Moreover, breakdown products of KMPS are potassium and sulphate ions, which are both hydrophilic essential metabolites. Bioaccumulation of the degradation products in the body is thus not expected. Application of KMPS in concentrations which do not cause irritation/corrosion, results in physiological concentrations of potassium and sulphate ions. Thus, no adverse effects besides the local corrosion/irritation are expected. In the 90-days repeated dose oral toxicity study in rats, all observations could be attributed to the local irritant/corrosive mode of action of KMPS. This toxicological effect (i.e. the local irritation/corrosion) is not specific to any particular mammalian species

	or organ. Notably, it does not depend on toxicokinetic or toxicodynamic parameters of a certain species or organ and is rather concentration than time dependent and limited to the site of first contact. Thus, it can be assumed that the effects seen in rats would also be observed in the second sub-chronic study performed with another species. In other words: testing in a second species would lead to doubling of results. Consequently, and taking into account the predictability of the study results, a sub-chronic toxicity study in a second species would not provide any additional information for the assessment of KMPS, and should therefore not be conducted due to animal welfare reasons.

3.6.2 Sub-chronic dermal toxicity

No animal or human data on sub-chronic dermal toxicity is available for KMPS.

Value used in Risk Assessment – Sub-chronic dermal toxicity	
Value/conclusion	Considering the chemical mode of action, KMPS is expected to induce skin corrosion or irritation at the site of first contact with skin. KMPS is not considered to cause adverse systemic effects after sub-chronic dermal exposure.
Justification for the value/conclusion	Skin corrosion and irritation is expected after exposure to KMPS. This is substantiated by acute dermal toxicity studies and studies on skin irritation/corrosion (please refer to chapters 3.2.2 and 3.3.1). Please see the following justification on data waiving for more information. A semi-quantitative risk assessment for KMPS needs to be performed for the local dermal effects.

Data waiving	
Information requirement	Sub-chronic dermal toxicity
Justification	No sub-chronic dermal toxicity study has been performed with KMPS. The conduct of a dermal sub-chronic toxicity study is considered to be not necessary for the following reasons: According to chapter 1.4.3 of the Technical Notes for Guidance on Data Requirements, a study may be waived if the study is not scientifically necessary and "if the result may be predicted reliably from the intrinsic properties of the chemical or from other test results". Moreover, the Guidance on the BPR, Volume III, Part A Section 8.9.2 states that dermal repeated dose toxicity studies should be avoided, "if the substance is a severe irritant or corrosive, […] unless it can be performed at doses that do not cause irritation or

	corrosion and such doses are still toxicologically relevant." Due to its oxidative and corrosive/irritative properties, KMPS will cause skin destructions when applied topically. These effects are considered to be of local nature due to the reaction of the substance with the surrounding tissue. Systemic toxicity would therefore occur only secondary to locally irritating effects at the site of first contact. In the available studies there are no indications for any other mechanism of toxicity than the local corrosion/irritation. Since this mode of action is chemically driven, it is not species specific. Moreover, breakdown products of KMPS are potassium and sulphate ions, which are both hydrophilic essential metabolites. Bioaccumulation of the degradation products in the body is thus not expected. Application of KMPS in concentrations which do not cause irritation/corrosion, results in physiological concentrations of potassium and sulphate ions. Thus, no adverse effects besides the local corrosion/irritation are expected. The skin irritating potential of KMPS was investigated *in vivo* (please refer to chapter 3.3.1). Severe erythema as well as irreversible skin destruction was observed around the white coloured treated skin. Erythema were irreversible within the post-exposure period of 14 days. Moreover, no systemic effects were observed neither in the dermal irritation study nor in the acute dermal toxicity study (please refer to chapters 3.3.1 and 3.2.2). In the acute dermal irritation study, skin destruction was immediately visible after an exposure time of 4 h, as it can be expected for a corrosive substance. Systemic toxicity after dermal exposure towards KMPS would therefore occur only secondary to local irritating effects. Taken together: the outcome of a sub-chronic dermal study is predictable due to the local mode of action of KMPS, namely local corrosion/skin irritation at the site of first contact. Since these local effects are rather concentration than time dependent, it can be assumed that the effects seen in acute studies (such as acute dermal toxicity and skin irritation studies) would also be observed in sub-chronic dermal studies. In other words: an extension of the study duration would lead to doubling of results. Consequently, and taking into account the predictability of the study results, a sub-chronic dermal toxicity study would not provide any additional information for the assessment of KMPS, and should therefore not be conducted due to animal welfare reasons.

3.6.3 Sub-chronic inhalation toxicity

No animal or human data on sub-chronic inhalation toxicity is available for KMPS.

Value used in Risk Assessment – Sub-chronic inhalation toxicity	
Value/conclusion	KMPS is not considered to cause adverse systemic effects after sub-chronic inhalation exposure, but only local corrosion/irritation (as observed in the short-term inhalation toxicity study).
Justification for the value/conclusion	See the following justification for waiving a sub-chronic inhalation toxicity study.

Data waiving	
Information requirement	Sub-chronic inhalation toxicity study
Justification	No sub-chronic inhalation toxicity study has been performed with KMPS. The conduct of a sub-chronic inhalation toxicity study is considered to be not necessary for the following reasons: According to chapter 1.4.3 of the Technical Notes for Guidance on Data Requirements, a study may be waived if the study is not scientifically necessary and "if the result may be predicted reliably from the intrinsic properties of the chemical or from other test results". Due to its oxidative and corrosive/irritative properties, KMPS will cause destruction of mucous membranes of the respiratory tract when inhaled. These effects are considered to be of local nature due to the reaction of the substance with the surrounding tissue. Systemic toxicity would therefore occur only secondary to locally irritating effects at the site of first contact. In the available studies there are no indications for any other mechanism of toxicity than the local corrosion/irritation. Since this mode of action is chemically driven, it is not species specific. Moreover, breakdown products of KMPS are potassium and sulphate ions, which are both hydrophilic essential metabolites. Bioaccumulation of the degradation products in the body is thus not expected. Application of KMPS in concentrations which do not cause irritation/corrosion, results in physiological concentrations of potassium and sulphate ions. Thus, no adverse effects besides the local corrosion/irritation are expected. There is a 2-week sub-acute inhalation study in rats available (please refer to chapter 3.5.3), with reliability 2 (reliable with restrictions). Rationale for reliability including deficiencies: comparable to guideline study with acceptable restrictions. During the exposure period, the main observations were severe ocular irritation. The 13-day post-exposure observation period allowed only partial recovery from the ocular effects. Moreover, no systemic effects were observed neither in this sub-acute 2-week inhalation study nor in the acute inhalation study (please refer to chapters 3.5.3 and 3.2.3). In the acute inhalation study, local effects at eyes, nose and lungs were noted as it can be expected for a corrosive substance. Systemic toxicity after inhalation exposure towards KMPS would therefore occur only secondary to local irritating effects. Taken together: the outcome of a sub-chronic inhalation study is predictable due to the local mode of action of KMPS, namely local corrosion/irritation at the site of first contact. Since these local effects are rather concentration than time dependent, it can be assumed that the effects seen in acute and sub-acute 14-days inhalation studies would also be observed in sub-chronic inhalation studies. In other words: an extension of the study duration would lead to doubling of results. Consequently, and taking into account the predictability of the study results, a sub-chronic inhalation toxicity study would not provide any additional information for the assessment of KMPS, and should therefore not be conducted due to animal welfare reasons.

3.6.4 Overall conclusion on sub-chronic repeated dose toxicity

Value used in the Risk Assessment – Sub-chronic repeated dose systemic toxicity	
Value	Not relevant.
Justification for the selected value	KMPS does not exert primary systemic effects.
Classification according to CLP	

Value/conclusion used in the Risk Assessment – Sub-chronic repeated dose local effects	
Value/conclusion	sub-chronic repeated dose oral toxicity: NOAEL 200 mg/kg bw/day (20 mg/mL); sub-chronic repeated dose dermal toxicity: no data available, waiving sub-chronic repeated dose inhalation toxicity: no data available, waiving
Justification for the selected value/conclusion	**Sub-chronic repeated dose oral toxicity:** In a 13-week oral toxicity study in rats, no systemic toxicity was observed in treated animals at doses of up to 1000/600 mg/kg bw/day Oxone®. Primary toxicity was noted at the site of first contact in the organism (gastrointestinal tract) characterised by inflammation and necrosis of the stomach. Systemic effects are considered secondary to these primary irritating effects which are triggered by the direct chemical reactivity of KMPS. A NOAEL of 200 mg/kg bw/day was determined based on local effects observed in stomach of animals treated with 1000/600 mg/kg bw/day. **Sub-chronic repeated dose dermal toxicity:** No data is available. Due to the local mode of action of KMPS which is mainly concentration-dependent no additional study to the available human volunteer studies was considered necessary (please refer to the information on data waiving provided above). **Sub-chronic repeated dose inhalation toxicity:** No data is available and not considered necessary due to the local mode of action of KMPS which is mainly concentration- and not time-dependent (please refer to the information on data waiving provided above).
Classification according to CLP	No classification of KMPS is required based on the sub-chronic repeated dose studies available according to Regulation (EC) 1272/2008. Classification of KMPS as Skin Corr. 1, H314 "Causes severe skin burns and eye damage" in line with the results obtained in acute toxicity studies (irritation/corrosion) is considered sufficient to account for local effects on skin and respiratory tract after sub-chronic repeated exposure.

3.7 LONG-TERM REPEATED DOSE TOXICITY

3.7.1 Long-term oral toxicity

No animal or human data on long-term oral toxicity is available for KMPS.

Value used in Risk Assessment – Long-term oral toxicity	
Value/conclusion	KMPS is not considered to cause adverse systemic effects after long-term oral exposure.
Justification for the value/conclusion	Based on the chemical mode of action, KMPS is expected to induce corrosion or irritation at the site of first contact. This is substantiated by the data available (acute toxicity studies, short-term and sub-chronic oral toxicity studies). Please see the following justification on data waiving for more information.

Data waiving	
Information requirement	Long-term/chronic oral toxicity
Justification	For KMPS, one 14-day and one 90-day oral toxicity study in the rat are available and no chronic studies have been performed with KMPS. The conduct of chronic toxicity studies is considered to be not necessary for the following reasons: According to chapter 1.4.3 of the Technical Notes for Guidance on Data Requirements, a study may be waived if the study is not scientifically necessary and "if the result may be predicted reliably from the intrinsic properties of the chemical or from other test results". Due to its oxidative and corrosive/irritating properties, KMPS will cause destruction of skin and mucous membranes of the respiratory tract when applied topically or inhaled. These effects are considered to be of local nature due to the reaction of the substance with the surrounding tissue. Systemic toxicity would therefore occur only secondary to locally irritating effects at the site of first contact. In the available studies there are no indications for any other mechanism of toxicity than the local corrosion/irritation. Since this mode of action is chemically driven, it is not species specific. Moreover, breakdown products of KMPS are potassium and sulphate ions, which are both hydrophilic essential metabolites. Bioaccumulation of the degradation products in the body is thus not expected. Application of KMPS in concentrations which do not cause irritation/corrosion, results in physiological concentrations of potassium and sulphate ions. Thus, no adverse effects besides the local corrosion/irritation are expected. KMPS did not show any systemic effects in the two oral repeated dose studies presented in chapters 3.5.1 and 3.6.1. In the oral 14-days dose range finding study, concentrations of up to the highest test dose of 1000 mg/kg bw/day were well tolerated by rats of both sexes. In the 90-day oral sub-chronic study, no systemic adverse effects were observed under treatment with 600 mg/kg bw/day.

	All clinical findings – such as damage of the non-glandular stomach characterized by inflammation, necrosis, ulceration, and hyperplasia – could be attributed to the local irritant/corrosive mode of action of KMPS after bolus administration by oral gavage. This toxicological effect (i.e. the local irritation/corrosion) is not specific to any particular mammalian species or tissue and does not depend on toxicokinetic or toxicodynamic parameters of a certain species or organ. Notably, it is rather concentration than time dependent and limited to the site of first contact. Taken together: the outcome of a chronic study is predictable due to the local mode of action of KMPS, namely local corrosion/irritation at the site of first contact. Since these local effects are rather concentration than time dependent, it can be assumed that the effects seen in acute, sub-acute and sub-chronic studies would also be observed in chronic studies. In other words: an extension of the study duration would lead to doubling of results. Consequently, and taking into account the predictability of the study results, a chronic toxicity study would not provide any additional information for the assessment of KMPS, and should therefore not be conducted due to animal welfare reasons.

3.7.2 Long-term dermal toxicity

No animal or human data on long-term dermal toxicity is available for KMPS.

Value used in Risk Assessment – Long-term dermal toxicity	
Value/conclusion	KMPS is not considered to cause adverse systemic effects after long-term dermal exposure.
Justification for the value/conclusion	Based on the chemical mode of action, KMPS is expected to induce skin corrosion or irritation at the site of first contact with skin. This is substantiated by acute dermal toxicity studies and studies on skin irritation/corrosion. Please see the following justification on data waiving for more information. A semi-quantitative risk assessment for KMPS needs to be performed for the local dermal effects.

Data waiving	
Information requirement	Long-term/chronic dermal toxicity
Justification	Please refer to the chapter on sub-chronic dermal toxicity (chapter 3.6.2) for a detailed justification on data waiving.

3.7.3 Long-term inhalation toxicity

No animal or human data on long-term inhalation toxicity is available for KMPS.

Value used in Risk Assessment – Long-term inhalation toxicity	
Value/conclusion	KMPS is not considered to cause adverse systemic effects after long-term inhalation exposure.
Justification for the value/conclusion	Please refer to the chapter on sub-chronic inhalation toxicity (chapter 3.6.3) for a detailed justification on data waiving.

Data waiving	
Information requirement	Long-term/chronic inhalation toxicity
Justification	Please refer to the chapter on sub-chronic inhalation toxicity (chapter 3.6.3) for a detailed justification on data waiving.

3.7.4 Overall conclusion on long-term repeated dose toxicity

Value used in the Risk Assessment – Long-term repeated dose systemic toxicity	
Value	No primary systemic toxicity signs are foreseen after repeated exposure to KMPS regarding its mode of action and findings observed in oral and inhalation repeated exposure studies in rats and developmental toxicity study. Expected outcome of the long-term toxicity studies would be local effects at site of first contact, such as corrosion and irritation.
Justification for the selected value	Not relevant
Classification according to CLP	No classification regarding long-term repeated exposure to KMPS is required according to the criteria of Regulation 1272/2008.

Value/conclusion used in the Risk Assessment – Long-term repeated dose local effects	
Value/conclusion	Depending on the concentration, KMPS causes irritation/corrosion at the site of first contact.
Justification for the selected value/conclusion	Based on the chemical mode of action, KMPS is expected to induce corrosion or irritation at the site of first contact. This is substantiated by the available acute, sub-acute and sub-chronic toxicity studies. Any potential systemic effects are considered secondary to primary irritation/corrosion. Moreover, the breakdown products of KMPS (i.e. potassium and sulphate ions) are not likely to accumulate due to their hydrophilic nature. Due to the local

	mode of action of KMPS which is mainly concentration- and not time-dependent, long-term repeated dose/chronic toxicity studies are not deemed necessary.
Classification according to CLP	No classification of KMPS is required for sub-chronic repeated dose toxicity according to Regulation (EC) 1272/2008. Classification of KMPS as Skin Corr. 1, H314 "Causes severe skin burns and eye damage" in line with the results obtained in acute toxicity studies (irritation/corrosion) is considered sufficient to account for local effects after long-term/chronic repeated exposure.

3.8 GENOTOXICITY

3.8.1 In vitro

Summary table of in vitro genotoxicity studies					
Method, Guideline,GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks**	**Reference**
Bacterial reverse mutation test (Ames Test) OECD 471 GLP: Yes Reliability: 1	Oxone® Monopersulphate Compound (KMPS) 5 to 5000 µg/plate First test (range finding): +S9 mix/-S9 mix: 5000, 1500, 500, 150, 50, 15 and 5 µg/plate Main test: +S9 mix: 5000, 1500, 500, 150 and 50 µg/plate, -S9 mix: 500, 150, 50, 15 and 5 µg/plate	*Salmonella typhimurium,* TA1535, TA1537, TA98, TA100 and *Escherichia coli* WP2 Positive controls: +S9 mix: 2-Aminoanthracene, Benzo[a]pyrene -S9 mix: Sodium azide, 9-Aminoacridine, 2-Nitrofluorene, 2-(2-Furyl)-3-(5-nitro-2-furyl)acrylamide 2 independent tests (plate incorporation and pre-incubation test) were performed	Not mutagenic No increase in number of revertant colonies was observed under study conditions in the presence or absence of metabolic activation (S9 mix). Cytotoxicity: - in all strains at 5000 µg/pl. (+S9 mix) - in E.coli at 1500 µg/pl. (-S9 mix) - in S. typhimurium at 500 µ g/pl. (-S9 mix)	Deviation:/	A6.6.1/01 [redacted] (2001) (Doc. No. 557-001)
Mammalian chromosome aberration test OECD 473 GLP: Yes Reliability: 1	Oxone® Monopersulphate Compound (KMPS) First test: +S9 mix/-S9 mix: 312.5, 625 and 1250 µg/mL Second test: +S9 mix/-S9 mix: 0, 500, 1000 and 1250 µg/mL Treatment time: 3 h Recovery time: 17 h	Human peripheral blood lymphocytes Positive controls: +S9 mix: cyclophosphamide -S9 mix: Mitomycin C	KMPS increased the frequency of chromosomal aberrations under the test conditions. Positive in the presence and absence of S9. No increase in polyploid cells was noted. Clastogenic effects: at 1250 µg/mL (+S9 mix/-S9 mix) Reduction in the mitotic index to 52% (-S9 mix) and 45% (+S9 mix) of the solvent control at 1250 µg of KMPS/mL	Deviations: continuous treatment with test substance not performed (1.5 cell cycle), only 200 metaphases scored	A6.6.2/01 [redacted] (2001) Doc. No. 557-002

In vitro mammalian cell gene mutation assay OECD 476 GLP: Yes Reliability: 1	Oxone® Monopersulphate Compound (KMPS) Preliminary test: +S9 mix/-S9 mix: 39-5000 µg/mL Test 1: +S9 mix: 200-1200 µg/mL, -S9 mix: 100-800 µg/mL Test 2: +S9 mix: 200-1000 µg/mL, -S9 mix: 200-700 µg/mL	Mouse lymphoma L5178Y cells ($TK^{+/-}$) Positive controls: +S9 mix: 3-Methylcholanthrene -S9 mix: Methylmethanesulphonate	KMPS induced gene mutations under conditions of this test in the presence and absence of metabolic activation (S9 mix). Positive results were noted at the following test concentrations: Test 1: +S9 mix: 600 or 800 µg/mL, -S9 mix: 400 or 500 µg/mL Test 2: +S9 mix: 700 or 800 µg/mL -S9 mix: 400 – 600 µg/mL	/ Deviations: RS (relative survival) used to measure cytotoxicity, mutant frequency of negative control above the recommended acceptable spontaneous mutant frequency, colony sizing not performed	A6.6.3/01 [redacted] (2002) Doc. No. 557-004
In vitro mammalian cell gene mutation assay OECD 490 GLP: Yes Reliability: 1	KMPS (technical) Oxone™ Monopersulfate Compound Pre-experiment: + / - S9-mix: 25, 50, 150, 500, 1000, 2000 µg/mL Main test: + / - S9-mix: 50, 100, 125, 250, 500, 1000 and 2000 µg/mL	Mouse lymphoma L5178Y cells ($TK^{+/-}$) Positive controls: +S9 mix: B[a]P -S9 mix: Methylmethane-sulphonate and Ethylmethane-sulphonate	KMPS did not increase mutant formation under conditions of this test in the presence and absence of metabolic activation (S9 mix). The test item was neither mutagenic nor clastogenic under the conditions of the study	Large and small colonies were differentiated allowing the assessment for both mutagenic and clastogenic activity.	A6.6.3/02 [redacted] (2019) Doc. No. 557-005

Bacterial reverse mutation test (Ames test)

A key study on mutagenicity in bacteria was with Oxone® Monopersulphate compound (KMPS) conducted on *Salmonella typhimurium* strains TA1535, TA1537, TA98, TA100 and *Escherichia coli* strain WP2 with and without a metabolic activation system. Cytotoxicity was observed in the definitive assay in all strains at the highest concentration of 5000 µ g of Oxone® Monopersulphate Compound/plate with metabolic activation and in strains, TA1535, TA1537, TA98 and TA100 at 500 µ g Oxone® Monopersulphate Compound/plate without metabolic activation. Under the test conditions of the study, Oxone® Monopersulphate Compound (KMPS) did not show mutagenic activity.

Mammalian chromosome aberration test

Oxone® Monopersulphate Compound (KMPS) was tested for structural and numerical chromosomal aberrations in human blood lymphocytes in the presence and absence of a metabolic activation system. The concentrations tested were: 312.5, 625 and 1250 µg of Oxone® Monopersulphate Compound/mL (first test), and 500, 1000 and 1250 µg of Oxone® Monopersulphate Compound /mL (second test) with and without S9 mix. Oxone® Monopersulphate Compound was found to have clastogenic activity at 1250 µg/mL when compared with control value in the presence and absence of metabolic activation that contained only vehicle.

In the first test, Oxone® Monopersulphate Compound caused a reduction in the mitotic index to 53% of the vehicle control, both in the presence and absence of S9 mix.

In the second test, a clastogenic activity was also found at 1250 µg of Oxone® Monopersulphate Compound/mL with and without S9 mix when compared with control value that contained only vehicle. Oxone® Monopersulphate Compound caused a reduction in the mitotic index to 52% of the vehicle control in the absence of S9 mix and 45% in the presence of S9 mix.

In both tests, Oxone® Monopersulphate Compound caused a significant increase in the proportions of cells with chromosomal aberrations at 1250 µg/mL (with and without S9 mix), when compared to the control (vehicle) value. Under these experimental conditions, Oxone® Monopersulphate Compound is found to have clastogenic activity *in vitro*, in both the presence and absence of S9 mix.

Both tests showed no statistically significant increase in the number of polyploid metaphase cells when compared with the solvent control, i.e. no increase in numerical chromosomal aberrations was noted for Oxone® Monopersulphate Compound.

Mammalian cell gene mutation assay

Oxone® Monopersulphate Compound (KMPS) was tested for mutagenicity potential in mouse lymphoma L5178Y cells ($TK^{+/-}$). Cells were exposed to different concentrations of the test substance in the presence and absence of S9 mix. S9 mix was prepared from liver cells pre-treated with Aroclor 1254. Concentrations of Oxone® Monopersulphate Compound ranged from 39-5000 µg/mL. After a period of time, cells were incubated with trifluorethymidine, a selective agent that monitors the loss of functional $TK^{+/-}$ enzyme. Cell deficient in TK locus are resistant to toxic effects of TFT and do proliferate in the presence of TFT, whereas the non-mutant cells are not able to proliferate. The highest dose tested was selected based on RS (relative survival) and not on RTG (relative total growth) which is a more reliable indicator of cytotoxicity.

In Test 1, mean mutant frequencies at 400 or 500 µg/mL Oxone® Monopersulphate Compound were significantly increased without S9 mix, compared to control. Mean mutant frequencies were also increased at 600 or 800 µg/mL Oxone® Monopersulphate Compound in the presence of S9 mix. Number of induced mutants exceeded the global evaluation factor (GEF), indicating positive response in line with the currently valid guidance.

Test 2 confirmed the results of Test 1. Again, the statistically significant increase in the mean mutant frequencies was reported at 400 – 600 µg/mL Oxone® Monopersulphate Compound when no S9 mix was used. In the presence of S9 mix, the mean mutant frequencies were significantly elevated at 700 or 800 µg/mL Oxone® Monopersulphate Compound. This study deviates from the currently valid OECD 490 (2016) also in frequency of spontaneous mutants, which is higher as recommended in the guidance. However, in test 1 the recommended frequency is only slightly higher as recommended. Colony sizing was not performed in any test or control group.

In the 2nd study in mouse lymphoma L5178Y cells ($TK^{+/-}$), cells were exposed to different concentrations of the test item in the presence and absence of metabolic activation (S9-mix prepared from male Wistar rats induced with phenobarbital and beta-naphthoflavone). Concentrations ranged from 50 to 2000 µg/mL. After a period of time, cells were incubated with trifluorethymidine, a selective agent that monitors the loss of functional TK+/- enzyme. Cell deficient in TK locus are resistant to toxic effects of TFT and do proliferate in the presence of TFT, whereas the non-mutant cells are not able to proliferate. The second study was conducted taking into consideration the colony sizes to differentiate between mutagenic and clastogenic responses.

No precipitation of the test item was noted. No growth inhibition was observed both in the presence and absence of metabolic activation. No biologically relevant increase of mutants was found after treatment with the test item both in the presence and absence of metabolic activation. The global evaluation factor (GEF defined as the mean of the negative / vehicle mutant frequency plus one standard deviation) was not exceeded by the induced mutant frequency at any concentration. The positive controls showed distinct and biologically relevant effects in mutation frequency and showed the ability of the test system to differentiate between mutagenic and clastogenic responses. Thus, the test item was considered to be non-mutagenic and non-clastogenic under the conditions of the study.

The second mouse lymphoma assay ([redacted] 2019) did not confirm the result of the first study ([redacted] 2002), even though higher concentrations were tested in the second, fully OECD 490 GD compliant, study. Results of both gene mutation studies might differ due to presence of impurities in the test material, however, this can not be supported by any evidence since identity of batch used in study by [redacted] (2002) is not known. Additionally, the different toxicity may have been observed due to the use of different cells and different test protocols. The chromosomal aberration test by [redacted] (2001) was done in human lymphocytes. This is another type of cells than the cells used in the MLA studies. The [redacted] study was done as per OECD 490 (2016) whereas the [redacted] study was done as per OECD 476 (from 1997). Therefore, the two studies were not done according to the same protocol and therefore direct comparison between those two studies should be avoided.

Conclusion used in Risk Assessment – Genotoxicity *in vitro*	
Conclusion	KMPS has clastogenic potential *in vitro*, while clastogenic activity of KMPS *in vitro* is considered equivocal and can not be excluded
Justification for the conclusion	KMPS was evaluated in four *in vitro* genotoxicity assays. Under the test conditions, KMPS did not increase the number of revertants in any of the bacteria strains tested in an Ames test in the presence and absence of metabolic activation. KMPS increased the frequency of chromosomal aberrations in human lymphocytes and the number of gene mutations in *TK loci* of mouse lymphoma L5178Y cells with and without S9 mix in one assay only. The result of the second mouse lymphoma assay was negative. The second study is more recent, fully OECD 490 guideline compliant and performed with higher doses of test substance compared to first gene mutation study, thereafter more weight was given to the second study, but gene mutating potential of KMPS *in vitro* can not be excluded. Results of both gene mutation studies might differ due to presence of impurities in the test material, which are not known for the first gene mutation study ([redacted], 2002). The positive findings are considered to be a consequence of the oxidative nature of KMPS resulting in an impairment of the cellular physiology in *in vitro* systems. *In vitro* tests, however, resemble more static and closed system conditions lacking the required defence mechanisms for oxidative agents which are generally operating in *in vivo* systems. Thus, the oxidizing KMPS has direct access to the DNA, resulting in chromosomal aberrations and gene mutations.

3.8.2 In vivo

Summary table of in vivo genotoxicity studies					
Method, Guideline, GLP status, Realibility	**Test substance, Doses**	**Relevant information about the study**	**Observations**	**Remarks**	**Reference**
Mammalian Erythrocyte Mouse Micronucleus Test OECD 474 GLP: Yes Reliability: 1	Oxone® Monopersulphate Compound (KMPS) Preliminary study: 1500, 1750, 2000 mg/kg bw (corresponding to 75, 87.5, 100 mg/mL) Main study: Males: 0, 437.5, 875, 1750 mg/kg bw (corresponding to 0, 21.88, 43.75, 87.5 mg/mL) Females: 0, 500, 1000, 2000 mg/kg bw (corresponding to 0, 25, 50, 100 mg/mL) Positive control: Mitomycin C: 12 mg/kg bw	Mouse CD-1 Preliminary study: 2/sex/group Main study: 5/sex/group 12/sex/ group for 1750 mg/kg bw (males) and 2000 mg/kg bw (females) Single exposure by gavage Post-exposure period: 24, 48 h	Clinical signs: At 1750 mg/kg bw (males) and 2000 mg/kg bw (females), fast and irregular respiration, flat and hunched posture, underactivity, abnormal gait, partially closed eyes, piloerection/ungroomed and incidence of weight loss was recorded. No significant increase in number of micronucleated immature (polychromatic) or mature (normochromatic) erythrocytes at either sampling time in male and female animals (P>0.01). No significant decrease in the proportion of immature erythrocytes at either sampling time in male animals (P>0.01). Statistically significant decrease in the proportion of immature erythrocytes at the 24 h sampling time was observed in female animals, but not at 48 h sampling interval.	Reduction in the PCE/(PCE+NCE) ratio in female mice at the 24 h sampling time is considered to be a direct consequence of the local toxicity of KMPS rather than related to systemic toxicity. These signs were noted during the first 24 hours of treatment which is consistent with the observations made in the acute oral study in rats. Deviations: 2000 PCE scored for the presence of micronuclei Concentration and stability of the dosing solutions was not assessed during the study.	A6.6.4/01 [redacted] (2001) Doc. No. 557-003

In vivo Mammalian Alkaline Comet Assay OECD 489 GLP: Yes Reliability: 1	KMPS Triple Salt, OxoneTM Monopersulfate Compound, Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) Purity: 89.55% considering KMPS Triple Salt but Oxone as the product was the basis for dosing Preliminary study: 75, 125, 250, 500, 750, 1000 and 2000 mg/kg bw, 1 animal/sex/dose, except 3 animals/sex/dose at 750 mg/kg bwMain study: 0, 150, 300, 600, 750 mg/kg bw Positive control: Ethyl methanesulfonate: 250 mg/kg bw	Rat Crl: WI (Han) Preliminary study: Both sexes Main study: 5 males per group	Result: The test item tested negative for the induction of DNA breaks in any of the tissues evaluated, under the conditions of this study. Preliminary study: Dose-range finding study determined no sex differences in toxicity and identified 750 mg/kg bw as maximum tolerated dose. Clinical signs: No signs at 150 and 300 mg/kg bw. Reduced spontaneous activity at 600 mg/kg bw. At 750 mg/kg bw, reduced spontaneous activity after first administration, and reduction of spontaneous activity, prone position and ataxia after second administration. Body weight: Total body weight variation in the main experiment was 7.5 %. While control gained weight (4/5 animals), weight loss was noted after application of the test substance at all concentrations. **Histopathology and comet assay:** Liver, forestomach, glandular stomach and duodenum were investigated histopathologically and DNA breaks in those organs were analysed using the alkaline comet assay. Histopathology: The test item caused inflammatory and reactive lesions in a dose dependent manner in the stomach at doses ≥ 300 mg/kg bw and in the duodenum at doses ≥ 600 mg/kg bw. In forestomach inflammation was observed in only one treated animal (at the dose of 600 mg/kg); in glandular stomach inflammation was observed in 3 out of 5 animals at the top dose of 750 mg/kg. Inflammation was scored as mild to slight. Comet assay: Results shown as tail intensity. Negative control was within historical negative control data. Positive control showed a significant increase in tail intensity in all organs analysed. Test item showed no increase in tail intensity in no organ.	Devation: Limited HCD for forestomach (6 studies negative control, 9 studies positive control)	A6.6.5/01 [redacted] (2021) Doc. No. 557-006

Oxone® Monopersulphate Compound (KMPS) was tested *in vivo* in CD-1 mice for the induction of micronuclei formation. At the highest doses tested (males: 1750 mg/kg bw; females: 2000 mg/kg bw, corresponding to KMPS concentrations of 87.5 and 100 mg/mL, respectively) no mortalities were observed. Males showed fast and irregular respiration, flat and hunched posture, underactivity, abnormal gait, partially closed eyes, piloerection/ungroomed and incidence of weight loss, whereas females showed fast respiration, flat and hunched posture, underactivity, abnormal gait, partially closed eyes and piloerection/ungroomed.

No statistically significant increases in the frequency of micronucleated immature (polychromatic) and mature (normochromatic)

erythrocytes were observed in mice of both sexes treated with Oxone® Monopersulphate Compound and killed 24 or 48 hours later, compared to vehicle control values.

No statistically significant decrease in the proportion of immature erythrocytes was recorded at either sampling time in male mice. In female mice, a significant decrease was observed at the highest treatment dose 2000 mg/kg bw at the 24 hour sampling time only, while no such effect was evident at the 48 hour sampling time point.

Reduction in the PCE/(PCE+NCE)-ratio observed in female mice at the highest concentration level at the 24 hour sampling time point could be a direct consequence of the local (acute) toxicity of KMPS rather than related to systemic toxicity. The oral doses given to male and female mice were in the range of the LD_{50} observed in rats and although no mortalities occurred in mice, there were clinical signs of toxicity evident at the top dose levels. These signs were noted during the first 24 hours of treatment which is consistent with the observations made in the acute oral study in rats. This supports the conclusion above that the decreased PCE/(PCE+NCE)-ratio at the high dose level of female mice at the 24 hours sampling time point is related to the acute toxicity of KMPS. Moreover, oral gavage represents a bolus administration and the test concentration of 100 mg/mL (which is clearly above the threshold for irritation) leads to damage of the stomach and upper gastrointestinal tract. Even moderate tissue or organ damage is expected to lead to leakage of food ingredients and gastric acid as well as to compromise efficient uptake of nutrients. Any alterations in the PCE/(PCE+NCE)-ratio are therefore considered to be secondary to the sound local toxicity of KMPS after bolus administration. Due to the uncertainty with regard to the availability of the test substance at the target organ, the biological significance of this result is questionable.

Moreover, KMPS was tested *in vivo* in Crl: WI (Han) Wistar rats for the induction of DNA breaks. As identified in the dose-range finding experiment, the maximum tolerable dose was 750 mg/kg bw and no sex differences in toxicity were present. Therefore, only males were used for the main experiment. In dose range finding study animals were treated with 75, 125, 250, 500, 750, 1000 and 2000 mg/kg bw. At 2000 mg/kg bw reduced spontaneous activity and, piloerection, ataxia, half eyelid closure and lacrimation were observed. At 1000 mg/kg bw the same clinical signs were reported. Additionally, dark reddened stomach mucosa and stomach dilated with gas were seen. At next lower dose 750 mg/kg bw/d prone position, reduced spontaneous activity, ataxia, piloerection, half eyelid closure, moving the bedding and hunched posturewere reported. No difference between sexes were found. According to the histopathological analysis, the test item caused inflammatory and degenerative lesion in the stomach from 250 mg/kg bw onwards. The findings consisted of increased mixed inflammatory cell foci in the submucosa up to 500 mg/kg bw. Moreover, with increasing dose, from 750 mg/kg bw onwards, there were subacute submucosal inflammation associated with edema, erosion and/or ulceration in the stomach. The findings in the stomach at a dose of 750 mg/kg bw were considered adverse in nature. Based on these results doses selected for the main study were 150, 300, 600 and 750 mg/kg bw to demonstrate a dose-dependency in histopathological findings and to induce clinical symptoms in the highest dose of 750 mg/kg bw.

Comet assay was performed on forestomach, duodenum and glandular stomach to observe genotoxicity at site of first contact and on liver cells as tissue indicative of systemic genotoxicity. In the main test at the highest doses tested (750 mg/kg bw) no mortalities were observed. Animals treated with the test item showed reduced spontaneous activity at 600 mg/kg bw and 750 mg/kg bw. In addition, prone position and ataxia were observed at 750 mg/kg bw. Histopathology revealed inflammatory and reactive lesions caused by the test item in a dose dependent manner in the stomach at doses ≥ 300 mg/kg bw and in the duodenum at doses ≥ 600 mg/kg bw. The alkaline comet assay detected no increases in DNA breaks in liver, forestomach, glandular stomach and duodenum after administration of the test item when compared to the vehicle control thereby demonstrating the lack of gene mutating and clastogenic potential of KMPS *in vivo* at site of first

contact and systemically.

No human data on *in vivo* genotoxicity of KMPS is available.

Conclusion used in Risk Assessment – Genotoxicity *in vivo*	
Conclusion	KMPS is not genotoxic *in vivo*.
Justification for the conclusion	In a mammalian erythrocyte mouse micronucleus test KMPS did not increase micronuclei formation under study conditions. However, bone marrow exposure was not demonstrated. To demonstrate lack of genotoxic activity at site of first contact and systemically an *in vivo* Comet Assay in rats was performed on liver, forestomach, glandular stomach and duodenum. KMPS did not induce DNA strand breaks in any of any studied organ *in vivo* under study conditions. Negative comet assay confirmed that KMPS is not clastogenic and does not induce gene mutations *in vivo* neither at site of first contact, nor systemically.

Data waiving	
Information requirement	Germ cell effects
Justification	No studies investigating germ cell effects have been performed with KMPS. The conduct of studies on germ cell effects are considered to be not necessary for the following reasons: According to the TNsG on data requirements for biocidal products, chapter 2, point 6.6.6, possible germ cell effects are only to be assessed, if positive effects were observed in section 6.6.4 (*in vivo* bone marrow assay for chromosomal damage or micronucleus test). As no genotoxic potential of KMPS was found in the *in vivo* micronucleus test and in *in vivo* Comet assay in rats, a study investigating germ cell effects is not required.

Data waiving	
Information requirement	Further testing for genotoxicity

Justification	No further testing of KMPS with respect to genotoxicity of metabolites is required since KMPS is rapidly degraded to non-genotoxic potassium and sulphate ions at the site of first contact (leading to local irritation/corrosion). In addition, potassium and sulphate cannot be considered as xenobiotics in conventional terms but constitute rather physiological elements which are essential for the maintenance of the intermediary metabolism and are to be considered of no concern. Based on this local mode of action, KMPS will not become systemically available and any *in vivo* genotoxicity test can be predicted to be negative. Negative outcome of *in vivo* micronucleus and *in vivo* Comet assay also demonstrated that KMPS is not genotoxic at site of first contact or systemically For the reasons stated above, it is concluded that KMPS has no genotoxic potential *in vivo*, and thus no further genotoxicity testing with emphasis on metabolites/degradation products is required.

3.8.3 Overall conclusion on genotoxicity

Conclusion used in the Risk Assessment – Genotoxicity	
Conclusion	KMPS has clastogenic potential *in vitro*. Its potential to induce gene mutations *in vitro* can not be excluded. KMPS is not genotoxic *in vivo*.
Justification for the conclusion	***In-vitro* genotoxicity** KMPS did not increase the number of revertant colonies in an *in vitro* bacterial reverse mutation assay (Ames test). KMPS increased the formation of chromosomal aberrations in human peripheral blood lymphocytes and the number of gene mutations in mouse lymphoma cells *in vitro* in one assay. A more recent mouse lymphoma assay, fully guideline compliant and performed with higher dose of KMPS was also performed. Study result was clearly negative. The positive findings in mammalian cell cytogenicity and gene mutation assay are considered to be a consequence of the oxidative nature of KMPS resulting in an impairment of the cellular physiology in *in vitro* systems. *In vitro*, the oxidizing KMPS has direct access to the DNA, resulting in mutations and chromosomal aberrations. ***In-vivo* genotoxicity** In an *in vivo* mouse micronucleus test performed with KMPS, no increase in micronucleated immature (PCE) or mature (NCE) erythrocytes was observed under study conditions. A significant decrease in PCE/(PCE+NCE)-ratio was reported in females at 24 hrs post-application. Due to the local mode of action of KMPS it is questionable if decrease in PCE/(PCE+NCE)-ratio is a result of acute local toxicity of KMPS or a sporadic finding.

	In order to demonstrate the lack of genotoxic activity of KMPS *in vivo*, at site of first contact and systemically, an *in vivo* rat Comet assay was conducted. In the *in vivo* Comet assay no indication of DNA-damage was observed in all four organs investigated (liver, forestomach, glandular stomach, and duodenum) covering both the first site of contact and the metabolism organs. The dose levels in this study were up to and including the maximum tolerated dose (MTD) of 750 mg/kg bw as determined by respective organ damage. For example, in the duodenum mucosal degeneration and mucosal hyperplasia were noted at the MTD and below. In the glandular stomach acute inflammation and mucosal necrosis together with bloody stomach were noted at the MTD. Likewise in the forestomach hyperkeratosis at the MTD and below. Negative result of Comet assay indicated that KMPS did not induce chromosomal aberrations or gene mutations *in vivo* under study conditions. *In vivo* genotoxicity study investigating germ cell effects or further testing for genotoxicity of metabolites are not necessary due to the negative outcome of *in vivo* micronucleus assay and comet assay, local mode of action of KMPS and the rapid degradation to physiological potassium and sulphate ions which are non-genotoxic.
Classification according to CLP	No classification of KMPS is warranted for genotoxicity according to Regulation (EC) 1272/2008.

3.9 CARCINOGENICITY

No animal or human data on carcinogenicity is available for KMPS.

Conclusion used in Risk Assessment – Carcinogenicity	
Value/conclusion	KMPS is not considered carcinogenic.
Justification for the value/conclusion	No carcinogenicity study has been performed with KMPS. Based on the available data from the 14- and 90-day oral repeated dose toxicity studies in rats, the *in vivo* genotoxicity study in mice, and the *in vivo* Comet assay in rats KMPS is considered to act via a local mode of action based on direct chemical reactivity only. Any potential systemic effects are considered to be secondary to the local irritation/corrosion caused by KMPS at the site of first contact. Please see the following justification on data waiving for more information.
Classification according to CLP	No classification of KMPS is warranted for carcinogenicity according to Regulation (EC) 1272/2008.

Data waiving	
Information requirement	Carcinogenicity
Justification	No carcinogenicity study has been performed with KMPS. The conduct of a carcinogenicity toxicity study is considered to be not necessary based on the results from: • the 14-day and 90-day oral toxicity studies in rats • the *in vivo* genotoxicity study in mice • the in vivo Comet assay in rats According to chapter 1.4.3 of the Technical Notes for Guidance on Data Requirements, a study may be waived if the study is not scientifically necessary and "if the result may be predicted reliably from the intrinsic properties of the chemical or from other test results". For this reason, a carcinogenicity study for KMPS is being waived considering also the guidance given in chapter 1.4.2 of the TNsG on data requirements (other existing data/read across). Due to its oxidative and corrosive/irritative properties, KMPS will cause destruction of skin and mucous membranes of the respiratory tract when applied topically or inhaled. These effects are considered to be of local nature due to the reaction of the substance with the surrounding tissue. Systemic toxicity would therefore occur only secondary to locally irritating effects at the site of first contact. In the available studies there are no indications for any other mechanism of toxicity than the local corrosion/irritation. Since this mode of action is chemically driven, it is not species specific. Moreover, breakdown products of KMPS are potassium and sulphate ions, which are both hydrophilic essential metabolites. Bioaccumulation of the degradation products in the body is thus not expected. Application of KMPS at concentrations

	which do not cause irritation/corrosion, results in physiological concentrations of potassium and sulphate ions. Thus, no adverse effects besides the local corrosion/irritation are expected. KMPS did not show any systemic effects in the two oral repeated dose studies presented in chapters 3.5.1 and 3.6.1. In the oral 14-days dose range finding study, doses of up to 1000 mg/kg bw/day were well tolerated by rats of both sexes. In the 90-day oral sub-chronic study, no systemic adverse effects were observed under treatment with 600 mg/kg bw/day. All clinical findings – such as damage of the glandular stomach characterized by inflammation, necrosis, ulceration, and hyperplasia – could be attributed to the local irritant/corrosive mode of action of KMPS after bolus administration by oral gavage. This toxicological effect (i.e. the local irritation/corrosion) is not specific to any particular mammalian species or organ and does not depend on toxicokinetic or toxicodynamic parameters of a certain species or organ. Notably, it is rather concentration than time dependent and limited to the site of first contact. Thus, it can be assumed that any effect in chronic studies will be similar to those observed in the available sub-acute and sub-chronic studies. In other words: an extension of the study duration would lead to doubling of results. Additionally, an *in vivo* micronucleus test (MNT) in mice and an *in vivo* Comet assay were performed with KMPS (please refer to chapter 3.8.2). Although KMPS did show genotoxic potential in *in vitro* studies, no chromosome damaging evidence was observed *in vivo* in either male or female mice: The incidence of micronucleated immature erythrocytes was not increased, demonstrating that KMPS is not genotoxic *in vivo*. In female mice, a significant decrease in the proportion of immature erythrocytes was observed at the high treatment level (2000 mg/kg bw Oxone) at the 24 hour sampling time, but could be attributed to cytotoxic potential of KMPS. No statistically significant decrease in the proportion of immature erythrocytes was evident at the 48 hour sampling time point in female mice and at either sampling time in male mice. In the *in vivo* Comet assay no indication of DNA-damage was observed in all four organs investigated (liver, forestomach, glandular stomach, and duodenum) covering both the first site of contact and the metabolism organs. The dose levels in this study were up to and including the maximum tolerated dose (MTD) of 750 mg/kg bw as determined by respective organ damage. For example, in the duodenum mucosal degeneration and mucosal hyperplasia were noted at the MTD and below. In the glandular stomach acute inflammation and mucosal necrosis together with bloody stomach were noted at the MTD. Likewise in the forestomach hyperkeratosis at the MTD and below. Taken together: the outcome of a carcinogenicity study is predictable due to the local mode of action of KMPS, namely local corrosion/irritation at the site of first contact. These local effects can be assumed that the effects seen in acute, sub-acute and sub-chronic studies would also be observed in a carcinogenicity study. In other words: an extension of the study duration would not lead to additional information. Finally, there is no indication for a carcinogenic potential of KMPS as shown in an *in vivo* genotoxicity study. Consequently, and taking into account the predictability of the study results, a carcinogenicity toxicity study would not provide any additional information for the assessment of KMPS, and should therefore not be conducted due to animal welfare reasons. In view of data from 90 day subchronic oral toxicity study (thickening of the forestomach and inflammation, oedema, haemorrhage in the mucosal and submucosal areas, epithelial necrosis, ulceration and hyperplasia were noted at the highest test concentration in surviving animals) it is important to clarify possible non-genotoxic mode of action (MOA) of KMPS in relation to carcinogenic potential.

The corrosivity of a strong oxidizer like KPMS is different compared to strong acids and strong bases. KMPS releases reactive oxygen, which oxidizes macromolecules of the cell wall and membranes in unspecific manner leading to the cell wall disruption and loss of membrane integrity. In addition, after penetration into cells, intracellular molecules such as amino acids, polypeptides, RNA and DNA are also oxidized leading to the disruption of protein synthesis and cell death. KMPS shares a MOA with other approved peroxygen active substances, peracetic acid and hydrogen peroxide, which is the release of reactive oxygen species (ROS) and oxidation of organic material at the site of first contact leading to local corrosion/irritation. Many cancers arise from sites of chronic irritation, infection, or inflammation. Recent data have expanded the concept that inflammation is a critical component of tumour progression. ROS-sensitive signalling pathways are persistently elevated in many types of cancers, where they participate in cell growth/proliferation, differentiation, protein synthesis, glucose metabolism, cell survival and inflammation (Liou and Storz, 2010). ROS, particularly hydrogen peroxide, can act as second messengers in cellular signalling. A well-known MOA for non-genotoxic carcinogenesis is sustained cytotoxicity and related regenerative proliferation. Within the MOA of sustained cytotoxicity, oxidative stress represents a central event.

To facilitate risk assessment, [redacted] (2018) and [redacted] (2018) have used the MOA for ethyl acrylate (EA) and forestomach tumours caused by non-genotoxic initiating events, to develop Adverse Outcome Pathways (AOPs). For EA, a pre-molecular initiating event (pre-MIE) of sustained glutathione depletion is probable. Especially relevant for EA is the assessment of the threshold leading to critical GSH depletion, followed by inflammation, cytotoxicity, and hyperplasia. These AOPs are applicable for hazard identification, risk assessment and human relevance assessment for other chemicals that also act by these AOP, possibly KMPS.

Indirect non-genotoxic MOAs of carcinogenicity by definition involve a precursor key event other than DNA reactivity i.e. a test substance dose below which the molecular initiating event is not triggered and/or the sequence of key events will not progress so that tumour formation is prevented ([redacted] 2018; [redacted], 2021). In the 90-day oral toxicity study in rats at the highest concentration of KMPS, the initiating event after the reactive oxygen in situ was released from KMPS at the site of gavage dosing in the forestomach, may have been a depletion of glutathione (GSH) in the mucosal cell lining of the intestinal tract. The later than lead to an increase in epithelial damage, hyperplasia, and inflammation. Glutathione is known to be at the forefront in cell defense against oxidative stress that results from a free radical overload. It works with other antioxidants to preserve the functions of several vital proteins that are susceptible to oxidative damage, thereby rescuing cells from stress induced apoptosis. The enzymes involved in GSH redox cycling are important for both cellular free radical and non-radical detoxification ([redacted] 2021). [redacted] (1992) have shown that cells maintain the steady state balance of GSH as protective mechanism to prevent cytotoxicity and toxic responses in tissues remote from the dosing site.

An important topic of discussion, in particular in the area of carcinogenicity, is the human relevance of tumours observed in rodents. To address this issue, the WHO International Programme on Chemical Safety developed a conceptual framework for assessment of species concordance. According to this framework, assessment of human relevance should address the plausibility of a hypothesized MOA based on a thorough weight-of-evidence evaluation including mode-of-action/species concordance analysis ([redacted] 2020). The utility of rodent forestomach tumour data for hazard and risk has been examined for decades because humans do not have a forestomach, and these tumours occur by varying modes of action (MOAs) ([redacted] 2018). Identification of non-genotoxic carcinogens (NGTXC) is difficult compared

	to genotoxic substances and has traditionally relied on rodent carcinogenicity assay, but there is considerable scientific doubt regarding the reliability of the model due to a high number of false positive results arising from long-term exposure of animals to high doses of the test substance and a low reproducibility making relevance to human risk assessment questionable ([redacted] 2020). Further supporting in this matter is the Guidance on BPR: Volume III Parts B+C (Version 4.0, December 2017, p. 241) where the relevance of the rat forestomach irritation for human risk assessment is questioned. There are differences in pH and epithelia structure between human stomach and rodent forestomach, but probably most important, the contact time between the oesophagus epithelium and ingested material is negligible in humans when compared to the rodents' forestomach, which functions as a storage organ. It was suggested that only those part of GI tract should be included in human risk assessment that have counterpart in humans, such as oral cavity, pharynx and oesophagus, glandular stomach, or intestine. Leaving the forestomach out of consideration, which is the target organ in the 90-day rodent study, necrotic and inflammatory lesions of the glandular stomach and the small intestine were reported in the decedent animals exposed to 1000 mg/kg bw/day. These lesions were considered to be factors contributory to death. No pathological changes related to treatment were identified in animals receiving 200 mg/kg bw/day. The complete absence of any effect of treatment at this dose level indicates a steep dose-response curve between 200 and 1000 mg/kg bw/day. No treatment-related signs of inflammation, necrosis, and hyperplasia were reported in glandular stomach and the small intestine of the surviving animals. Therefore, a non-genotoxic MOA for carcinogenicity relevant to humans is not expected. In view of the 90-day oral gavage study results discussed above, KMPS MOA, as well as the possible applicability of AOPs presented by substances with similar initiating events and adverse outcomes, a non-genotoxic MOA for KMPS for carcinogenicity is not expected to be relevant for human hazard and risk assessment.

3.10 REPRODUCTIVE TOXICITY

3.10.1 Developmental toxicity

Summary table of animal studies on adverse effects on development						
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/ group**	**Test substance Dose levels, Duration of exposure**	**NOAELs, LOAELs**	**Results**	**Remarks**	**Reference**
Developmental Toxicity Study in Rats OECD 414 GLP: Yes Reliability: 1	Rat Crl:CD®(SD)IGS BR Females 22/dose	Oxone® Monopersulphate Compound (KMPS) Purity: 95.4% 0, 75, 250, 750 mg/kg bw/day (corresponding to¸0, 7.5, 25, 75 mg/mL) Gestation day 6-20 Gavage	Maternal NOAEL: 250 mg/kg bw/day (corresponding to NOAEC 25 mg/mL) Maternal LOAEL 750 mg/kg bw/day (corresponding to LOAEC 75 mg/mL); based on body weight gain, food consumption and stomach findings. Developmental NOAEL ≥ 750 mg/kg bw/day (corresponding to NOAEC: ≥75 mg/mL) Developmental LOAEC was not determined	At 750 mg/kg bw/day: significant decrease in body weight gain and food consumption was noted as well as thickening of non-glandular stomach (4/22), red discolouration of glandular stomach (1/22) and intestine distention with fluids (1/22). Clinical signs: No test substance related findings. The mean number of corpora lutea, implanation sites, resorptions, live foetuses and sex ratio were comparable across all groups. No teratogenic effects were observed at any dose level.	None	A6.8.1/01 [redacted] (2004) (Doc. No. 551-001)

In the rat teratogenicity study, females received Oxone® Monopersulphate Compound (KMPS) from days 6 to 20 of gestation at doses of 0, 75, 250 or 750 mg/kg bw/day (corresponding to concentrations of 0, 7.5, 25, 75 mg/mL). One animal receiving KMPS at the highest dose 750 mg/kg bw/day was found dead on day 13 of gestation. Before death weight loss and decreased food consumption on days 8-10 of gestation were observed. Later the animal regained weight and food consumption was normal. Necropsy revealed no gross postmortem abnormalities.

On day 21 day of gestation, stomach abnormalities (like thickened nonglandular stomach, red discoloration of the glandular stomach, distension of the intestine with fluids) were observed in 4 dams receiving 750 mg/kg bw/day. Animals also gained less weight and consumed less food compared to control animals.

The number of corpora lutea, implantation sites, resorptions, number of live foetuses, and sex ratio were comparable across the groups. Mean fetal weight was 4% lower (statistically not significant) in the 75 mg/mL group.

The maternal and foetal NOAEL for Oxone® Monopersulphate Compound was derived at 250 mg/kg bw/day, based on decreased maternal weight gain, food consumption, mortality and stomach findings and based on the slightly lower foetal weight in the 750 mg/kg bw/day group. No teratogenic effects were observed at any concentration. Thus, the NOAEL for embryotoxic/teratogenic effects is ≥ 750 mg/kg bw/day. Thereafter it can be concluded that KMPS is not toxic for fetal development in the rat.

No human data on developmental toxicity study is available for KMPS.

Conclusion used in Risk Assessment – Effects on development	
Value/conclusion	KMPS in not considered to adversely affect development of foetuses.
Justification for the value/conclusion	In a teratogenicity study performed with KMPS in rats, no maternal and fetal toxic effects were observed at 250 mg/kg bw/d (corresponding to 25 mg/mL). No developmental effects were observed up to and including the highest tested dose of 750 mg/kg/bw/d (corresponding to a concentration of 75 mg/L).

Data waiving	
Information requirement	Teratogenicity study in 2nd species (rabbit)
Justification	No teratogenicity study in rabbits has been performed with KMPS. The conduct of a teratogenicity study in rabbits is considered to be not necessary based on the results from: • the 14-day and 90-day oral toxicity studies in rats • the teratogenicity study in rats • the *in vivo* genotoxicity studies in rats and mice According to chapter 1.4.3 of the Technical Notes for Guidance on Data Requirements, a study may be waived if the study is not scientifically necessary and "if the result may be predicted reliably from the intrinsic properties of the chemical or from other test results". For this reason, a teratogenicity study in rabbits for KMPS is being waived considering also the guidance given in chapter 1.4.2 of the TNsG on data requirements (other existing data/read across). Due to its oxidative and corrosive/irritative properties, KMPS will cause destruction of skin and mucous membranes of the respiratory tract when applied topically or inhaled. These effects are considered to be of local nature due to the reaction of the substance with the surrounding tissue. Systemic toxicity would therefore occur only secondary to locally irritating

	effects. In the available studies there are no indications for any other mechanism of toxicity than the local corrosion/irritation. Since this mode of action is chemically driven, it is not species specific. Moreover, breakdown products of KMPS are potassium and sulphate ions, which are both hydrophilic essential metabolites. Bioaccumulation of the degradation products in the body is thus not expected. Application of KMPS in concentrations which do not cause irritation/corrosion, results in physiological concentrations of potassium and sulphate ions. Thus, no adverse effects besides the local corrosion/irritation are expected. KMPS did not show any systemic effects in the two oral repeated dose studies in rats (presented in chapters 3.5.1 and 3.6.1) and in the teratogenicity study in rats (chapter 3.10.1). Since KMPS is rapidly degraded to physiological metabolites (i.e. potassium and sulphate), it can be predicted that the embryo/fetuses will not be exposed to any high levels of KMPS. The predominant toxicological effect observed in the 14-day and 90-day studies in rats as well as in the teratology study in rats was local irritation/corrosion of the stomach. This mode of action is strictly concentration dependent, limited to the site of first contact, and not specific to any particular mammalian species or organ. Notably, it is not depend on toxicokinetic or toxicodynamic parameters. Thus, systemic exposure of the embryo/foetus does not occur and any potential systemic effects are considered to be only secondary to changes in the gastrointestinal tract. Importantly, no foetal malformations or variations were observed at any dose level in rats. Taken together, no teratogenic effects were observed when KMPS was administered to rats up to and including the highest dose 750 mg/kg bw/day. Notably, the active substance is not genotoxic in vivo neither at the first site of contact nor systemically. It can be assumed that the effects seen in rats would also be observed in the teratogenicity study performed with rabbits. Testing in a second species would lead to doubling of results. Consequently, and taking into account the predictability of the study results, a teratogenicity study in rabbits is not expected to provide any additional information for the assessment of KMPS, and should therefore not be conducted due to animal welfare reasons.

3.10.2 Fertility

No animal or human data on effects on fertility is available for KMPS.

Conclusion used in Risk Assessment – Fertility	
Value/conclusion	KMPS is not considered to affect fertility of exposed animals.
Justification for the value/conclusion	Please see the following justification on data waiving for more information.

Data waiving	
Information requirement	Two generation reproduction study
Justification	No two generation reproduction study has been performed with KMPS.

	The conduct of a two generation reproduction study is considered to be not necessary based on the results from: • the 14-day and 90-day oral toxicity studies in rats • the teratogenicity study in rats • the two *in vivo* genotoxicity studies in mice and rats According to chapter 1.4.3 of the Technical Notes for Guidance on Data Requirements, a study may be waived if the study is not scientifically necessary and "if the result may be predicted reliably from the intrinsic properties of the chemical or from other test results". For this reason, a two generation reproduction study for KMPS is being waived considering also the guidance given in chapter 1.4.2 of the TNsG on Data Requirements (other existing data/read across). Due to its oxidative and corrosive/irritative properties, KMPS will cause destruction of skin and mucous membranes of the respiratory tract when applied topically or inhaled. These effects are considered to be of local nature due to the reaction of the substance with the surrounding tissue. Systemic toxicity would therefore occur only secondary to locally irritating effects. In the available studies there are no indications for any other mechanism of toxicity than the local corrosion/irritation. Since this mode of action is chemically driven, it is not species specific. Moreover, breakdown products of KMPS are potassium and sulphate ions, which are both hydrophilic physiological metabolites. Bioaccumulation of the degradation products in the body is thus not expected. Application of KMPS in concentrations which do not cause irritation/corrosion, results in physiological concentrations of potassium and sulphate ions. Thus, no adverse effects besides the local corrosion/irritation are expected. KMPS did not show any systemic effects in the two oral repeated dose studies in rats presented in chapters 3.5.1 and 3.6.1 and in the teratogenicity study in rats (chapter 3.10.1). Since KMPS is rapidly degraded to physiological metabolites (i.e. potassium and sulphate), it can be predicted that the embryo/foetus will not be exposed to any high levels of KMPS. The predominant toxicological effect observed in the 14-day and 90-day studies in rats as well as in the teratology study in rats was local irritation/corrosion of the stomach. This mode of action is strictly concentration dependent, limited to the site of first contact, and not specific to any particular mammalian species or organ. Notably, it is not depend on toxicokinetic or toxicodynamic parameters. Thus, systemic exposure of the embryo/foetus does not occur and any potential systemic effects are considered to be only secondary to changes in the gastrointestinal tract. Notably, the active substance is not genotoxic *in vivo* neither at the first site of contact nor systemically. Consequently, and taking into account the predictability of the study results, a two generation reproduction study would not provide any additional information for the assessment of KMPS, and should therefore not be conducted due to animal welfare reasons.

3.10.3 Effects on or via lactation

No animal or human data on effects on or via lactation is available for KMPS.

Conclusion used in Risk Assessment – Effects on or via lactation	
Value/conclusion	KMPS is not considered to have any effects on or via lactation.
Justification for the value/conclusion	Please see the following justification on data waiving for more information.

Data waiving	
Information requirement	Effects on or via lactation
Justification	Due to its oxidative and corrosive/irritative properties, KMPS will cause destruction of skin and mucous membranes of the respiratory tract when applied topically or inhaled. These effects are considered to be of local nature due to the reaction of the substance with the surrounding tissue. Systemic toxicity would therefore occur only secondary to locally irritating effects. In the available studies there are no indications for any other mechanism of toxicity than the local corrosion/irritation. Since this mode of action is chemically driven, it is not species specific. Moreover, breakdown products of KMPS are potassium and sulphate ions, which are both hydrophilic physiological metabolites. Bioaccumulation of the degradation products in the body is thus not expected. Application of KMPS in concentrations which do not cause irritation/corrosion, results in physiological concentrations of potassium and sulphate ions. Thus, no adverse effects besides the local corrosion/irritation are expected. Consequently, no influence of KMPS on or via lactation is expected.

3.10.4 Overall conclusion on reproductive toxicity

Conclusion used in the Risk Assessment – Reproductive toxicity	
Value	KMPS shows no potential for developmental toxicity: • maternal NOAEL 250 mg/kg bw/d (corresponding to NOAEC 25 mg/mL) • embryotoxic/teratogenic NOAEL ≥750 mg/kg bw/d (corresponding to NOAEC ≥75 mg/mL) KMPS is not considered to affect fertility of exposed animals. KMPS is not considered to have any effects on or via lactation.

Justification for the selected value	In a teratogenicity study performed with KMPS in rats, no maternal toxic effects were observed 250 mg/kg bw/d. No embryotoxic/teratogenic effects were observed up to and including the highest test dose 750 mg/kg/bw/d. No teratogenicity study in a 2nd species (rabbit), fertility (two generation) studies or studies investigating effects on or via lactation are necessary due to the local mode of action of KMPS and the rapid degradation to potassium and sulphate ions which are physiological compounds in the body.
Classification according to CLP	No classification of KMPS is warranted for reprotoxicity or effects on or via lactation according to Regulation (EC) 1272/2008.

3.11 NEUROTOXICITY

No data is available on neurotoxicity of KMPS.

Conclusion used in Risk Assessment – Neurotoxicity	
Value/conclusion	KMPS is not considered to have any neurotoxic effects.
Justification for the value/conclusion	Please see the following justification on data waiving for more information.

Data waiving	
Information requirement	Acute and sub-chronic neurotoxicity
Justification	Symptoms that may be interpreted as neurotoxic effects were observed in several studies: • A reduced response to sound was observed in acute inhalation toxicity study. This clinical sign is considered to be a behavioural sign attributed to severe pain and inflammatory response at the point of contact (the nasal airway and its continuum - ears, sinuses, eyes). • The clinical signs such as hunched posture, lethargy, abnormal gait, body tremors, staining of the urogenital area in the acute oral toxicity study; flat and hunched posture, underactivity, abnormal gait, partially closed eyes, piloerection/ungroomed in the in vivo micornucleus test; reduced spontaneous activity, prone position, ataxia in the in vivo Comet assay (please refer to Section A.3.8.2 for a summary of *in vivo* genotoxicity studies), are behavioural signs attributed to severe pain at the point of contact (nonglandular stomach, since the animals were dosed via gavage). The conduct of an acute or sub-chronic neurotoxicity study with KMPS is not required for the following reasons:

	• KMPS does not belong to the chemical class of compounds inducing neurotoxicity from the structural point of view. • In the acute toxicity studies performed with KMPS, no signs of neurotoxicity after administration by the oral, dermal or inhalation route of exposure were observed (see chapters 3.2.1, 3.2.2, 3.2.3). • There were no clinical signs indicative of neurotoxicity in the 14-day toxicity study following repeated dose administration of KMPS to rats (see chapter 3.5.1). • Functional and observational battery and motor activity assessments were performed before initiation and during the 12th week and a shortened battery was performed during weeks 1-11 and week 13 in a 13-week oral toxicity study (see chapter 3.6.1). Treatment with KMPS for 13 weeks was not associated with any behavioural changes which are considered to be indicative for neurotoxicity. For the reasons mentioned above the conduct of an acute and sub-chronic neurotoxicity study is not required.

3.12 IMMUNOTOXICITY

No *in-vitro*, animal or human data is available on immunotoxicity of KMPS.

Conclusion used in Risk Assessment – Immunotoxicity	
Conclusion	KMPS is not considered to have immunotoxic effects.
Justification for the conclusion	See the following justification for waiving the immunotoxicity endpoint.

Data waiving	
Information requirement	Immunotoxicity
Justification	In the data available from studies performed with KMPS, there is no indication that KMPS would exert immunotoxic effects. In particular, KMPS was shown to act locally at the site of first contact and does not become systemically available. Consequently, no primary systemic effects were observed in the available studies.

3.13 DISRUPTION OF THE ENDOCRINE SYSTEM

The applicant has submitted an assessment of trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) (CAS No. 70693-62-8; KMPS) in accordance with the Guidance for the identification of endocrine disruptors in the context of Regulation (EU) No 528/2012 and (EC) No

1107/2009 (ECHA and EFSA, 2018) performed by LANXESS Deutschland GmbH and United Initiators GmbH.
This assessment report presents available information on potential endocrine disrupting (ED) properties of the active substance, the triple salt KMPS. However, in order to provide a comprehensive ED assessment, also data of the active constituent of the triple salt potassium hydrogen peroxomonosulphate (CAS No. 10058-23-8) were gathered and assessed. In particular, the database search and the literature search were performed for both substances due to the structural similarity.

Scientific data generated in accordance with internationally agreed study protocols

Referring to standard toxicity studies, a sub-chronic oral toxicity study according to OECD TG 408 (2002) and a developmental toxicity study according to OECD TG 414 (2004) were evaluated concerning ED effects and used as key studies. In addition to estrogen, androgen, thyroid or steroidogenic (EATS)-mediated effects, effects sensitive to, but not diagnostic of, EATS as well as general adversity were investigated.

In the two OECD conceptual framework (CF) level 4 (OECD, 2012) toxicity studies in rodents, adverse effects e.g. on body weight gain and food consumption, and clinical signs such as piloerection and mortality were observed at high doses. Further, KMPS induced irritating effects in the gastrointestinal tract after oral application. Overall, these signs of toxicity are considered related to local effects (i.e. corrosion/irritation) and associated secondary systemic effects based on the oxidative properties of KMPS.

As comprehensive relevant information is available concerning EATS-mediated activity and adversity, EATS-mediated parameters are considered sufficiently investigated for KMPS even though not all strict ED Guidance criteria are fulfilled, e.g. parameters like genital abnormalities (EAS), T3, T4 and thyroid-stimulating hormone (TSH) levels were not determined. In addition to the primary data sources (i.e. data generated using standardised test methods, systematic literature review), information from other sources (open access databases and *in silico* analyses) was gathered in line with the ED Guidance (ECHA and EFSA, 2018). No information was obtained which would be indicative of endocrine activity or endocrine-mediated adversity of the evaluated substances.

Summary animal data on endocrine disruption is presented in table below.

Summary table of animal data on endocrine disruption					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/ group**	**Test substance Dose levels, Route of exposure, Duration of exposure**	**Results**	**Remarks**	**Reference**

Sub-chronic oral toxicity study OECD 408 GLP: Yes Reliability: 1	Rat Crl:CD®(SD) IGS BR M/F 10/sex/ group	Oxone® Monopersulphate Compound (KMPS) 0, 25, 200, and 600/1000 mg/kg bw (0, 2.5, 20, 60/100 mg/mL) Gavage 7d/week 13 weeks	Histopathological examinations showed no EATS-mediated effects on the epididymis, mammary gland, ovary, testis, thyroid and the uterus. Further, no toxicological effect on the weight of the epididymis, mammary gland, ovary, testis, thyroid and the uterus was observed. Regarding endpoints suitable to detect effects sensitive to, but not diagnostic of, EATS no effects were noted in adrenal and brain weight. Furthermore, no histopathological findings were ob-served on adrenals, brain and pituitary. Statistically significantly increased liver weight was observed at 1000/600 mg/kg bw/day. But due to the absence of histopathological changes on the liver, this finding was considered not to represent adverse target organ toxicity. No effect on kidney histopathology and kidney weight was detected. <u>Local effects:</u> Thickening of the forestomach and inflammation, oedema, haemorrhage in the mucosal and submucosal areas, epithelial necrosis, ulceration and hyperplasia were noted at 1000/600 mg/kg bw/d. <u>General adversity:</u> The reduced body weight gain in males at all dose levels was suggestive of a toxic effect. However, the absence of an effect on food utilisation efficiency for males at 25 and 200 mg/kg bw/day indicated that the reduced body weight gain in the two lower-dosed groups was not treatment-dependent. Only at the highest dose level of 1000 mg/kg bw/day, reduced food consumption was noted in males. No adverse treatment-related changes were observed in clinical chemistry and haematology. Clinical signs such as salivation, pi-loerection, abnormal gait, gasping, hunched posture, noisy respiration, wet coat, and paddling of forepaws were mostly noted at 1000 mg/kg bw/day and 600 mg/kg bw/day. At 1000 mg/kg bw/day, 3 males and 1 female were humanely sacrificed in Weeks 3 and 4 due to adverse clinical effects. NOAEL: 200 mg/kg bw/day (20 mg/ml) LOAEL: 600 mg/kg bw/day (60 mg/ml)	Due to 4 unscheduled deaths, the highest test dose of 1000 mg/kg bw was reduced to 600 mg/kg bw after 4 weeks of treatment	A6.4.1/01 [redacted] (2002) (Doc. No. 533-001)

Developmental Toxicity Study in Rats OECD 414 GLP: Yes Reliability: 1	Rat Crl:CD®(SD)IGS BR Females 22/dose	Oxone□ Monopersulphate Compound (KMPS) 0, 75, 250, 750 mg/kg bw/day (corresponding to¸0, 7.5, 25, 75 mg/mL) Gestation day 6-20 Gavage	Regarding endpoints suitable to detect effects sensitive to, but not diagnostic of, EATS no effects were noted in fetal development, resorptions, mean fetal weight, the number of corpora lutea, implantation sites, number of live foe-tuses and sex ratio. Further, no presence of anomalies was observed at any dose level. Local effects: Thickening of non-glandular stomach (4/22), red discolouration of glandular stomach (1/22) and intestine distention with fluids (1/22) were noted. General adversity: Maternal toxicity: At 750 mg/kg bw/day, statistically significant de-crease in body weight gain and food consumption was noted. No test substance related clinical signs or mortality were observed.		A6.8.1/01 [redacted] (2004) (Doc. No. 551-001)

bw = body weight. CAS No. = Chemical Abstracts Service Registry Number. EATS = estrogen, androgen, thyroid or steroidogenesis.

Relevant human health data and epidemiological data

No human health or epidemiological data relevant for the ED assessment were available.

Scientific data selected applying systematic review methodology

A literature search on potential ED properties of the active substance pentapotassium bis (peroxymonosulphate) bis(sulphate) (CAS No. 70693-62-8; KMPS) and its main constituent potassium hydrogenperoxomonosulphate (CAS No. 10058-23-8) was performed according to the ECHA and EFSA ED Guidance.

Based on the evaluation of the summary records (titles/abstracts) 54 publications were assessed as obviously not relevant for the assessment of potential ED properties of the active substance trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate). Two full-text documents were assessed in detail. None of these publications provided relevant information on the potential ED properties of the active substance.

Data of *in vitro* methods and from open-source databases

In silico analyses on potential ED properties were performed using software tools recommended in ECHA/EFSA ED Guidance, e.g. the OECD (Q)SAR Toolbox (OECD, ECHA), Endocrine Disruptome and the VEGA platform.

In the open source databases no additional information on endocrine activity or endocrine adversity was identified (see table below).

Summary table of other evidence on endocrine disruption					
Method, Duration of exposure, Route of exposure, Guideline, GLP status, Reliability, Key/supportive study	**Species, Strain, Sex, No/group**	**Test substance (in-cluding purity), Vehicle, Dose lev-els,**	**Results**	**Remarks (e.g. ma-jor deviations)**	**Reference**
OECD (Q)SAR Toolbox Estrogen Receptor Bind-ing, profiling model non GLP, supporting	N.a. Prediction model	CAS No. 70693-62-8	Non binder, MW>500		OECD, ECHA
OECD (Q)SAR Toolbox Estrogen Receptor Bind-ing, profiling model non GLP, supporting	N.a. Prediction model	CAS No. 10058-23-8	Non binder, non-cyclic structure		OECD, ECHA
OECD (Q)SAR Toolbox Retinoic Acid Receptor Binding, profiling model, non GLP, supporting	N.a. Prediction model	CAS No. 70693-62-8	Not possible to classify according to these rules		OECD, ECHA
OECD (Q)SAR Toolbox Retinoic Acid Receptor Binding, profiling model, non GLP, supporting	N.a. Prediction model	CAS No. 10058-23-8	Not possible to classify according to these rules		OECD, ECHA
OECD (Q)SAR Toolbox rtER Expert System – US-EPA profiling model, non GLP, supporting	N.a. Prediction model	CAS No. 70693-62-8	No alert found		OECD, ECHA
OECD (Q)SAR Toolbox rtER Expert System – US-EPA profiling model, non GLP, supporting	N.a. Prediction model	CAS No. 10058-23-8	No alert found		OECD, ECHA
Software tool for pre-dicting endocrine activi-ty, Endocrine Disrup-tome, prediction model, non GLP, supporting	N.a. Prediction model	CAS No. 70693-62-8	Very weak androgen receptor antagonist activity The model scores w "-3.4" and "-3.5, respectively.	(below to the threshold of "-3.1" (lowest threshold is -3.1 and highest thresh-old is -7.1 for the „yel-low" probability binding class)	(Faculty of Pharmacy, University of Ljubljana, National Institute of Chemistry, Slovenia)
Software tool for pre-dicting endocrine activi-ty, Endocrine Disrup-tome, prediction model,	N.a. Prediction model	CAS No. 10058-23-8	Very weak androgen receptor antagonist activity The model scores w "-3.4" and	(below to the threshold of "-3.1" (lowest threshold is -3.1 and highest thresh-old is -	(Faculty of Pharmacy, University of Ljubljana, National Institute of

non GLP, supporting			"-3.5, respectively.	7.1 for the „yel-low" probability binding class)	Chemistry, Slovenia)
Software tool for predicting endocrine activity, Endocrine Disruptome, prediction model, non GLP, supporting	N.a. Prediction model	CAS No. 70693-62-8	Low probability of bind-ing for androgen recep-tor ("green" binding class)		(Faculty of Pharmacy, University of Ljubljana, National Institute of Chemistry, Slovenia)
Software tool for predicting endocrine activity, Endocrine Disruptome, prediction model, non GLP, supporting	N.a. Prediction model	CAS No. 10058-23-8	Low probability of bind-ing for androgen recep-tor ("green" binding class)		(Faculty of Pharmacy, University of Ljubljana, National Institute of Chemistry, Slovenia)
Software tool for predicting endocrine activity, Endocrine Disruptome, prediction model, non GLP, supporting	N.a. Prediction model	CAS No. 70693-62-8	Low probability of bind-ing for estrogen recep-tor alpha and beta ("green" binding class)		(Faculty of Pharmacy, University of Ljubljana, National Institute of Chemistry, Slovenia)
Software tool for predicting endocrine activity, Endocrine Disruptome, prediction model, non GLP, supporting	N.a. Prediction model	CAS No. 10058-23-8	Low probability of bind-ing for estrogen recep-tor alpha and beta ("green" binding class)		(Faculty of Pharmacy, University of Ljubljana, National Institute of Chemistry, Slovenia)
Software tool for predicting endocrine activity, Endocrine Disruptome, prediction model, non GLP, supporting	N.a. Prediction model	CAS No. 70693-62-8	Low probability of bind-ing for glucocorticoid receptor ("green" bind-ing class)		(Faculty of Pharmacy, University of Ljubljana, National Institute of Chemistry, Slovenia)
Software tool for predicting endocrine activity, Endocrine Disruptome, prediction model, non GLP, supporting	N.a. Prediction model	CAS No. 10058-23-8	Low probability of bind-ing for glucocorticoid receptor ("green" bind-ing class)		(Faculty of Pharmacy, University of Ljubljana, National Institute of Chemistry, Slovenia)
Software tool for predicting endocrine activity, Endocrine Disruptome, prediction model, non GLP, supporting	N.a. Prediction model	CAS No. 70693-62-8	Low probability of bind-ing for thyroid hormone receptor alpha and be-ta("green" binding class)		(Faculty of Pharmacy, University of Ljubljana, National Institute of Chemistry, Slovenia)

Software tool for predicting endocrine activity, Endocrine Disruptome, prediction model, non GLP, supporting	N.a. Prediction model	CAS No. 10058-23-8	Low probability of bind-ing for thyroid hormone receptor alpha and beta("green" binding class)		(Faculty of Pharmacy, University of Ljubljana, National Institute of Chemistry, Slovenia)
Software tool for predicting endocrine activity, Endocrine Disruptome, prediction model, non GLP, supporting	N.a. Prediction model	CAS No. 70693-62-8	Low probability of bind-ing for estrogen recep-tor alpha and beta ("green" binding class)		(Faculty of Pharmacy, University of Ljubljana, National Institute of Chemistry, Slovenia)
Software tool for predicting endocrine activity, VEGA platform Estrogen Receptor Relative Binding Affinity model (IRFMN), prediction model, non GLP, supporting	N.a. Prediction model	CAS No. 70693-62-8	inactive , prediction probability: low	Applicability Domain Index =0	VEGA in silico platform, version1.1.4 (build date:13/02/2017)
Software tool for predicting endocrine activity, VEGA platform Estrogen Receptor Relative Binding Affinity model (IRFMN), prediction model, non GLP, supporting	N.a. Prediction model	CAS No. 10058-23-8	inactive , prediction probability: low	Applicability Domain Index =0	VEGA in silico platform, version1.1.4 (build date:13/02/2017)
CAS No. = Chemical Abstracts Service Registry Number. N.a. = not applicable/not available. ECHA= The European Chemicals Agency, OECD= The Organisation for Economic Co-operation and Development, (Q)SAR: (Quantitative) structure activity relationship., rtER Expert System = rainbow trout estrogen receptor Expert System.					

Summary of data gathering according to the ECHA/EFSA ED Guidance.

The available database of *in vivo* studies on KMPS revealed no relevant, consistent nor conclusive indications for EATS-mediated adversity. Although comprehensive relevant information is available concerning EATS-mediated activity and adversity, EATS-mediated parameters are considered not sufficiently investigated for KMPS in view of strict ED Guidance criteria with respect to the toxicological data package. For KMPS, in the absence of level 5 studies e.g., OECD TG 416 (version 2001) or 443 according to the ED guidance Section 3.4.1 (ECHA/EFSA 2018), it cannot be considered that adversities are sufficiently investigated. Although there is QSAR analysis data, in the absence of OECD CF level 2 and/or level 3 studies, the dataset regarding activities cannot be considered as sufficiently investigated according to the ED guidance, Section 3.4.2. The only available information for T-modality is the OECD TG 408 study, however, parameters like genital abnormalities (EAS), T3, T4 and thyroid-stimulating hormone (TSH) levels were not determined. In the absence of long-term studies

following TG 416 and 451-3, it cannot be considered that T-modality is sufficiently investigated. Thus, overall, neither EATS-mediated adversities nor activities are investigated sufficiently.
The ED guidance points out that the determination of adversity shall be based on a weight of evidence approach taking into account all the available information in the dossier. This means that the studies abovementioned should not be considered in isolation, and that the specific guideline on assembling and assessing the lines of evidence should be followed. Because an unequivocal justification for proposal for non-ED must be given, the scenario 2a(iii) (No endocrine activity, but not sufficiently investigated) must be followed according to the ED guidance (p. 32, ECHA, EFSA, 2018). The scenario includes two options to proceed with the assessment. If the endocrine activity has not been sufficiently investigated it is necessary to generate further information, described for each EATS modality (Section 3.4.2). In case of KMPS, this would include as follows: a) for E-modality, ToxCast ER Bioactivity Model or 'Uterotrophic bioassay in rodents' (OECD TG 440); b) for A modality, 'Hershberger bioassay in rats' (OECD TG 441); c) for T modality, the thyroid parameters should be drawn from OECD test guidelines 407, 408, 409 studies (and/or the one-year dog study, if available), 416 (or 443 if available), and 451-3; and d) for S-modality, the level 2 *in vitro* assays 'H295R steroidogenesis assay' OECD TG 456 and the 'aromatase assay (human recombinant)', the US EPA OPPTS 890.1200 or partially, OECD TG 441, must be considered together with the results of the E and A modalities in order to conclude on the absence of endocrine activity for the S modality. Alternatively, the ED guidance advises to consider complementing the information available on 'EATS-mediated' adversity, e.g. by carrying out level 5 studies, as described in Section 3.4.1.: an extended one-generation reproductive toxicity study (EOGRTS; OECD TG 443; with cohort 1a/1b including the mating of cohort 1b to produce the F2 generation or a two-generation reproductive toxicity study (OECD TG 416; test protocol according to latest version of January 2001). Depending on the outcome of these further investigations, the assessment needs to be continued following the corresponding scenario.
In case of KMPS, the ED guidance and the use of scenario 2a (iii) cannot be strictly followed because none of the above listed assays is deemed feasible. KMPS is a strong oxidant with exclusively local action exerting irritating effects at the point of contact with any tissue. It is also highly unstable: it dissociates immediately into potassium and sulphate (K^+, SO_4^{2-} and HSO_4^-) ions at the site of first contact with the tissues after causing primary irritating effects. Thus, any observed general adversity is considered to be secondary caused by the primary irritating effects. The breakdown products of KMPS, i.e. K^+ and SO_4^{2-} ions are chemically and biologically not further degradable because they constitute simple basic structures of inorganic nature. Both breakdown products (i.e. potassium ions and sulphate ions) constitute physiologically essential metabolites in the human body which are efficiently excreted via the urine after oral uptake.
It follows, that the studies required for further information must be waived because of the nature of KMPS. The only choice left in order to make conclusions in case of KMPS is a weight of evidence approach. Based on the weight of evidence analysis, the overall conclusion is that KMPS has no EATS-mediated endocrine adversity and also no ED-related activity and that the observed general adversity was considered to be secondary caused by the primary irritating effects.

EATS-mediated adversity

Based on a weight of evidence (WoE) approach, EATS-mediated adversity of KMPS was assessed using the two available reliable and guideline compliant toxicological studies (Sub-chronic oral toxicity study according to OECD TG 408 and Developmental Toxicity Study according to OECD TG 414). A large number of important EATS-mediated adversity parameters were covered (*e.g.* effects on thyroid histopathology, ovary weight and histo-pathology, mammary gland histopathology, uterus and testis histopathology and weight), however, some relevant parameters demanded in the ED Guidance were not recorded *e.g.* genital abnormalities (EAS), T3, T4 and thyroid-stimulating hormone (TSH) levels. Thus, with regards to the strict ED Guidance criteria, KMPS has to be considered as "not sufficiently investigated"

regarding EATS-mediated adversity. However, findings potentially related to ED (effects sensitive to, but not diagnostic of, EATS) were also investigated and no effects were found in adrenals, pituitary gland and brain weight and histopathology. Additionally no effects were observed in reproductive parameters (fetal development, litter weight, number of implantations, corpora lutea and number of embryonic or feotal deaths and viable foetuses) and developmental parameters. The analysis of the toxicological information revealed neither relevant nor conclusive indications for EATS-mediated adversity and no sensitive to, but not diagnostic of, EATS effects attributable to treatment with KMPS.

Consequently, the overall conclusion is that using a weight of evidence approach, no ED properties were revealed for KMPS in this reliable ED assessment.

EATS-mediated endocrine activity

The determination of activity was based on a WoE approach taking all available information into account. No information was found in the databases indicating evidence of EATS mediated activity of KMPS. OECD QSAR Toolbox, (Version 4.3.1.) profilers notice KMPS and potassium hydrogenperoxomonosulphate as "no binder" for the estrogen receptor due to the high molecular weight (> 500) and the absence of a cyclic structure. Additionally, no profiling alert was found for the binding activity of KMPS and potassium hydrogenperoxomonosulphate for the estrogen receptor via *OECD QSAR Toolbox, Version 4.3.1* and *VEGA in silico platform, version 1.1.4*. KMPS possess low binding probability ("green class") for androgen receptor, estrogen receptor alpha and beta, thyroid hormone receptors alpha and beta and glucocorticoid receptor according to the *Endocrine Disruptome software.* A very weak androgen receptor antagonist activity was identified for KMPS and potassium hydrogenperoxomonosulphate, whereby the activity scores (-3.4 and -3.5) were only marginal above the threshold of -3.1 established for the medium probability binding class (*Endocrine Disruptome software)*.
Overall, based on the databases search and the Q(SAR) analyses no concern is given indicating putative endocrine activity of KMPS and potassium hydrogenperoxomonosulphate. The WoE suggests that KMPS has no EATS-mediated activity. This is considered to also apply to potassium hydrogenperoxomonosulphate.
Detailed information relevant for the ED assessment is presented in the Appendix VII.

Conclusion used in Risk Assessment – Endocrine disruption	
Conclusion	KMPS is not considered to have endocrine disrupting properties.
Justification for the conclusion	The available data set for KMPS and potassium hydrogenperoxomonosulphate was evaluated in accordance to the ED criteria laid out in the ED Guidance (ECHA and EFSA, 2018) in a weight of evidence approach. The present weight of evidence shows clearly that KMPS and its main constituent potassium hydrogenperoxomonosulphate display neither EATS-mediated adversity nor activity and are thus no endocrine disruptors.

Data waiving	
Information requirement	Endocrine disruption

Justification	Based on the weight of evidence analysis, the overall conclusion is that KMPS has no EATS-mediated endocrine adversity and also no ED-related activity. Although comprehensive relevant information is available concerning EATS-mediated activity and adversity, EATS-mediated parameters are considered not sufficiently investigated for KMPS in view of strict ED Guidance criteria with respect to the toxicological data package. Because an unequivocal justification for proposal for non-ED must be given, the scenario 2a(iii) (No endocrine activity, but not sufficiently investigated) must be followed according to the ED guidance (p. 32, ECHA, EFSA, 2018). In case of KMPS, the ED guidance and the use of scenario 2a (iii) cannot be strictly followed because none of the required assays is deemed feasible due to the nature of KMPS. KMPS is a strong oxidant which dissociates immediately into potassium and sulphate (K^+, SO_4^{2-} and HSO_4) ions at the site of first contact. Thus, the observed general adversity was considered to be secondary caused by the primary irritating effects. Both breakdown products (i.e potassium and sulfate ions) are chemically and biologically not further degradable because they constitute ubiquitous simple basic structures of inorganic nature. Both breakdown products (i.e. potassium ions and sulphate ions) constitute physiologically essential metabolites in the human body which are efficiently excreted via the urine after oral uptake.

3.14 FURTHER HUMAN DATA

Summary table of further human data				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
Medical surveillance no guideline applicable	KMPS (Caroat®)	150 persons (males and females) were exposed daily towards KMPS. Exposure was continuously during production, analysis and application of KMPS. Neither exposure concentration nor overall time of exposure are stated. Workers of KMPS production were examined for health effects periodically within 6 years. Examinations included a hearing test, sight test, lung function test, ECG under exercise, blood and urine examinations.	No specific adverse effects of KMPS on health were observed within a period of 6 years.	A6.12.1/01 [redacted] (2005) (Doc. No. 574-001)
Respiratory health surveillance	Oxone	33 active employees at Oxone manufacturing site, Memphis. Employees filled out Interval Health History and Wellness Appraisal or OSHA questionnaires including questions regarding respiratory health. Additionaly pulmonary function test was performed to evaluate pulmonary obstructive disease.	No pulmonary symptoms were reported among the employees for the 2013-2016 calendar year.	[redacted] (2016) (Report No. EPI-06022016)

Conclusion used in Risk Assessment – Further human data	
Conclusion	KMPS does not have adverse health effect on workers at the production site.
Justification for the conclusion	In a medical surveillance with 150 persons, no specific adverse effects were observed for KMPS. More recent surveillance of respiratory health of active employees in Oxone manufacturing facility showed no pulmonary symptoms among employees.

3.15 OTHER DATA

No further data on KMPS is necessary for the purposes of the BPD dossier.

4 ENVIRONMENTAL EFFECTS ASSESSMENT

4.1 FATE AND DISTRIBUTION IN THE ENVIRONMENT

4.1.1 Degradation

4.1.1.1 Abiotic degradation

Hydrolysis and oxidation upon contact with oxidizable substances (organic and inorganic)

Summary table – Abiotic degradation							
Method, Guideline, GLP status, Realibility	**Test medium**	**pH**	**Temp. [°C]**	**Initial TS conc., C_0 [g a.i./L] [1]**	**Half-life, DT_{50} [h]**	**Rate constant k [h^{-1}] [4]**	**Reference**
Hydrolysis							
OECD 111 GLP Ri = 2	Buffer	4.0	20	3.0	> 800 [2]	n.d.	[redacted] (2007) Doc. No. 119-003; A7.1.1.1.1/01 key study
			30		440 [2]	n.d.	
			50		n.d.	0.0066	
	Buffer	7.0	20	3.0	145 [2]	n.d.	
			30		53 [2]	n.d.	
			50		n.d.	0.12	
	Buffer	9.0	20	3.0	2.8 [2]	n.d.	
			30		n.d.	0.4	
			50		n.d.	0.68	
	seawater	8.0-8.2	20	3.0	5.6 [2]	n.d.	
			30		2.5 [2]	n.d.	
			50		1.4 [2]	n.d.	
	freshwater	7.8-8.2	20	3.0	215 [2]	n.d.	
			30		65 [2]	n.d.	
			50		8.7 [2]	n.d.	
Oxidation upon contact with oxidizable substances (organic and inorganic)							
No guideline mentioned Not GLP Ri = 2	Synthetic pool water with Body Fluid Analogue	7.4-7.6	29 ± 1	12	3 [3]	n.d.	[redacted] (2007) Doc. No. 711-002; A7.1.1.1.1/02 key study
	Synthetic pool water without Body Fluid	7.4-7.6	29 ± 1	12	120 [3] (extrapolated)	n.d.	

	Analogue						
No guideline mentioned Not GLP Ri = 2	Activated sludge	-	12	0.3	0.187 [4]	3.7	[redacted] 713-002; A7.1.1.1/02 key study
No guideline mentioned Not GLP Ri = 2	Activated sludge	-	20	0.3	5.25E-03 [5] (rapid phase) 8.24 [5] (slow phase)	132.1 0.08413	[redacted] No. 713-001; A7.1.1.1/01 key study
No guideline mentioned Not GLP Ri = 2	Activated sludge	-	16	0.3	1.13 [6] (Denny activated sludge) < 0.083 [3] (Drumnadrochit activated sludge)	0.611 (Denny activated sludge)	[redacted] (2018) Doc. No. 713-003; A7.1.1.1/03 key study
No guideline mentioned Not GLP Ri = 3	Soil	-	22	100 ppm	<1	-	Anonymous (2005) Doc. No. 721-002

1: nominal concentration
2: DT_{50} values were determined by visual examination of the plot 'ln (normalised % KMPS) vs time'
3: DT_{50} values were determined by visual examination of the plot 'concentration KMPS (ppm Oxone) vs time'
4: DT_{50} value was determined based on logarithmic diagram 'ln rate vs ln [Oxone]'
5: DT_{50} values were derived by CAKE v3.3 software using Double-First-Order in Parallel model (DFOP) fit.
6: DT_{50} value was derived by CAKE v3.3 software using Single first-order kinetics (SFO) fit
n.d.: not determined

$KHSO_5$, the active ingredient in KMPS, can be degraded abiotically

a) by hydrolysis
b) by a disproportionation reaction
c) by an oxidation reaction upon contact with oxidizable substances (organic and inorganic)

a) In the **hydrolysis** study, the degradation of KMPS was measured by determining the loss of active oxygen by iodometric titration.

The degradation of KMPS in aqueous solution is pH and temperature dependant. Degradation is accelerated with increasing temperature and increasing pH. While KMPS has a half-life of above 800 h (at 20 °C) in a buffered solution of pH 4, the half-life at pH 7 is 145 hours and only 2.8 hours at pH 9. Degradation in seawater is considerably faster (DT_{50} = 5.6 hours, pH 8.0-8.2, 20 °C) than in freshwater (DT_{50} = 215 hours, pH 7.8-8.2, 20 °C).

Since the titration method would also detect other peroxide species and a loss of active

oxygen was observed it can be concluded that no other peroxide species is built upon hydrolysis.

Furthermore, it was shown that the formation of hydrogen peroxide via hydrolysis occurs only after long time and results only in negligible amounts ([redacted] (2016) Doc. No. 711-004, A7.1.1.1.1/03 and [redacted] (2016) Doc. No. 711-005, A7.1.1.1.1/04).

The reason for the faster degradation of KMPS in seawater is the so-called Haber-Will-Statter Reaction. In this, the sodium chloride of the seawater is oxidised by KMPS so that chlorine is released.

$HSO_5^- + 2Cl^- + 2H^+ \rightarrow HSO_4^- + Cl_2 + H_2O$

The chlorine reacts with water to form hypochlorous acid:

$Cl_2 + H_2O \rightarrow HOCl + HCl$

Hypochlorous acid (HOCl) is only of transient nature. As shown in Annex II (Kinetic model on the long term hypochlorite decay in the environment) to the ESD on drinking water disinfectants (EUBEES2), hypochlorous acid is extremely rapidly eliminated in the environment due to reaction with ammonia and organic material which act as reductants.

b) The **disproportionation** reaction seems to occur spontaneously and slowly according to the following reaction scheme generating hydrogen sulphate and oxygen:

$2\ HSO_5^- \rightarrow 2\ HSO_4^- + O_2$

c) Oxidation reactions upon contact with oxidizable substances

1. In the study on the "Depletion of Potassium Monopersulfate in Synthetic Pool Water" ([redacted] (2007) Doc. No. 711-002, A7.1.1.1.1/02), it was shown that the decomposition of KMPS in water is very dependent on the presence of **oxidizable** contaminants. The addition of a 'body fluid analog' to the synthetic pool water used in this laboratory test reduced the half-life for decomposition of KMPS from ca. 120 hours (synthetic pool water without 'body fluid analog') to ca. 3 hours. This is explained by the consumption of $KHSO_5$ in many different oxidation reactions with reduced amine substrate components of the added 'body fluid analog', according to the general reaction:

$KHSO_5 + X \rightarrow KHSO_4 + X = O$

It can be assumed that KMPS is degraded at similar rates in natural waters, such as pond and river water. The higher the concentration of oxidizable organic substrate is in the water, the faster KMPS will be degraded.

Such oxidizing reactions can also occur in soil due to the high content of oxidizable agents in soil.

2. The degradation of KMPS by reactions upon contact with oxidizable substances was also determined in activated sludge, i.e. in a medium containing inorganic and organic oxidizable substances in abundance.

In order to check the design firstly a pre-study was performed ([redacted] (2011) Doc. No. 713-002, A.7.1.1.1/02). In the main study ([redacted] (2012) Doc. No. 713-001, A.7.1.1.1/01) this design was mostly applied (pre-study: test temperature 12 °C; main study: test temperature 20 °C). Since the sampling

for both studies took place separately and at a different time, the investigated sewage sludges are considered as individual systems in the following.

The purity of the test substance Oxone (KMPS) was analyzed at the beginning of the test.

A reaction mixture of Oxone (KMPS) and activated sludge was prepared by mixing activated sludge and Oxone (KMPS) solution with initial concentration of 300 ppm KMPS. Oxone concentration in activated sludge and deionized water was determined indirectly by the addition of Oxone containing sample to a known, excess concentration of FAS. As Oxone reacts rapidly with Fe(II) in a redox reaction and results in the formation of Fe(III) salts, subsequent titration of the remaining FAS with potassium dichromate determines the residual concentration of Fe(II) in the solution.

KMPS reacts immediately and extremely quickly upon contact with the diverse substances that can be oxidized and which are abundantly available in activated sludge. Therefore, it is absolutely impossible to measure the immediate initial concentration of 300 ppm KMPS in the reaction mixture.

The three measurements from the first sampling time in the main study showed all very similar KMPS values. For this reason and since the test substance purity was determined directly before starting the test, it can be concluded that no experimental mistake had occurred and that the initial concentration was equal 300 ppm, according to the mass of KMPS which was added to the system.

Such rapid degradation behaviour is very well known also from other peroxides like hydrogen peroxide and peracetic acid, for which degradation half lives in activated sludge of 2 - 3 minutes have been determined (AR Hydrogen peroxide, 2015 and AR Peracetic acid, 2015).

These other peroxygen compounds have the same general spectrum of various different potential reaction partners for oxidation and decomposition as KMPS: organic material, inorganic material (such as halides and sulphides), transition and heavy metals (catalytic degradation), particle surfaces (heterogeneous catalytic decomposition).

These diverse reaction partners and reaction pathways explain why the reaction kinetics for the peroxides are not constant over the whole degradation time, as the observed degradation is the overall result of various decomposition pathways. This could also be seen for KMPS.

In the study [redacted] (2011, Doc. No. 713-002, A.7.1.1.1/02), Oxone was degraded below 100 ppm very rapidly. A DT_{50} of 11.23 min (0.187 h) was determined using a logarithmic diagram for 300 ppm Oxone in the presence of activated sludge at 12 °C.

In the study [redacted] (2012, Doc. No. 713-001, A.7.1.1.1/01), the pattern of degradation suggests that dissipation followed biphasic kinetics with very rapid degradation in the first minute, but slower degradation afterwards. Kinetic analysis using CAKE v3.3 software has shown that based on visual assessment, chi-square test and t-test, DFOP is providing best fit of the measured data. The following DT_{50} values were determined at 20 °C:

Rapid phase: DT_{50} = 5.25E-03 h (k_1 = 132.1 h^{-1})
Slow phase: DT_{50} = 8.24 h (k_2 = 0.08413 h^{-1})

In order to obtain more profound information on degradation of KMPS in activated sludge, a further study was performed in 2018 ([redacted] (2018) Doc. No. 713-003, A7.1.1.1/03).

The degradation of Oxone (KMPS) in activated sludge from two municipal STPs was determined via titration of ferrous ammonium sulphate (FAS). The initial Oxone concentration was 300 ppm, likewise in the study ((2011) Doc. No. 713-002, A7.1.1.1/02) and the study ((2012) Doc. No. 713-001, A7.1.1.1/01). Limit of quantification was determined to be ≥ 53.6 ppm based on fivefold measurement. Oxone concentration was determined over 8 points at 0, 5, 10, 20, 40, 80, 140 and 240 minutes. Degradation tests of Oxone were performed at 16 °C. For the Drumnadrochit activated sludge, the results fell below the limit of quantification after 5 minutes. The results also show that Oxone concentration tends toward zero over time. Therefore, DT_{50} < 5 min at 16 °C (< 0.083 h) has been determined for the Drumnadrochit activated sludge. Kinetic analysis using CAKE v3.3 software has shown that degradation in Denny activated sludge follows single first order kinetics, with rate constant k = 0.611 h^{-1}. Determined DT_{50} was 1.13 h at 16 °C. The difference in half-lives for Drumnadrochit and Denny activated sludge can be attributed to the difference in organic loading of the sludge samples as evidenced by the measurement of the COD (chemical oxygen demand). The Drumnadrochit activated sludge sample with 239.8 mg/L has a significantly higher COD value than the Denny activated sludge sample with COD of 27.2 mg/L. Since Oxone is consumed in the reaction with organic species, the Drumnadrochit activated sludge is expected to show faster degradation which is in agreement with obtained study results.

From the studies on degradation of KMPS in activated sludge, the following experimentally derived DT_{50} values at 12 °C were obtained by using the equation for temperature correction as indicated in TAB ENV 182 (November, 2021) but considering a molar activation energy of 54 KJ/mol for abiotic degradation processes as agreed in WG ENV I-2023:

(2011):	0.187 h
(2012):	15.34 h (slow phase)
(2018):	1.55 h (Denny activated sludge)
	< 0.114 h (Drumnadrochit activated sludge)

Since the half-lives determined in the different studies differ between <0.114 h and 15.34 h, a reliable DT_{50} value needs to be derived on the basis of the available experimental data. According to TAB ENV 13 (November, 2021) a geometric mean value is to be used when more than three DT_{50} values are available. As the degradation of KMPS was tested in four sludge systems, it is appropriate to use the geomean DT_{50} for the risk assessment. In contrast to the other studies, in the sludge tested in the study (2012), the degradation of KMPS could be described best with the DFOP kinetic model. Following discussion in WG ENV I 2023, it was agreed to use only the slow phase DT_{50} derived from the DFOP model for fate modelling and to include all timepoints in the fitting. This procedure is in line with guidance given in Figure 7-2 of the FOCUS degradation kinetics report (2014). Thus, the four experimentally derived DT_{50} values in activated sludge were used to calculate the geometric mean value.

Geometric mean DT_{50} value in activated sludge is: 0.844 h at 12 °C.

It is very challenging, if not impossible, to obtain a reliable experimental DT_{50} in soil. A soil degradation study was submitted for KMPS (Annex point 7.2.1/01, Anonymous 2005, Doc. No. 721-002). Even if the submitted soil degradation study showed deficiencies (in the reporting and the difficulty in determining initial concentration due to rapid degradation), it could be shown, that after one hour, no KMPS remained in soil. This is in line with expectations as the peroxymonosulfate ion is kinetically more reactive than other oxidising substances such as hydrogen peroxide.

Value used in Risk Assessment	
Value/conclusion	DT_{50} for hydrolysis at pH 7 and 20 °C: 145 h DT_{50} in STP at 12 °C: 0.844 h DT_{50} in soil at 12 °C: <1 h
Justification for the value/conclusion	Please refer to the text above.

Data waiving	
Information requirement	Phototransformation in water
Justification	KMPS does not absorb light in the relevant wavelength range (290 – 800 nm). Therefore, phototransformation of KMPS can be excluded.

Estimated photo-oxidation in air

Summary table – Photo-oxidation in air					
Model	**Substance**	**Estimated daily (24h) OH concentration [OH/cm³]**	**Overall OH rate constant [cm³/molecule sec]**	**Half-life [hr]**	**Reference**
AOPWIN Atkison calculation Ri = 1	Potassium peroxomonosulfate	0.5 x 10^6	4.0000 × 10^{-12}	96.264	[redacted] (2007) Doc No. 743-001; A7.3.1/01 key study
	Caro's acid	0.5 x 10^6	4.1400 × 10^{-12}	93.009	

The DT_{50} of KMPS in air considering photochemical and oxidative decomposition was calculated according to Atkinson (programme used: AOPWIN, A7.3.1/01) to be 4.011 days (24-hr day, corresponding to 96.264 hours).

For Caro's acid (peroxysulfuric acid), a DT_{50} in air of 3.875 days (24-hr day, corresponding to 93.009 hours) was determined.

As both substances contain no olefinic carbon-carbon double or acetylic triple bonds, they are not supposed to react with ozone.

Value used in Risk Assessment	
Value/conclusion	DT_{50} according to Atkinson calculation: 96 h
Justification for the value/conclusion	-

4.1.1.2 Biotic degradation

Data waiving	
Information requirement	Biotic degradation
Justification	As KMPS is an inorganic compound, biodegradation tests are not applicable.

4.1.1.3 Rate and route of degradation including identification of metabolites and degradation products

Data waiving	
Information requirement	Rate and route of degradation including identification of metabolites and degradation products
Justification	As KMPS is an inorganic compound, biodegradation tests to simulate biodegradation in environmental compartments are not applicable. Biodegradation is not relevant for KMPS, but as explained in paragraph 4.1.1.1. KMPS can be decomposed abiotically. For $KHSO_5$, which is the active ingredient in KMPS, several abiotic decomposition pathways exist forming potassium ions, hydrogen sulphate ions, O_2 and oxidation products X=O.

4.1.2 Distribution

4.1.2.1 Adsorption onto/desorption from soils

Data waiving	
Information requirement	Adsorption onto/desorption from soils
Justification	KMPS is an inorganic salt with ionic structure. It is readily soluble in water and dissociates completely in aqueous solution. Due to its high solubility in water, its low vapour pressure (< 1.2 x 10^{-4} Pa at 20 °C), resulting in a very low Henry's Law Constant (2.04 x 10^{-7} Pa x m³ x mol^{-1}), and due to its low partition coefficient n-octanol/water (log Pow < 0.30 measured at 20 °C and -3.90 calculated), KMPS can be expected to partition nearly exclusively into the water phase. Upon contact with soil, KMPS decomposes either by hydrolysis or disproportionation to potassium ions, hydrogen sulphate and oxygen. Furthermore, very fast decomposition of KMPS in soil can be expected, due to the ubiquitous presence of oxidizable organic substrate. Leaching of KMPS in the soil profile to groundwater can therefore be excluded.

4.1.2.2 Higher tier soil adsorption studies

No higher tier studies are required, see paragraph 4.1.2.1.

4.1.3 Bioaccumulation

Value used in Risk Assessment	
Value/conclusion	No bioaccumulation potential
Justification for the value/conclusion	The low log Pow (< 0.30 measured at 20 °C and -3.90 calculated) indicate that KMPS has a low potential for bioconcentration and bioaccumulation (according to guideline OECD 117, log Pow values below 3 are regarded to be indicators of low accumulation potential). Moreover, KMPS dissipates rapidly in the environment. Considering these facts, it can be concluded that KMPS has no potential for bioaccumulation.

4.1.4 Monitoring data

No data available.

4.2 EFFECTS ON ENVIRONMENTAL ORGANISMS

4.2.1 Atmosphere

The likelihood of exposure of organisms via air is considered negligible, given the Henry's law constant of KMPS, calculated to be 2.04 x 10^{-7} Pa x m^3 x mol^{-1} at 20 °C.

4.2.2 Sewage treatment plant (STP)

Inhibition of microbial activity was tested in a 3-hour respiration inhibition test with activated sludge.

Inhibition of microbial activity (aquatic)

Summary table – inhibition of microbial activity								
Method, Guideline, GLP status, Reliability	**Species/ Inoculum**	**Endpoint**	**Exposure**		**Results [mg KMPS/L]**			**Reference**
			Design	**Duration**	**EC_{20}**	**EC_{50}**	**EC_{80}**	
OECD 209 GLP Ri = 1	Activated sludge	Respiration rate	Static	3 h	> 100	> 100	> 100	[redacted] (2001) Doc. No. 842-002; A7.4.1.4/01 key study

Inhibition of microbial activity of KMPS was tested in a 3-hour respiration inhibition test with activated sludge. The EC_{50} from the study is > 100 mg a.i./L based on nominal concentrations.

Value used in Risk Assessment	
Value/conclusion	EC_{50} > 100 mg KMPS/L
Justification for the value/conclusion	The EC_{50} is used in risk assessment, since no NOEC/EC_{10} is reported.

4.2.3 Aquatic compartment

4.2.3.1 Freshwater compartment

Acute toxicity (freshwater)

Summary table – acute aquatic toxicity									
Method, Guideline, GLP status, Reliability	**Species**	**Endpoint**	**Exposure**		**Results [mg KMPS/L]**			**Remarks**	**Reference**
			Design	**Duration**	**LC/EC$_0$**	**LC/EC$_{50}$**	**LC/EC$_{100}$**		
Fish									
Directive 92/69/EEC, Part C.1, OECD 203 GLP Ri = 1	*Oncorhynchus mykiss* (Rainbow trout)	Mortality	Semi-static	96 hour	27	53	101	Nominal concentrations	[redacted] (2001) Doc. No. 821-003; A7.4.1.1/01 key study
Invertebrates									
Directive 92/69/EEC, Part C.2, OECD 202 GLP Ri = 3*	*Daphnia magna*	Immobility	Semi-static	48 hour	1.4	1.98	2.6	Mean measured concentrations	[redacted] (2001) Doc. No. 822-002; A7.4.1.2/01 key study
Algae (growth inhibition)					**72-h NOE$_r$C**	**72-h E$_b$C$_{50}$[1]**	**72-h E$_r$C$_{50}$[2]**		
Directive 92/69/EEC, Part C.3, OECD 201 Ri = 2	*Pseudokierchneriella subcapitata*	Growth inhibition	Static	96 hour	0.43	0.84	>0.87	Mean measured concentrations	[redacted] (2001) Doc. No. 823-002; A7.4.1.3/01 key study

[1] calculated from the area under the growth curve

[2] calculated from growth rate

* In BPC-ENV WG I-2023 it was agreed to change the RI from 3, not reliable.

Acute/short-term toxicity to fish

Acute toxicity of KMPS on Rainbow trout (*Oncorhynchus mykiss*) was studied in a 96 hour semi-static test system according to Directive 92/69/EEC, Part C.1 and OECD 203 guideline. The study was conducted at nominal exposure concentrations of 6.25, 12.5, 25.0, 50.2, 100 mg KMPS/L, based on the results of preliminary range finding study. Temperature, pH, and dissolved oxygen were monitored for control as well as for test item during the entire study at 0, 24, 48, 72 and 96 hours. The test item concentrations were monitored for freshly prepared media at 0 and 72 hours and for old test media at 24 and 96 hours. Analytical concentrations were 100 - 107 % of nominal. The 96 hour LC_{50} toxicity value was determined to be 53 mg/L. The highest concentration at which no mortality occurred was 27 mg/L. The lowest concentration at which 100 % mortality occurred was 101 mg/L.

Acute/short-term toxicity to invertebrates

The acute toxicity of KMPS in *Daphnia magna* was determined in a 48 hour semi-static test system conducted according to Directive 92/69/EEC, Part C.2 and OECD 202 guideline. Nominal test concentrations of KMPS used were 0.625, 0.125, 0.25, 0.50, 10 mg/L, based on the results of preliminary range finding study. Temperature, pH, and dissolved oxygen were monitored for control as well as for test item for freshly prepared media at 0 and 24 hours and for old test media at 24 and 48 hours. The stock solution concentrations were analysed at 0 and 24 hours. In addition, the highest test concentration of 10 mg/L was analysed at 0 (fresh media) and 24 hours (old media) resulting in concentrations of 7.8 mg/L and 4.0 mg/L, respectively. These results are below the stated LOQ for the analytical method of 10 mg/L.

The validity criterion in OECD 202 guideline that the initial concentrations of the test substance are ≥ 80 % of nominal is not met in this test. Despite measured stock solution concentrations are above LOQ, it is not clear whether the stock solutions were kept under similar conditions as the test media. Stability of the test substance in a stock solution that is kept in a refrigerator in the dark does not prove stability under the test conditions. Analytical measurements in the highest test concentration resulted in an initial concentration of 78 % of nominal and a concentration of 40 % of nominal after 24 hours, indicating a low stability under the conditions of the test. The pH of the test media was around 8. The hydrolysis study resulted in DT_{50} values (20 °C) of 145 hours at pH 7 and 2.6 hours at pH 9, so some dissipation at a pH of 8 seems likely. The geometric mean measured concentration in the highest test concentration was 5.6 mg/L which corresponds to 56 % of nominal. As best estimate, RMS recalculated the EC_{50} with the trimmed Spearman-Karber method assuming a geometric mean concentration of 56 % of nominal for all test concentrations.

This results in the following endpoints based on mean measured concentration:

48 h EC_{50} = 1.98 mg/L
48 h EC_{0} = 1.4 mg/L
48 h EC_{100} = 2.6 mg/L

The measured concentration for the highest test concentration is however below the limit of quantification and the analytical results cannot

be relied upon. In BPC-ENV WG I-2023 it was agreed to change the RI to 3, not reliable, in particular because of the high LOD of the analytical method in this study compared to the other studies.

Acute/short-term toxicity to algae

The effects of KMPS on the growth of the alga *Pseudokierchneriella subcapitata* were determined in accordance with Directive 92/69/EEC, Part C.3 and OECD 201 guideline in a static 96 hour test. Algal cultures were exposed to 5 test concentrations (0.0625, 0.125, 0.25, 0.50 and 1.0 mg/L nominal), based on the results of preliminary range finding study. These cultures, together with one untreated control group of six replicates, were incubated under continuous illumination of approximately 4000 lux at 23 ± 1 °C for 96 hours. The OECD and EU guideline recommend a 72 hour study under a 6000 - 10000 lux lighting regime. This deviation from the OECD and EU guideline recommendations is not considered to have affected the validity of this study with respect to the outcome of the OECD and EU guidelines or the outcome of the study, because a 32 fold increase in cell numbers was achieved in the control cultures after a 72 hour exposure period. This rate of cell growth therefore satisfies the validity criteria of the OECD and EU guidelines.

The analytical method was insufficiently sensitive to analyse the test concentration due to the LOQ of 1.5 mg/L. Therefore, only the concentrated aqueous stock solutions were analysed. Initial concentrations of the stock solutions were not verified as the test substance was not stable in the stock solutions and dissipation may have occurred before dosing of the test media. This is assumed to be without influence on the plausibility of the results according to the OECD 201 guideline updated in 2006 (the study was performed following the older OECD 201 guideline dated 1984) which states that analytical verification of the test concentrations is not mandatory, if an analytical method for determination of the test substance in the concentration range used is not available.

Considering the updated OECD 201 guideline, its validity criteria are met, as based on the cell count data in the study report, the calculations resulted in mean coefficients of variation of 3.09 for day 0-1, 7.85 for day 1-2, 2.77 for day 2-3 and 5.08 for day 3-4. The coefficient of variation of average specific growth rate during the whole test period was calculated as 2.87.

In BPC-ENV WG I-2023, it was agreed that the endpoints need to be recalculated based on the geomean approach following the guidance in Vol. IV Part B+C (2017) for rapidly degrading substances taking ½ LOQ as concentration at the end of the test. For the highest test concentration the geometric mean calculated with the nominal concentration and ½ LOQ equals 0.866 mg KMPS/L, corresponding to 86.6% of nominal. This may be extrapolated to all test concentrations resulting in nominal endpoints to be corrected by a factor 0.866. The following endpoints are derived from this study based on mean measured concentrations:

72 h NOEC = 0.43 mg/L
72 h E_bC_{50} = 0.84 mg/L
72 h E_rC_{50} > 0.87 mg/L

Value used in Risk Assessment	
Value/conclusion	Not applicable
Justification for the value/conclusion	Since chronic data are available, acute toxicity data are not used in derivation of the PNEC.

Chronic toxicity (freshwater)

No further chronic data for KMPS on freshwater species were submitted.

Value used in Risk Assessment	
Value/conclusion	NOEC = 0.222 mg KMPS/L (*Cyprinodon variegatus*)
Justification for the value/conclusion	The available data demonstrate a higher toxicity to marine species compared to freshwater species (see below). Data for marine species can therefore be relied upon for a conservative estimate of the $PNEC_{freshwater}$.

4.2.3.2 Sediment compartment

Data waiving	
Information requirement	Effects on sediment swelling organisms
Justification	The physico-chemical properties of KMPS (calculated log K_{OW} = -3.90) and its rapid degradation in surface waters suggest that the active substance is not likely to partition into sediment to a significant extent. With regard to the negligible exposure, toxicity tests with sediment organisms are not deemed to be relevant and necessary.

4.2.3.3 Marine compartment

Acute toxicity (seawater)

Summary table – acute aquatic toxicity									
Method, Guideline, GLP status, Reliability	**Species**	**Endpoint**	**Exposure**		**Results [mg KMPS/L]**			**Remarks**	**Reference**
			Design	**Duration**	**LC/EC$_0$**	**LC/EC$_{50}$**	**LC/EC$_{100}$**		
Fish									
US EPA 850.1075, 1996 GLP Ri = 2	*Cyprinodon variegatus* (Sheepshead minnow)	Mortality	Static	96 hour	0.190	0.467	0.762	Mean measured concentrations	[redacted] (2007) Doc. No. 821-004; A7.4.1.1/02 key study
Invertebrates									
US EPA 850.1035 (1996), draft GLP Ri = 2	*Americamysis bahia* (Mysid shrimp)	Mortality	Static	96 hour	0.193	0.513	0.774	Mean measured concentrations	[redacted] (2007) Doc. No. 825-001; A7.4.1.2/02 key study
Algae (growth inhibition)					**96-h NOEC**	**96-h E_bC_{50}[1]**	**96-h E_rC_{50}[2]**		
US EPA 850.5400 GLP Ri = 2	*Skeletonema costatum*	Growth inhibition	Static	96 hour	0.074 (biomass) 0.295 (growth rate)	0.325	0.370	Mean measured concentrations	[redacted] (2007) Doc. No. 823-003; A7.4.1.3/02 key study

[1] calculated from the area under the growth curve

[2] calculated from growth rate

Acute/short-term toxicity to fish

The acute toxicity of KMPS to marine species *Cyprinodon variegatus* (Sheepshead minnow) was determined in a static, 96 hour test. The test was conducted in accordance with the US EPA 850.1035 guideline. Nominal test concentrations of KMPS used were 222, 444, 889, 1780 and 3560 µg/L, based on the results of preliminary range finding study. Dissolved oxygen concentration, pH, temperature and salinity were monitored for control as well as for test item during the entire study at 0, 24, 48, 72 and 96 hours.

The stock solution concentrations were analysed at 0 hours. In addition, control and the two highest test concentrations of 1780 and 3560 µg KMPS/L were analysed at 0 and 96 hours. The concentration of the test substance in the stock solution was determined to be 93 - 108 % of nominal, while in the two highest solutions tested KMPS recoveries were from 78 - 86 % at test start and decreased below the LOQ at test end. This is a major deviation from the US EPA 850.1035 guideline, as the study was not performed with a flow-through design, although concentrations after 96 hours were below the LOQ in this static test. In BPC-ENV WG I-2023, it was agreed that the endpoints should be corrected to mean measured concentrations following the guidance in Vol. IV Part B+C (2017) for rapidly degrading substances taking ½ LOQ as concentration at the end of the test. For the highest test concentration the geometric mean of the initial measured concentration and ½ LOQ equals 0.686 mg $KHSO_5$/L, corresponding to 42.8% of nominal. This may be extrapolated to all test concentrations resulting in nominal endpoints to be corrected by a factor 0.428.

Mortality of sheepshead minnow was 0, 0, 20, 100 and 100 % at 222, 444, 889, 1780, 3560 µg KMPS/L, respectively, at the end of 96 hours. The 96 h LC_{50} was determined to be 0.467 mg/L, based on mean measured concentrations. The highest mean measured concentration causing no mortality at test end was 0.190 mg/L. The lowest mean measured concentration causing 100 % mortality at test end was 0.762 mg/L.

Acute/short-term toxicity to invertebrates

The acute toxicity of KMPS to marine species *Americamysis bahia* (Mysid shrimp), was determined in a 96 hour static-renewal test. The test was conducted in accordance with the US EPA 850.1035 guideline. Nominal test concentrations of KMPS used were 222, 444, 889, 1780 and 3560 µg/L, based on the results of preliminary range finding study. Dissolved oxygen concentration, pH, temperature and salinity were monitored for control as well as for test item for freshly prepared media at 0, 24, 48, 72 and 96 hours and for old test media at 24, 48 and 72 hours.

The stock solution concentrations were analysed at 0 and 72 hours. In addition, control and the highest test concentration of 3560 µg KMPS/L were analysed at 0 and 72 hours in new solutions and at 24 and 96 hours in old solutions. The concentration of the test substance in the stock solution was determined to be 83 to 91 % of nominal at 0 hours and 85 to 97 % of nominal at 72 hours, while in the highest solution tested KMPS recoveries were 61 - 81 % at 0 hours and 96 - 102 % at 72 hours. Concentrations in the old solutions were below the LOQ after 24 hours. In BPC-ENV WG I-2023, it was agreed that the endpoints should be corrected to mean measured concentrations following the guidance in Vol. IV Part B+C (2017) for rapidly degrading substances taking ½ LOQ as concentration at the end of the test. For the highest test concentration the geometric mean calculated with the aritmetric mean of initial measured concentration and ½ LOQ equals 0.696 mg $KHSO_5$/L, corresponding to 43.5% of nominal. This may be extrapolated to all test concentrations resulting in nominal endpoints to be corrected by a factor 0.435.

Mortality of mysid shrimp was 0, 0, 10, 100 and 100 % at 222, 444, 889, 1780, 3560 µg KMPS/L,

respectively, at the end of 96 hours. The 96-h LC_{50} was determined to be 0.513 mg KMPS/L, based on mean measured concentrations. The highest mean measured concentration causing no mortality at test end was 0.193 mg KMPS/L. The lowest mean measured concentration causing 100 % mortality at test end was 0.774 mg KMPS/L.

Acute/short-term toxicity to algae

The toxicity of KMPS to marine algae *Skeletonema costatum*, was determined in a 96 hour, static toxicity test. The test was conducted in accordance with US EPA 850.5400 guideline. Nominal test concentrations of KMPS used were 55.6, 111, 222, 444, 889 and 1780 µg/L, based on the results of preliminary range finding study. pH and temperature were monitored for control as well as for test item at 0 and 96 hours.

The stock solution concentrations were analysed at test initiation. In addition, control and the highest test concentration of 1780 µg KMPS/L were analysed at 0 and 96 hours. Measured concentrations in the stock solution samples ranged from 88 - 100 % of nominal concentrations, while in the highest solution tested the measured concentrations of KMPS at 0 and 96 hours were less than the LOQ, which was determined to be 700 µg/L. Moreover, the test substance was not stable in the stock solutions and dissipation may have occurred before dosing of the test media. Dissipation of the test substance was demonstrated to be very fast in the presence of chloride (seawater) and at high pH. Both conditions apply to the test medium for the marine algae test. In BPC-ENV WG I-2023, it was agreed that the endpoints should be corrected to mean measured concentrations following the guidance in Vol. IV Part B+C (2017) for rapidly degrading substances taking ½ LOQ as concentration at the end of the test. For the highest test concentration the geometric mean calculated with the nominal concentration and ½ LOQ equals 0.529 mg $KHSO_5$/L, corresponding to 66.5% of nominal. This may be extrapolated to all test concentrations resulting in nominal endpoints to be corrected by a factor 0.665.

Considering the updated OECD 201 guideline (the study was performed following the older OECD 201 guideline dated 1984), its validity criteria are met, as based on the cell count data in the study report, the calculations resulted in mean coefficients of variation of 22.21 for day 0-1, 28.52 for day 1-2, 21.14 for day 2-3 and 50.30 for day 3-4. The coefficient of variation of average specific growth rate during the whole test period was calculated as 4.10. Conclusion is that control behaviour becomes too variable after 96 hours, because exponential growth is not maintained. Therefore, the validity criteria are met during the first 72 hours in this test.

The following endpoints are derived from this study based on mean measured concentrations:

96 h NOE_bC = 0.074 mg/L
96 h NOE_rC = 0.295 mg/L
96 h E_bC_{50} = 0.325 mg/L
96 h E_rC_{50} = 0.370 mg/L

Value used in Risk Assessment	
Value/conclusion	Not applicable
Justification for the value/conclusion	Since chronic data are available, acute toxicity data are not used in derivation of the PNEC.

Chronic toxicity (seawater)

Summary table – chronic aquatic toxicity							
Method, Guideline, GLP status, Reliability	**Species**	**End point/ Type of test**	**Exposure**		**Results [mg KMPS/L]**	**Remarks**	**Reference**
			Design	**Duration**	**LOEC/NOEC/EC_{10}**		
Fish							
US EPA 850.1400 GLP Ri = 1	*Cyprinodon variegatus* (Sheepshead minnow)	Egg hatchability	Flow-through	37 days	> 0.889 / 0.889 / n.d.	Nominal concentrations	[redacted] (2007) Doc.No. 826-002; A7.4.3.2/01 key study
		Fry survival			0.889 / 0.444 / n.d.		
		Standard length			> 0.444 / 0.444 / n.d.		
		Blotted wet weight			0.444 / 0.222 / n.d.		
Invertebrates							
US EPA 850.135 ASTM E1191-970 GLP Ri = 2	*Americamysis bahia* (Mysid shrimp)	Adult survival	Flow-through	28 days	0.533 / 0.267 / n.d.	Nominal concentrations	[redacted] (2007) Doc. No. 829-001; A7.4.3.4/01 key study
		96 h juvenile survival			> 0.267 / 0.267 / n.d.		
		Length			> 0.267 / 0.267 / n.d.		
		Young / female			> 0.267 / 0.267 / n.d.		

Chronic/long-term toxicity to fish

The early-life stage toxicity of KMPS to *Cyprinodon variegatus* (Sheepshead minnow), was determined under flow-through conditions where organisms were exposed to the test substance for a total of 37 days, which resulted in an exposure of 28 days post-hatch. The test was conducted in accordance with the US EPA 850.1400 guideline. Nominal test concentrations of KMPS used were 28.9, 55.6, 111, 222, 444 and 889 µg/L, based on the results of preliminary range finding study. Temperature, dissolved oxygen concentration, pH and salinity were monitored for control as well as for test item at 0, 7, 14, 21, 28, 35 and 37 days.

The concentration of $KHSO_5$ in the control and stock solution containing 1.540 mg $KHSO_5$/L were determined one day prior test initiation and on study days 0, 7, 14, 21, 28, 35 and 37. The measured concentrations of the stock solution ranged from 92 to 120 % of the nominal concentration. According to the raw data, stock solutions were prepared on the following days: 1, 8, 15, 23, 31 and 36. Stock solutions were added to the test system daily (aside from D19 and D21). Analytical samples were taken on the following days: 0, 7, 14, 21, 28, 35

and 37. Given these data, it appears that KMPS was stable in the system. For example, stock solution prepared on D8 of the study was added to the test system daily, but were not sampled analytically until D14 (i.e., the stock was 6 days old), at which time the analytical recovery was 118%.

Hatching success in the control was 89 % and ranged from 85 to 93 % in the test item treatments without significant differences to the control. Based on hatching success, the NOEC was 0.889 mg/L and the LOEC was estimated to be > 0.889 mg/L. Post hatch survival of fry in the control was 97 % and ranged from 2 to 96 % in the test item treatments, with significant effects in the highest tested concentration of 889 µg/L. Based on post-hatch survival, the NOEC was 0.444 mg/L and the LOEC was 0.889 mg/L. Blotted wet weight was significantly reduced at 0.444 mg/L, while mean length was not significantly different compared to the control considering the 0.889 mg/L treatment was not included in the analysis due to survival effects. Therefore, NOEC values for standard length and blotted wet weight were 0.444 and 0.222 mg/L, respectively. The LOEC values for standard length and blotted wet weight were > 0.444 and 0.444 mg/L, respectively.

Chronic/long-term toxicity to invertebrates

The life-cycle toxicity of KMPS to the *Americamysis bahia* (Mysid shrimp), was determined under flow-through test conditions where the organisms were exposed to the test substance for a total of 28 days. The test was conducted in accordance with US EPA 850.135 ASTM E1191-970 guideline. Nominal test concentrations of KMPS used were 33.3, 66.7, 133, 267, 533 µg/L, based on the results of preliminary range finding study. Temperature, dissolved oxygen concentration, pH and salinity were monitored for control as well as for test item at 0, 8, 14, 21 and 28 days.

The concentration of $KHSO_5$ in the control and stock solution containing 1.870 mg $KHSO_5$/L were determined one day prior test initiation and on study days 0, 7, 14, 21 and 28. The measured concentrations of the stock solution ranged from 96 to 116 % of the nominal concentration. According to the raw data, stock solutions were prepared on days 1, 9, 17 and 24. Stock solutions were added to the test system daily. Analytical samples were taken on days 0, 7, 14, 21 and 28. Based on this information it appears that KMPS is stable in this study as well. For example, stock solution prepared on D9 was added to the test system daily yet not analysed until D14, at which time the analytical recovery was 98%.

Mean % survival of the adult population was statistically reduced only at 0.533 mg/L (i.e. 0 %) on test day 7 through day 28 as compared to the negative control survival. Therefore, the NOEC and LOEC were 0.267 and 0.533 mg/L, respectively. The 96 hour survival of the juvenile mysids ranged from 94 to 98 % in all treatment replicates and was 91 % in the controls. The average 96 hour juvenile survival in KMPS treatments was not statistically different as compared to the negative control survival. Since there was not a concentration dependent response, the 96 hour NOEC and LOEC for juvenile survival were 0.267 and > 0.267 mg/L, respectively.

The NOEC and LOEC values for adult male and female body lengths (day 14 and 28) were 0.267 and > 0.267 mg/L, respectively, due to the lack of statistically significant reduction in this parameter in comparison to the mean control male and female body length data.

The total young per female was not statistically reduced in any treatment as compared to the total young per female of the negative controls. Therefore, the NOEC and LOEC values for this parameter were 0.267 and > 0.267 mg/L, respectively.

The available data demonstrate a higher toxicity to marine species compared to freshwater species. This difference might be due to:

1. Formation of active chlorine in seawater;
2. An intrinsic higher toxicity of $KHSO_5$, the active ingredient in KMPS, to marine species compared to freshwater species. There is no theoretical or experimental basis to assume that this is generally the case and hence cause 1, the oxidation of halide ions in sea water is the reason for the greater sensitivity of marine species to KMPS.

Overall, the study results for aquatic organisms demonstrate a rapid toxic mode of action.

Value used in Risk Assessment	
Value/conclusion	NOEC = 0.222 mg KMPS/L *(Cyprinodon variegatus)*
Justification for the value/conclusion	Lowest available NOEC for saltwater organisms.

4.2.3.4 Sea sediment compartment

Data waiving	
Information requirement	Effects on saltwater sediment dwelling organisms
Justification	The physico-chemical properties of KMPS (calculated log K_{OW} = -3.90) and its rapid degradation in seawater suggest that the active substance is not likely to partition into sediment to a significant extent. With regard to the negligible exposure, toxicity tests with sediment organisms are not deemed to be relevant and necessary.

4.2.3.5 Higher tier studies on aquatic organisms

No data available.

4.2.4 Terrestrial compartment

Toxicity to terrestrial organisms, acute tests

Summary table – acute terrestrial toxicity										
Method, Guideline,GLP status, Reliability	**Species**	**End point/ Type of test**	**Exposure**		**Organic matter**	**Results (in dry weight) [mg KMPS/kg dw soil]**			**Remarks**	**Reference**
			Design	**Duration**		**LC/EC$_0$**	**LC/EC$_{10}$**	**LC/EC$_{50}$**		
Earthworm/soil-dwelling non-target invertebrates										
OECD 207, 1984 GLP Ri = 1	*Eisenia fetida*	Mortality Mixed with soil	Dose-response test	14 days	10 %	1000	n.d.	> 1000	Nominal concentrations	Warbritton, R. (2007) Doc. No. 833-001; A7.5.1.2/1 key study

Value used in Risk Assessment	
Value/conclusion	LC_{50} > 1000 mg/kg dw soil (*Eisenia fetida*)
Justification for the value/conclusion	Only terrestrial endpoint available

Data waiving	
Information requirement	Acute toxicity to soil microflora, non-target plants, bees and non-target arthropods
Justification	KMPS in not applied directly to soil. Given the reactive nature of KMPS, any exposure of the terrestrial compartment will be very short-lived.

Toxicity to terrestrial organisms, chronic tests

Data waiving	
Information requirement	Chronic effects on earthworms, soil microflora, non-target plants, bees and non-target arthropods
Justification	KMPS in not applied directly to soil. Given the reactive nature of KMPS, any exposure of the terrestrial compartment will be very short-lived.

4.2.5 Groundwater

Upon contact with soil, KMPS decomposes either by hydrolysis or disproportionation to potassium ions, hydrogen sulphate and oxygen. Very fast decomposition of KMPS in soil can be expected, due to the ubiquitous presence of oxidizable organic substrate. Leaching of KMPS in the soil profile to groundwater can therefore be excluded.

4.2.6 Birds and mammals

Data waiving	
Information requirement	Effects on birds and mammals
Justification	A dietary LC_{50} study with KMPS in Northern Bobwhite was terminated after 1 day of exposure. When dissolved in deionised water to prepare dosing solutions, KMPS creates an acidic solution. Animal welfare concern prohibited the dosing of an acidic solution that would cause acid burns in the upper digestive tract. Therefore, the dosing solutions were buffered prior to dosing. Subsequent analysis revealed that when buffered, KMPS could not be maintained in solutions. The study was therefore terminated and no further attempts to determine the acute toxicity in birds were undertaken. This is justified because there is no exposure of wild birds and mammals to KMPS foreseen.

4.2.7 Primary and secondary poisoning

Primary poisoning

Data waiving	
Information requirement	Primary poisoning
Justification	Not relevant for the product types concerned

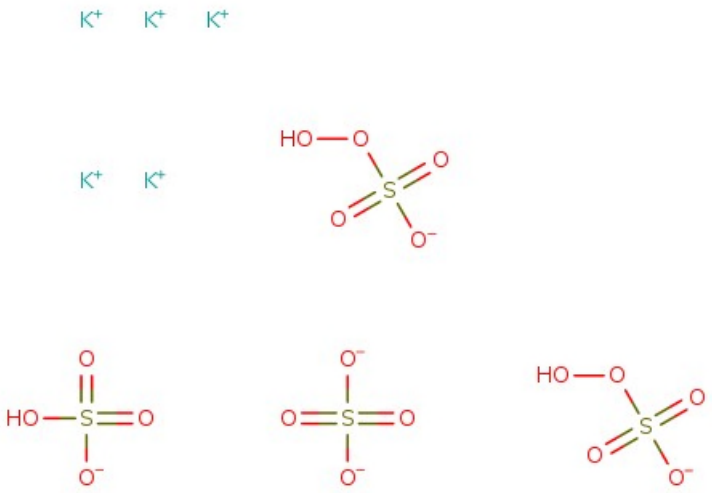
Secondary poisoning

Data waiving	
Information requirement	Secondary poisoning
Justification	KMPS does not bioaccumulate. It is an inorganic salt with ionic structure, which is readily soluble in water and dissociates completely. The estimated log Pow value is below 0.30 at 20 °C (calculated value -3.90). Furthermore, KMPS is not a surface active substance (surface tension measured: 72.9 mN/m at 23 °C) and it breaks down to inorganic salts (potassium and sulphate ions) of ubiquitous nature. It can therefore be excluded that KMPS should concentrate in the food chain.

4.3 ENDOCRINE DISRUPTING PROPERTIES

Introduction

Endocrine disrupting properties induced by KMPS (see KMPS structure in the figure below) were performed according to the Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 (June 2018) by LANXESS Deutschland GmbH and United Initiators GmbH. ED assessment from the applicant is available in the Appendix VII.



KMPS structure

Gathering relevant information

The assessment report presents available information on potential endocrine disrupting (ED) properties of the active substance, the triple salt KMPS. However, in order to provide a comprehensive ED assessment, also data of the active constituent of the triple salt $KHSO_5$, potassium hydrogenperoxomonosulphate (CAS No. 10058-23-8) were gathered and assessed. In particular, the database search and the literature search were performed for both substances due to the structural similarity.

OECD Level 1 data
In silico analyses on potential ED properties were performed using software tools recommended in Appendix D.2. of the ED Guidance (2018), i.e. the OECD (Q)SAR Toolbox, Endocrine Disruptome and the VEGA platform.

OECD Level 2 data
No available OECD Level 2 data with non-mammalian species.

OECD Level 3 data
No available OECD Level 3 data with non-mammalian species.

OECD Level 4 data
A fish early life stage (ELS) toxicity study performed according to the US EPA TG OPPTS 850.1400 under flow-through conditions with *Cyprinodon variegatus* (Sheepshead minnow) is available (2007). The in-life phase of the definitive test was performed at nominal KMPS concentration of 0 (control), 28.9, 55.6, 111, 222, 444 and 889 µg KMPS/L (13, 25, 50, 100, 200 and 400 µg $KHSO_5$/L, respectively).

No statistically significant effects were observed on time to hatch, hatching success and behavior up to and including the highest dose tested (889 µg KMPS/L). Morphological abnormalities were observed in one fish of the negative control which had a poorly developed eye, one fish of the 55.6 µg KMPS/L treatment exhibited curvature of the spine, and congenitally united twins were observed in the 111 µg KMPS/L treatment. However, the morphological abnormalities did not follow a dose-response relationship and were hence considered not to be related to the test substance.

Post-hatch survival was statistically significantly affected at the 889 µg KMPS/L (i.e. 2 % fry survival) and therefore, this treatment was omitted from all further statistical analysis procedures. The LOEC values for standard length and blotted wet weight were > 444 µg KMPS/L and 444 µg KMPS/L, respectively.

OECD Level 5 data
No available OECD Level 5 data with non-mammalian species.

Review of scientific open litearture
A literature search on potential ED properties of the active substance KMPS and its main constituent $KHSO_5$ was conducted accessing the following databases: AGRICOLA, BIOSIS, CABA, EMBASE, ESBIOBASE, HCAPLUS, MEDLINE, PQSCITECH, TOXCENTER via the service provider STN-International.

Based on the evaluation of the summary records (titles/abstracts) 54 publications were assessed as obviously not relevant for the assessment of potential ED properties of the active substance KMPS. Two full-text documents were assessed in detail. However, none of these publications provided relevant information on the potential ED properties of the active substance KMPS. For more details, please refer to the Appendix II of the applicants' ED assessment.

ED assessment for non-target organisms other than mammals

Limited data to assess the ED properties for other non-target organisms are available for KMPS.

Nevertheless, the ED GD (2018) states the following:
There may be cases in which due to the knowledge on the physico-chemical and (eco)toxicological properties of the substance an ED assessment does not appear scientifically necessary or testing for this purpose not technically possible (BP Regulation, Annex IV or PPP Regulation, Annex, Point 1.5).

And the Annex IV, section 1.2 of the BPR states:
There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or does not have a particular dangerous property, while the information from each single source alone is considered insufficient to support this notion. […] Where consideration of all the available data provides sufficient weight of evidence for the presence or absence of a particular dangerous property:

- *further testing on vertebrates for that property shall not be undertaken,*
- *further testing not involving vertebrates may be omitted.*

The following discussion focusses on a weight of evidence based argumentation to determine whether an ED assessment for KMPS and $KHSO_5$, and the subsequent vertebrate testing appear scientifically necessary.

Substance physico-chemical properties: KMPS is inorganic salt (2 $KHSO_5$ $KHSO_4$ K_2SO_4) with an ionic structure which is readily soluble in water and will therefore dissociate completely in aqueous solution. In the presence of organic compounds, KMPS dissociates immediately into inert potassium and sulphate (K^+, SO_4^{2-}, HSO_4^-) ions that are naturally occurring and well-known compounds. These ions are chemically and biologically not further degradable because they constitute stable simple basic structures of inorganic nature.

KMPS has no potential for bioaccumulation (log K_{OW} of < 0.30 and -3.90 were determined). Moreover, rapid reaction of KMPS with organic matter suggests that a long-term exposure of non-target organisms to KMPS is unlikely.

Classification and labelling: KMPS has no harmonized classification according to the Regulation (EC) No 1272/2008. However, proposed hazard classes H302, H314, H318, H400 and H412 do not indicate suspicion of endocrine disrupting properties of KMPS.

Analysis of the data set: Endocrine activity was investigated using *in silico* methods. OECD QSAR Toolbox (v4.3.1) profilers notice KMPS and $KHSO_5$ as "no binder" for the estrogen receptor due to the high molecular weight (> 500) and the absence of a cyclic structure. Additionally, no profiling alert was found for the binding activity of KMPS and $KHSO_5$ for the estrogen receptor via OECD QSAR Toolbox (v4.3.1) and VEGA *in silico* platform (v1.1.4). KMPS possess low binding probability ("green class") for androgen receptor, estrogen receptor alpha and beta, thyroid hormone receptors alpha and beta and glucocorticoid receptor according to the Endocrine Disruptome software. A very weak

androgen receptor antagonist activity was identified for KMPS and $KHSO_5$, whereby the activity scores (-3.4 and -3.5) were only marginal above the threshold of -3.1 established for the medium probability binding class (Endocrine Disruptome software).

Moreover, available free databases listed in Appendix D.1. of the ED GD (2018) were searched for indications of EATS mediated activity of KMPS and $KHSO_5$. However, no information was found in the databases indicating evidence of EATS mediated activity or endocrine adversity of KMPS and $KHSO_5$.

Additionally, no effects directly indicative of endocrine disrupting properties were observed in the ELS toxicity study with *Cyprinodon variegatus*. Considering also mammalian dataset, no adverse effects were identified in the available OECD Level 4 *in vivo* toxicity studies.

Conclusion

The available data set for KMPS and $KHSO_5$ was evaluated in accordance with the ED criteria laid out in the ED GD (2018).. There are no indications of endocrine disruption in the data set. However, there is insufficient information available to fully assess the endocrine disrupting properties of the substance
regarding non-target organisms. Nevertheless, no additional information is requested based on the following justification:
Adverse effects of KMPS cannot clearly be assigned to an endocrine mode of action. Instead, KMPS induces oxidative stress and cytotoxicity which can lead to secondary effects on the endocrine system of test organisms. As a consequence, these indirect effects on the endocrine system would be difficult to separate from adverse effects directly caused by an endocrine mode of action. Therefore, the reliability of in vivo tests would be low and uncertainties would remain concerning the ED properties of KMPS. Hence, further tests with non-mammalian non-target organisms such as fish or amphibians are scientifically not justified and should be avoided in terms of animal welfare.

Conclusion used in Risk Assessment – Endocrine disruption	
Conclusion	KMPS does not meet the endocrine disruptor criteria with respect to human health and environment
Justification for the conclusion	The available data set for KMPS and its main constituent potassium hydrogenperoxomonosulphate, $KHSO_5$ was evaluated according to the ED criteria laid out in the ED GD (2018). There is no evidence of EATS-mediated adversity or activity in the human health or ecotoxicological dataset presented in the dossier.

4.4 DERIVATION OF PNECS

Compartment	PNEC	Remarks/Justification
STP	$PNEC_{STP}$: 1 mg/L	Organism: Activated sludge Endpoint: EC_{50} > 100 mg/L Assessment factor: 100 Justification: EC_{50} with standard assessment factor. No NOEC/EC_{10} available.
Freshwater	$PNEC_{freshwater}$: 0.0222 mg/L	Organism: Fish (*Cyprinodon variegates*) Endpoint: NOEC (37 d) = 0.222 mg/L Assessment factor: 10 Extrapolation method: assessment factor Justification: The available data demonstrate a higher toxicity to marine species compared to freshwater species. Data for marine species can therefore be relied upon for a conservative estimate of the $PNEC_{freshwater}$. Since the three taxonomic groups (fish, invertebrates, algae) are covered for saltwater species and also long-term toxicity data are available for saltwater fish and invertebrates, an assessment factor of 10 is applied on the lowest NOEC.
Freshwater	$PNEC_{intermittent\ release}$: 0.087 mg/L	Organism: *Pseudokierchneriella subcapitata* Endpoint: EC_{50} (72 h) >0.87 mg/L Assessment factor: 10 Extrapolation method: assessment factor Justification: Three taxonomic groups (fish, invertebrates, algae) are covered for freshwater species. The range of acute toxicity endpoints was shown to be narrow. An assessment factor of 10 on the lowest acute endpoint is considered justified, because KMPS has a non-specific mode of action. As an oxidizing agent, the mode of action of KMPS is chemical oxidation of cellular components. Electrons are removed from susceptible chemical groups, oxidizing them. The unspecific mode of action means that there are multiple targets within a cell. These include nucleic acids, lipids, enzymes, proteins and amino acids. Susceptible chemical groups include thiols, amines, alkynes, aliphatic residues and aromatic residues. Consequently, cells can experience membrane disruption, loss of membrane integrity, loss of structure, loss of function, enzyme inhibition, impaired energy production, disruption of protein synthesis, disruption of cellular processes in general, destabilization of protein tertiary structure, protein

Compartment	PNEC	Remarks/Justification
		denaturation and fragmentation[1,2]. This is otherwise known as generalized narcosis. ECHA guidance (Chapter R10; R.10.3.3) and BPR Guidance (Volume IV, B+C, chapter 3.3.2). For substances with a known non-specific mode of action, interspecies variations may be low. In such cases, a lower factor may be appropriate.
Saltwater	$PNEC_{saltwater}$: 0.00222 mg/L	Organism: Fish (*Cyprinodon variegates*) Endpoint: NOEC (37 d) = 0.222 mg/L Assessment factor: 100 Extrapolation method: assessment factor Justification: Since the three taxonomic groups (fish, invertebrates, algae) are covered for saltwater species and also long-term toxicity data are available for saltwater fish and invertebrates, an assessment factor of 100 is applied on the lowest NOEC.
Sediment	-	The physico-chemical properties of KMPS (log K_{OW} < 0.30 at 20 °C) and its rapid degradation in the presence of oxidizable organic substrate suggest that the active substance is not likely to partition into sediment to a significant extent. With regard to the negligible exposure, a PNEC for sediment organisms is not deemed to be necessary.
Terrestrial	$PNEC_{soil}$ = $2.65 \cdot 10^{-3}$ mg/kg wwt	Extrapolation method: equilibrium partitioning method Justification: Only one $L(E)C_{50}$ for terrestrial organisms available and equilibrium partitioning method results in the lowest PNEC. $PNEC_{soil}$ = ($K_{soil\text{-}water}/RHO_{soil}$) x $PNEC_{water}$ x 1000 = $2.65 \cdot 10^{-3}$ mg/kg wwt $K_{soil\text{-}water}$ = 0.203 m^3/m^3 RHO_{soil} = 1700 kg/m^3 $PNEC_{water}$ = 0.0222 mg/L

[1] Michelle Finnegan, Ezra Linley, Stephen P. Denyer, Gerald McDonnell, Claire Simons, Jean-Yves Maillard, Mode of action of hydrogen peroxide and other oxidizing agents: differences between liquid and gas forms, Journal of Antimicrobial Chemotherapy, Volume 65, Issue 10, October 2010, Pages 2108–2115.

[2] Block,S.S. (2020) Disinfection, Sterilization, and Preservation. Wolters Kluwer Health, 6th Ed., pp. 108-109.

5 ASSESSMENT OF EXCLUSION CRITERIA, SUBSTITUTION CRITERIA AND POP

5.1 EXCLUSION CRITERIA

5.1.1 Assessment of CMR properties

Criteria (BPR Article 5[1])	**Assessment**
Active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen category 1A or 1B	Active substance is not classified and does not meet the criteria to be classified as Carc. Cat. 1A or 1B.
Active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B	Active substance is not classified and does not meet the criteria to be classified as Muta. Cat. 1A or 1B.
Active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B	Active substance is not classified and does not meet the criteria to be classified as Repr. Cat. 1A or 1B.

Conclusion on CMR properties	The exclusion criteria in BPR Article 5(1)a-c are not met.

5.1.2 Assessment of endocrine disrupting properties

Criteria (BPR Article 5)	**Assessment**
Active substances which, on the basis of the criteria specified pursuant to the first subparagraph of paragraph 3 are considered as having endocrine-disrupting properties that may cause adverse effects in humans and to the environment.	Active substance is not considered to be an endocrine disruptor with respect to human health and to the environment when applying the specific scientific criteria for endocrine disruption in accordance with the Commission Delegated Regulation (EU) 2017/2100 and the Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009.

Conclusion on ED properties	The exclusion criteria in BPR Article 5(1)d are not met.

5.1.3 PBT Assessment (following Annex XIII to Regulation (EC) No 1907/2006)

The criteria for PBT assessment are specified in the Annex XIII of Regulation (EC) No 1907/2006 (REACH). A substance is identified as a PBT substance if it fulfils the persistence, bioaccumulation and toxicity criteria of sections 1.1.1, 1.1.2 and 1.1.3 or very persistence and very bioaccumulation (vPvB) if it fulfils criteria of sections 1.2.1 and 1.2.2. The PBT and vPvB criteria of Annex XIII to the Regulation do not apply to inorganic substances such as KMPS but apply to all organic substances, including organo-metals.

5.2 SUBSTITUTION CRITERIA

Substitution criteria (BPR, Article 10)	**Assessment**
One of the exclusion criteria listed in Article 5(1) is met but AS may be approved in accordance with Article 5(2)	None of the exclusion criteria listed in Article 5(1) is met
The criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as a respiratory sensitiser is met	No
The acceptable daily intake, acute reference dose or acceptable operator exposure level, as appropriate, is significantly lower than those of the majority of approved active substances for the same product-type and use scenario	No
Two of the criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006 are met	No
There are reasons for concern linked to the nature of the critical effects which, in combination with the use patterns, amount to use that could still cause concern, such as high potential of risk to groundwater, even with very restrictive risk management measures	No
The AS contains a significant proportion of non-active isomers or impurities.	No

Conclusion on substitution criteria	The substitution criteria in BPR Article 10(1)a-f are not met.

5.3 ASSESSMENT OF LONG-RANGE ENVIRONMENTAL TRANSPORTATION AND IMPACT ON ENVIRONMENTAL COMPARTMENTS

	Assessment
The active substance or a degradation product is a persistent organic pollutant (POP) listed in Annex I of EC 850/2004	Not listed in Annex I of EC 850/2004
Assessment of long-range transport potential (LRTAP): ☐ Vapour pressure <1000 Pa and ☐ half-life in air > 2 days or ☐ Monitoring data in remote area showing that the substance is found in remote regions or ☐ Result of multi media modelling	Due to the reactive nature no long-range transport potential
The active substance or a degradation product is vP/vB or T?	No

Conclusion on LRTAP/POP assessment	KMPS does not fulfil criteria for LRTAP/POP

Part B Exposure assessment and effects of the active substance in the biocidal product(s)

1 GENERAL PRODUCT INFORMATION

1.1 IDENTIFICATION OF THE PRODUCT

Name(s) of the product	
Trade name or proposed Trade name	The Theoretical Product is a model product and has no trade name as it is not placed on the market.
Manufacturer's development code and number of the product	-
Formulation type	Granule (GR)

1.2 COMPLETE QUALITATIVE AND QUANTITATIVE COMPOSITION OF THE BIOCIDAL PRODUCT

Active substance					
ISO or Trivial name	**IUPAC name or other accepted chemical name**	**EC number**	**CAS number**	**Composition / all constituents (upper and lower concentration limit in % (w/w))**	**Concentration in the product in % (w/w)**
KMPS	-	274-778-7	70693-62-8	-	50

Other components / ingredients of the product					
ISO or Trivial name	**IUPAC name or other accepted chemical name**	**EC number**	**CAS number**	**Concentration in in the product in % (w/w)**	**Function**
Inert substances	-	-	-	50	-

1.3 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES

The representative product is a theoretical biocidal product with a 50 % content in KMPS characterized by white and odourless granular physical appearance, low density and pH slightly acidic.

From compositional and physical state, it can be predicted that it will have a shelf-life of at least 24 months The active substance of the representative product KMPS is a multicomponent inorganic mixture consisting of known stable peroxide molecular structures. At room temperature, the propensity of chemical reactions between $KMPS$ and other substances in the product is hindered by small molecular diffusivities of the components in the solid state (translated into low number of collisions per units of time).

Effects of light and temperature on content of the active substance and on general stability of the biocidal product are negligible due to storage of the product in opaque packages, high energy barriers for molecular diffusion (reactions are diffusion-limited) and high melting points of all the components (null probability of solid-liquid phase transitions). Further, due to the sealed packaging, interactions with humidity that could trigger decomposition reactions are excluded.

The biocidal product is expected to exhibit good wettability based on the presence of polar groups in the mixture which reduce the work for spreading (increase of adhesion forces) and by the presence of components with surface activity which decrease the surface tension (reduction of cohesive forces between water molecules).
The biocidal product is expected to exhibit high dilution stability based on the polar nature of the components in the mixture giving rise to favourable interactions with water molecules (e.g hydrogen bonds, dipolar forces). Aggregation phenomena such as flocculation are disregarded due to the absence of particles with colloidal size and chain steric repulsion of surfactants which supress any potential process of colloidal aggregation. Physical characteristics as surface tension and particle size distribution will be covered at the product level authorization.

1.4 HAZARD IDENTIFICATION FOR PHYSICAL AND CHEMICAL PROPERTIES

Concerning physical hazards, the following properties of the representative product can be inferred:
The biocidal product does not have explosive, flammability, self-reactive, oxidizing, self-heating and self-ignitable properties based on:
1. Read-across with available data from the active substance KMPS (and application of dilution criteria of CLP bridging principles).
2. Absence of meta-stable functional groups characteristic of explosives (e.g -NO_2) and a manifold of components with structures stabilized by π delocalization, functional groups with atoms in gas noble configuration, strong coordinate covalent bonds (high stability constants), low electrophilicity (low oxidative power reflected in negative reduction potentials) and mechanisms against hazard reactions to e.g potential quenching activity of radicals carriers and flammability dilution effects.
The biocidal product does not emit flammable substances in contact with water based on read-across with the active substance KMPS (and application of dilution criteria of CLP bridging principles) and chemical structures of the other components.
Following the Guidance on CLP criteria, the biocidal product cannot be classified as corrosive to metals based on the high melting points of all components.
It can be concluded that there is no hazard identified associated with physical-properties of the representative product.

1.5 ANALYTICAL METHODS FOR DETECTION AND IDENTIFICATION

Adequate methods exist for the determination of KMPS and impurities in the technical substance (for more detailed information, please see Part A, Chapter 1.7).

1.5.1 Formulation analysis

The methodology described in PART A, Chapter 1.7 applies.

2 EFFICACY

2.1 EFFICACY

The table: Experimental data on the efficacy of the biocidal product against target organism(s) is available in Appendix VI: **Confidential information**, Part B. - 2.1 EFFICACY.

Experimental data on the effectiveness of a KMPS based biocidal product against target organisms are obtained from the formulation of a proprietary product which contains 45% KMPS. The proprietary product is produced and placed on the market by a third party which is not part of the KMPS Registration Group. The companies have claimed confidentiality over the experimental data summarized in the Table in Appendix VI.

2.2 MODE OF ACTION

KMPS releases reactive oxygen, which unspecifically oxidises macromolecules of the cell wall, membranes and virus capsids leading to the cell wall disruption, loss of membrane integrity and disintegration of virus capsids. In addition, after penetration into cells or viruses, intracellular molecules such as amino acids, polypeptides, RNA and DNA are also oxidised which leads to the disruption of protein synthesis and cell death.

2.3 RESISTANCE

No resistance phenomenon has been reported with KMPS in the scientific literature for the time being.
Since KMPS is an inorganic substance with an unspecific mode of action (multisite oxidation process, see 7.2 Mode of action of this document) the development of resistance to KMPS is highly unlikely event.
Potential remedies should be available if resistance is ever observed with KMPS. These might include applying KMPS at the maximum approved dose level and frequency, adding an additional biocide (combination treatment) to broaden the spectrum of efficacy and/or provide different mechanisms of action, switching or alternating to another active ingredient which may improve efficacy by weakening the cells natural resistance defences.

2.4 CONCLUSION ON EFFICACY

The antimicrobial activity of KMPS based biocidal product relative to the PTs 2-5 was demonstrated with suspension as well as surface tests in originally submitted dossier when BPR guidance (2018) was not yet available. Studies were performed according to the directives of the German Society for Hygiene and Microbiology and according to the guidelines issued by the German Health Department and German Association for the Control of Virus Diseases for testing chemical disinfectants (version Sept. 1, 1982).
Four experimental studies were submitted to prove virucidal activity, whereas bactericidal and yeasticidal function and additional virucidal function was demonstrated based on 3 written expert opinions (Doc. No. 336-0219, Doc. No. 336-0220 and Doc. No. 336-0224), where the summary of efficacy data was provided and accepted for the purposes of active substance inclusion and approval at that time. Data are now considered as supporting data only.
Using the suspension tests, KMPS based product showed more than 5 log reduction of virus titre when used at concentrations of ≥500 ppm and contact times 5 to 15 minutes under clean and dirty conditions. Gram-positive and Gram-negative bacteria as well as *M.*

tuberculosis and *C. albicans* were inactivated, expressing the static effect at concentration of 0.1% KMPS, whereas cidal effect was demonstrated with 1% KMPS against tested organisms with 5 minutes contact time (suspension test) and 0.5% KMPS against tested organisms with 60 minutes contact time (surface test). It was assessed that KMPS, when used at the concentration ≥500 ppm for contact time 5 to 15 minutes, will be an efficacious disinfectant intended to be used in product types 2-5. It will control microorganisms such as bacteria (including mycobacteria), fungi and viruses on inanimate surfaces and/or in liquids in the industrial, medical, veterinary, food and feed area and in drinking water. The contact time required for efficacy will depend on the relative tolerance of the organism, the concentration of KMPS, the temperature, pH and the presence of organic material.

The applicant provided, upon request, additional efficacy data to demonstrate bactericidal and yeasticidal activity for PT2-5 uses in accordance with the BPR guidance (2018) and EN standards (EN1276, EN1650, EN1656, EN1657). With these phase 2 step 1 tests it was confirmed that using the KMPS based biocidal product in the formulation of a proprietary product which contains 45% KMPS, required log reduction of target organisms can be achieved under conditions stated in these EN norms. Since efficacy was demonstrated at the KMPS in-use concentrations indicated in section 2.1, therefore the same can be expected for the theoretical model product containing 50% KMPS. More information about the proprietary products used in efficacy studies is available in the Appendix VI: Confidential information, Part B.

We conclude that the efficacy data submitted in the dossier are sufficient to demonstrate the innate efficacy of a KMPS based biocidal product for the purposes of the active substance inclusion and approval. However, to support all intended use patterns against all claimed target organisms, additional tests, investigating the effects in real-life conditions and different means of biocide application in the area of use, need to be provided during the biocidal product authorisation.

3 HUMAN EXPOSURE ASSESSMENT

For a user-friendly handling of the data in this CAR, the following chapter is divided per PT:
Blue bars and arrows highlight the "start" (☐) and the "end" (☐) of the assessment for each PT in this chapter.

General remarks

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Any potential systemic toxic effect is considered secondary to local corrosion. Thus, a local exposure and risk assessment is performed for KMPS which is considered to cover also potential secondary systemic effects.

For the purpose of the human health risk assessment (HHRA), a theoretical product containing 50 % KMPS and 50 % of inert, non-toxic and non-classified substances is considered. The real-life products marketed typically contain around 50 % of KMPS, and sometimes less, and various co-formulants. However, as the individual product composition varies for different producers, a potential influence of the co-formulants should be assessed during product authorisation and is not considered relevant for the purpose of HHRA in the context of active substance approval.

For all intended uses, the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017) is followed for the local assessment of the theoretical product (50 % KMPS) as well as for the relevant diluted in-use solutions.

Oral exposure: For the oral route of exposure, a qualitative assessment is performed for KMPS, where relevant.

Dermal exposure: For the dermal route of exposure, a qualitative assessment is performed.

Inhalation exposure: For the inhalation route of exposure, a quantitative assessment (Tier-1 and Tier-2) is performed. Exposure towards dust and aerosol is conceivable. Due to the low vapour pressure of KMPS ($<1.7 \times 10^{-4}$ Pa at 25°C), formation of vapour is negligible, and is thus neglected. Moreover, in aqueous solutions KMPS dissociates rapidly into potassium and sulphate ions, and ionic species are not considered to evaporate in relevant amounts. For the inhalation route of exposure, a quantitative (Tier-1 and Tier-2) assessment, and if required (i.e. in case the AEC inhalation is exceeded in Tier-1 for the bystander), a qualitative assessment is performed in addition.

Oral, dermal and inhalation absorption: In the absence of clear systemic effects, absorption values for the oral, dermal and inhalation route are not deemed necessary.

Secondary exposure: Indirect exposure includes exposure of persons (bystanders/general public) who are present during or following the use of a biocidal product.
Secondary exposure of professional or non-professional bystanders/non-users upon

dermal contact with treated surfaces is considered to be irrelevant. Due to the high reactivity of KMPS, residues on surfaces degrade very rapidly. Decomposition to physiological potassium and sulphate ions takes place which are not expected to arise any concerns for human health.

Hence, residue formation and chronic secondary exposure is assumed to be negligible for aqueous solutions of KMPS and only inhalation exposure after application of KMPS is considered to be relevant for the assessment of secondary exposure. An exception is the use of KMPS for swimming pool disinfection and the potential secondary exposure of swimmers, for which oral and dermal exposure were assessed.

Assessment of disinfection-by-products (DBPs)

Guidance on the Biocidal Product Regulation, Volume V, Guidance on Disinfection By-Products (vers. 1.0, January 2017) refers to human health risk assessment for DBPs from halogenated oxidative biocides in PT2. KMPS is not a halogenated oxidative biocide, but it is able to oxidise bromide and chloride to hypobromous and hypocholorous acid, respectively. These can lead to the formation of halogenated DBPs. At the Human Health WG I 2023, it was concluded to include in the CAR the information provided by the applicant regarding formation of DBPs (presented below). Further information on DBPs should be requested at the product authorization stage.

The information provided by the applicant is presented below:

In the scenario that would represent the worst case (i.e. disinfection of salt water pools - pools with artificially added NaCl), the generation of DBPs is negligible, as explained below.

Chlorinated DBP

[redacted]

3 Water, S. and World Health Organization, 2006. Guidelines for safe recreational water environments. Volume 2, Swimming pools and similar environments. World Health Organization.

4 Bolyard, M., Fair, P., & Hautman, D., 1993. 'Sources of Chlorate Ion in US Drinking Water'. Journal (American Water Works Association), 85(9), 81- 88.

5 Gordon, G. and Tachiyashiki, S., 1991, 'Kinetics and mechanism of formation of chlorate ion from the hypochlorous acid/chlorite ion reaction at pH 6-10', Environmental Science & Technology, 25 (3), 468-474.

6 Black & Veatch Corporation (2010) 'Chapter 9 – Hypochlorination – Sodium Hypochlorite', White's Handbook of Chlorination and Alternative Disinfectants, Hoboken, New Jersey: John Wiley and Sons, pp. 463-470.

7 Adam, L. C. and Gordon, G., 1999, 'Hypochlorite Ion Decomposition: Effects of Temperature, Ionic Strength, and Chloride Ion', Inorg. Chem., 38 (6), 1299-1304.

[redacted]

8 Euro Chlor (2017), 'Chapter 7 – Physio-Chemical Properties', Physical, thermodynamic and selected chemical properties of chlorine, Brussels: Euro Chlor, pp 15-18.

[redacted]

We can conclude that no significant levels of chlorate are expected.

Brominated DBP

[redacted]

9 Yang, J., Dong, Z., Jiang, C., Wang, C. and Liu, H., 2019. An overview of bromate formation in chemical oxidation processes: Occurrence, mechanism, influencing factors, risk assessment, and control strategies. Chemosphere, 237, p.124521.

10 Wen, G., Qiang, C., Feng, Y., Huang, T. and Ma, J., 2018. Bromate formation during the oxidation of bromide-containing water by ozone/peroxymonosulfate process: Influencing factors and mechanisms. Chemical Engineering Journal, 352, pp.316-324.

11 Fang, J.Y. and Shang, C., 2012. Bromate formation from bromide oxidation by the UV/persulfate process. Environmental Science & Technology, 46(16), pp.8976-8983.

[redacted]

Therefore, we can conclude that while KMPS will oxidise chloride and bromide, the formation of halogenated DBPs is unfavourable and negligible.

Dietary risk assessment and livestock exposure

Due to the high reactivity of KMPS, residues on surfaces degrade very rapidly. Decomposition to physiological potassium and sulphate ions takes place which are not expected to arise any concerns for animal or human health. Thus, a systemic risk assessment for the transfer of residues into food or feed was not deemed necessary for intended uses in PTs 3, 4 and 5.

Exposure to potassium

Potassium ions constitute a physiologically essential metabolite in the human body, which is efficiently excreted via the urine after oral uptake (see Section A.3.1.1). No tolerable upper intake level is available for potassium (Scientific opinion on dietary reference values for potassium. EFSA Journal 2016; 14(10):4592). It was agreed at the WG I 2023 that the justification/assessment should be complemented by including a comparison of potassium exposure from KMPS use with adequate intake (AI) of potassium (Scientific opinion on dietary reference values for potassium. EFSA Journal 2016; 14(10):4592) to show safe use for the worst-case scenario.

Consumption of drinking water treated with KMPS is considered the worst-case scenario, although the applicant did not propose this use. Disinfection of animal drinking water is one of the proposed uses. It is considered that from all proposed uses, the amount of the possible potassium exposure is significantly lower than that from the indicative potassium exposure due to consumption of drinking water treated with KMPS.

The following parameters were used to calculate the exposure:

- KMPS concentration: 0.08% (as in PT5, Use# 1 Continuous water sanitation by dosing the header tank or application via a dosing system (professional use).
- Potassium concentration: As worst-case it was considered pure KMPS that contains 254,4 mg/L of potassium in 800 mg/L of KMPS.
- WHO 2003 default water consumption values: 2L/d for adult.
- Additional intake was calculated as default water consumption values multiplied by potassium concentration.
- Average intake and adequate intake values were taken from Scientific opinion on dietary reference values for potassium (EFSA Journal 2016; 14(10):4592).

Population	Average intake [mg/day]	Additional intake [mg/day]	Adequate intake [mg/day]
adults (≥18 years)	2,463 - 3,991	508,8	3,500 - man and non-lactating women 4,000 – lactating women

The additional intake of potassium due to drinking water disinfected with KMPS represents 12-23% of the average intake. Average intake is expected to be increased by approximately 500 mg/day, resulting in an upper-level average intake of approximately

4,500 mg/day. This is well below the levels that were identified as possible health concerns in a healthy population (Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Potassium; EFSA Journal (2005) 193, 1-19): "*Based on estimates of current potassium intakes in European countries, the risk of adverse effects from potassium intake from food sources (up to 5-6 g/day in adults) is considered to be low for the generally healthy population. Long-term intakes of about 3 g potassium per day as potassium chloride supplements, in addition to intake from foods, have been shown not to cause adverse effects (elevated plasma potassium or gastrointestinal symptoms) in healthy adults. However, a few case studies have reported that supplemental potassium in doses of 5-7 g/day can cause adverse effects on heart function in apparently healthy adults. In addition, gastrointestinal symptoms have been seen in healthy subjects taking some forms of potassium supplements with doses ranging from about 1 to 5 g potassium per day*." Even if considering the 95th to 97th percentile intake that is in the range of 4000-5500 mg/day (EFSA Journal (2005) 193, 1-19), the exposure to potassium due to drinking water disinfected with KMPS is considered safe. Additionally, balance can be maintained with intakes up to 195-390 mg/kg body weight /day, as renal excretion through a healthy kidney that is adapted to high intakes of potassium can effectively excrete potassium at 10 to 20 times the rate of a kidney that has not been adapted to a high intake (EFSA Journal (2005) 193, 1-19).

To conclude, exposure to potassium due to drinking water disinfected with KMPS is acceptable. As this is considered the worst-case scenario, no additional assessment for other uses is needed. There is no need to repeat the assessment at product authorisation.

PT2 - Disinfectants and algaecides not intended for direct application to humans or animals ☐

3.1 IDENTIFICATION OF MAIN PATHS OF HUMAN EXPOSURE TOWARDS ACTIVE SUBSTANCE FROM ITS USE IN BIOCIDAL PRODUCT

In the following table, relevant exposure routes towards KMPS from its use as a biocidal product in PT2 are briefly summarized.

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	yes	yes	n.a.	yes	yes	no
Dermal	n.a.	yes	yes	n.a.	yes	yes	no
Oral	n.a.	no	no	n.a.	no	yes	no

n.a.: not applicable (no industrial uses foreseen)

3.2 LIST OF SCENARIOS

Different applications of KMPS as a disinfectant in the intended uses within PT2 are described below.

Use #1: PT2 – Disinfection of swimming pools (professional use)

Representative product: Theoretical product (50 % KMPS), formulated as granules.

General description of use: The product is delivered in 5-10 kg containers. Granules are dosed manually into a dosing device. The dosing device is connected to a pump and the product is automatically dosed into the pool water. No exposure occurs during application. The standard concentration of KMPS in pool water is 130 mg/L (maintenance dose), in shock disinfection treatment 500 mg/L with an intermittent release 2 times per year.
Shock dosing is performed in case of high microbial loads with KMPS concentrations up to 500 mg/L. Shock dosing treatment is done outside of opening hours and/or overnight. Consequently, the pool is not used by swimmers during this special water treatment and the presence of personnel in the swimming hall is not expected. Personnel responsible for shock dosing treatment are normally trained and comprehensively instructed.

After the application, empty containers are stored and finally disposed of. Exposure during handling of empty containers is considered negligible.

Exposure to swimmers: The exposure via inhalation, dermal and oral route for the general public is considered in the secondary exposure assessments.

Use #2: PT2 – Dipping of equipment (professional use)

Representative product: Theoretical product (50 % KMPS), formulated as granules.
General description of use: The product is delivered in 5-10 kg containers. Granules are dosed manually with a scoop or comparable tool into a vessel containing some water. The granules are dissolved by gentle manual stirring with an adequate tool, and the vessel is filled up to a mark with water. The in-use concentration of KMPS is 5 g/L.
Contaminated equipment is put into the dipping bath by professionals and removed from the bath using a fork or tray.
After the application, treatment solution is disposed of by pouring into the drain. Dipping solution is replaced approximately every 4 days.

Empty containers are disposed of. Exposure during handling of empty containers is considered negligible.

Use #3: PT2 – Surface disinfection of industrial areas by wiping with mop (professional use)

Representative product: Theoretical product (50 % KMPS), formulated as granules.
General description of use: The product is delivered in 5-10 kg containers. Granules are dosed manually with a scoop or comparable tool into a bucket containing some water. The granules are dissolved by gentle manual stirring with an adequate tool, and the bucket is filled up to a mark with water. The in-use concentration of KMPS is 5 g/L.

Floors are wiped with a flat mop by professionals.
After the application, treatment solution is disposed of by pouring into the drain.

Empty containers are disposed of. Exposure during handling of empty containers is considered negligible.

Use #4: PT2 – Surface disinfection of industrial areas by manual spraying (low pressure) (professional use)

Representative product: Theoretical product (50 % KMPS), formulated as granules.

General description of use: The product is delivered in containers containing max. 5-10 kg. Granules are dosed manually with a scoop or comparable tool into the reservoir of the spray equipment containing some water. The granules are dissolved by gentle manual stirring with an adequate tool, and the reservoir is filled up to a mark with water. The in-use concentration of KMPS is 5 g/L.
The treatment solution is applied by low pressure sprayers. After the application, treatment solution is disposed of by pouring into the drain.

Empty containers are disposed of. Exposure during handling of empty containers is considered negligible.

Use #5: PT2 – Disinfection of swimming pools (non-professional use)

Representative product: Theoretical product (50 % KMPS), formulated as tabs.

General description of use: The product is delivered in 5-10 kg containers. For the non-professional user, the product is delivered as tabs, which are placed directly into the pool water. No application phase exists.

The standard concentration of KMPS in pool water is 130 mg/L (maintenance dose), in shock disinfection treatment 500 mg/L with an intermittent release 2 times per year.
Shock dosing is performed in case of high microbial loads with KMPS concentrations up to 500 mg/L. Shock dosing treatment is done overnight. Consequently, the pool is not used by swimmers during this special water treatment and presence of persons in the swimming hall is not expected. The label instructs about the shock dosing treatment.

After the application, empty containers are stored and finally disposed of. Exposure during handling of empty containers is considered negligible.

Exposure to swimmers: The exposure via inhalation, dermal and oral route for the general public is considered in the secondary exposure assessments.

Each exposure scenario is composed of different phases/processes/work tasks, which are presented in the table below.

Summary table: scenarios			
Scenario number	**Scenario/ work tasks**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1. Primary exposure of industrials			
No industrial uses are foreseen.			
2. Primary exposure of professionals			
2.1.1	Mixing & loading of granules – manual placing	Primary exposure of professionals during manual placing of KMPS granules (50 % KMPS) into dosing device.	professionals
2.1.2	Mixing & loading of granules – manual dosing	Primary exposure of professionals during manual dosing and dissolving of KMPS granules (50 % KMPS).	professionals
2.2.1	Application - Pool disinfection	Primary exposure of professionals during automated dosing of KMPS solution into pool water.	professionals
2.2.2	Application – Dipping of equipment	Primary exposure of professionals during dipping of equipment in the treatment solution.	professionals
2.2.3	Application - Wiping	Primary exposure of professionals during wiping of surfaces in industrial areas with a mop.	professionals
2.2.4	Application - Spraying	Primary exposure of professionals during manual spraying of KMPS solution onto surfaces in industrial areas at low pressure.	professionals
2.3.1	Post-application – Handling empty containers	Primary exposure during handling of empty containers.	professionals
2.3.2	Post-application – Disposal of treatment solution	Primary exposure of professionals during disposal of treatment solution (emptying of dipping bath, bucket/spray equipment).	professionals
3. Primary exposure of non-professionals			
3.1	Mixing & loading of tabs – manual dosing	Primary exposure during manual dosing of KMPS tabs (50 % KMPS) into pool water.	non-professionals
3.2	Application - Pool disinfection	The application of KMPS is the manual dosing of KMPS tabs in the pool water; no additional application phase exists.	non-professionals

3.3	Post-application – Handling empty containers	Primary exposure during handling of empty containers.	non-professionals
4. Secondary exposure			
4.1	Secondary exposure: Bystander during mixing & loading of granules - manual placing	Secondary inhalation exposure of professional bystanders during manual placing of KMPS granules (50 % KMPS).	professional bystander
4.2	Secondary exposure: Bystander during dipping	Secondary inhalation exposure of bystanders during disinfection of equipment by dipping.	professional bystander
4.3	Secondary exposure: Bystander during wiping	Secondary inhalation exposure of bystanders during surface disinfection by wiping with mop.	professional bystander
4.4	Secondary exposure: Bystander during spraying	Secondary inhalation exposure of bystanders during surface disinfection by manual spraying.	professional bystander
4.5	Secondary exposure: Swim instructor	Secondary inhalation exposure of a swim instructor supervising swimmers.	professional bystander
4.6	Secondary exposure: Swimming in pool	Secondary oral, dermal and inhalation exposure of general public (adult, child, baby) when swimming in disinfected pool water.	general public

3.3 INDUSTRIAL EXPOSURE

No industrial use of KMPS as biocidal product in PT2 is foreseen.

3.4 PROFESSIONAL EXPOSURE

3.4.1 Scenario 2.1.1: Mixing and loading of KMPS granules – manual placing into a dosing device

Description of Scenario 2.1.1: Mixing & loading of granules – manual placing into a dosing device		
Professionals place KMPS granules (50 % KMPS, quantities up to 100 kg, 4 times/25 kg bags) manually or using dosing aids into a dosing device. This scenario covers a loading task for public swimming pool disinfection. Inhalation exposure during mixing and loading is assessed quantitatively using the Advanced Reach Tool (ART). As the product itself is of hypothetical nature, as a Tier 1 approach, worst case assumptions and default-values were used in order to derive a worst worst-case exposure assumption. However, as Tier 3, a more realistic worst-case scenario was calculated to reflect a more probable use of the product. Dermal exposure is assessed semi-quantitatively considering the concentration of KMPS in the product.		
	Parameters	**Value**
Tier 1	***Dermal exposure***	
	KMPS concentration granules	50 % (w/w)
	Inhalation exposure	
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 107)	10 min per day
	Parameters for ART (Advanced Reach Tool)	
	What is the product type of the substance/preparation?	Powders, granules or pelletised material
	To which dustiness class does the substance belong?[1.]	Granules, flakes or pellets (Inhalable fraction: 101 - 500 mg/kg)
	What is the moisture content of the product?	Dry product (<5 % moisture content)
	What is the weight fraction of the substance in the powdered, granular or pelletised material?[2]	0.5
	Is the primary emission source located in the breathing zone of the worker (i.e. the volume of air within 1 metre in any direction of the worker's head)?	Yes
	To which activity class does your activity belong?	Activity class: Transfer of powders, granules or pelletised material Activity Subclass: Falling of powders, granules or pelletised material
	Which of the situations below does best represent your activity?[3]	Transferring 1 – 10 kg/minute
	What is the type of handling?	Routine transfer
	What is the drop height?	Drop height < 0.5 m
	What is the level of containment of the process?[4]	Handling that reduces contact between product and adjacent air

	Are there any control measures in close proximity of the near-field emission source intended to minimise emissions from the source?		No localised controls
	Is the process fully enclosed and is the integrity of that enclosure regularly monitored?		No
	Are demonstrable and effective housekeeping practices in place (e.g. daily cleaning using appropriate methods (e.g. vacuum), preventive maintenance of machinery and control measures, and use of protective clothing that will repel spills and reduce personal cloud)?		No
	Are general housekeeping practices in place?		Yes
	Is the work performed indoors, outdoors or in a spray room or downward laminar flow booth?		Choose site: Indoors What is the room size of the work area? Small workrooms only What is the ventilation rate of the general ventilation system in the work area? 0.3 Air changes per hour
	Are secondary sources present in the workroom in addition to the source in the breathing zone of the worker?		No
	PPE/RPE	Dermal protection:	no -
		Respiratory protection equipment:	no -
	ART (Advanced Reach Tool, full shift, 75th Percentile, inter-quartile confidence interval):		0.86 mg/m³
Tier 2	PPE/RPE	Dermal protection:	Coverall and gloves
		Respiratory protection equipment: RPE10	10 % penetration
Tier 3	Is the work performed indoors, outdoors or in a spray room or downward laminar flow booth?[5]		Choose site: Indoors What is the room size of the work area? 100 m³ What is the ventilation rate of the general ventilation system in the work area? 3 Air changes per hour
	ART (Advanced Reach Tool, full shift, 75th Percentile, inter-quartile confidence interval):		0.25 mg/m³

	RPE	Respiratory protection equipment: RPE4	25 % penetration

1. Worst-case default value for granules.
2. According to B1.2 IDENTIFICATION OF THE PRODUCT
3. Since the product is delivered in max. 10 kg containers, higher transfer rates than 10 kg/minute are not realistic.
4. As the product is filled into a dosing device, the dosing device is considered to reduce contact between product and adjacent air.
5. For Tier 3, more realistic values were chosen for calculations. Especially room size and ventilation rate are expected to be higher than the worst-possible worst case which were used for Tier 1.

Calculations for Scenario 2.1.1

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (dust)**	**Estimated dermal exposure**
Scenario 2.1.1	1/none	0.860 mg/m³	50 % (w/w)
	2/RPE10	0.086 mg/m³	<<50 % (w/w)
	3/RPE4	0.063 mg/m³	<<50 % (w/w)

Further information and considerations on scenario 2.1.1

The active substance KMPS as well as the theoretical product (50 % KMPS) is classified as Skin Corr. 1. The semi-quantitative assessment of dermal exposure towards granules containing 50 % KMPS leads to exceeding of the generic concentration limit for skin irritation. Thus, a qualitative local risk assessment is performed (see Part C, Chapter 12).

3.4.2 Scenario 2.1.2: Mixing and loading of KMPS granules – manual dosing

Description of Scenario 2.1.2: Mixing and loading of KMPS granules – manual dosing			
Professionals measure and dissolve KMPS granules (50 % KMPS, < 100 g) by filling the product with a scoop (or comparable tool) into a vessel (e.g. dipping bath, bucket, reservoir of spray equipment) containing some water. Granules are dissolved by manual stirring with an adequate tool, and the vessel is filled up with water to a mark. Inhalation exposure towards dust is expected to be negligible as only low amounts of product are handled via a scoop or comparable tools and as the degree of powder formation is expected to be generally low for granules. Dermal exposure is assessed semi-quantitatively considering the concentration of KMPS in the product.			
	Parameters		**Value**
Tier 1	KMPS concentration granules		50 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers.1 , 2015, p. 107)		10 min per day
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
Tier 2	PPE	Dermal protection:	Coverall and gloves

Calculations for Scenario 2.1.2

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (dust)**	**Estimated dermal exposure**
Scenario 2.1.2	1/none	n.r. (negligible)	50 % (w/w)
	2/ coverall and gloves	n.r. (negligible)	<<50 % (w/w)

Further information and considerations on scenario 2.1.2

The active substance KMPS as well as the theoretical product (50 % KMPS) is classified as Skin Corr. 1. The semi-quantitative assessment of dermal exposure towards granules containing 50 % KMPS leads to exceeding of the generic concentration limit for skin irritation. Thus, a qualitative local risk assessment is performed (see Part C, Chapter 12).

3.4.3 Scenario 2.2.1: Application – Pool disinfection

Description of Scenario 2.2.1: Application – Pool disinfection		
The product is automatically dosed into the pool water. No inhalation or dermal exposure occurs during application. The in-use concentration of KMPS is 130 mg/L (0.013 % w/w) for maintenance dose and 500 mg/L (0.05 % w/w) for shock dosing. Of note, shock dosing of pools is performed outside of opening hours and/or overnight. Consequently, the pool is not used during this special water treatment and presence of personnel in the swimming hall is not expected.		
	Parameters	**Value**
Tier 1	KMPS in-use concentration (maintenance dose)	0.013 % (w/w)
	KMPS in-use concentration (shock dosing)	0.050 % (w/w)

Calculations for Scenario 2.2.1

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure**	**Estimated dermal exposure**
Scenario 2.1.1	1/none	n.r. (no exposure)	n.r. (no exposure)

Further information and considerations on scenario 2.2.1
Not relevant.

3.4.4 Scenario 2.2.2: Application – Dipping of equipment

Description of Scenario 2.2.2: Application – Dipping of equipment			
Contaminated equipment is put into the dipping bath by professionals and removed from the bath using a fork or tray. The in-use concentration of KMPS is 5 g/L (0.5 % w/w). Inhalation exposure is assessed quantitatively with Dipping Model 4 (Biocides Human Health Exposure Methodology, vers. 1, 2015, pp. 106-7), which considers the exposure during mixing and loading of biocidal product as well as during application. As only low amounts of product are handled via a scoop or comparable tools and as the degree of powder formation is expected to be generally low for granules, inhalation exposure towards dust is expected to be negligible. However, the mixing and loading of KMPS granules (50 % w/w) by manual dosing was assessed separately (please refer to scenario 2.1.2) to account for the exposure towards the concentrated product. Dermal exposure is assessed semi-quantitatively considering the in-use concentration of KMPS.			
	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.5 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 106-7)		30 min per day
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	Dipping Model 4 (Biocides Human Health Exposure Methodology, vers. 1, 2015, pp. 106-7)	indicative value: inhalation	0.2 mg/m³

Calculations for Scenario 2.2.2

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (aerosol)**	**Estimated dermal exposure**
Scenario 2.2.2	1/none	0.001 g/m³	0.5 % (w/w)

Further information and considerations on scenario 2.2.2
Not relevant.

3.4.5 Scenario 2.2.3: Application – Wiping

Description of Scenario 2.2.3: Application – Wiping			
Professionals wipe floors in industrial areas with a flat mop. The in-use concentration of KMPS is 5 g/L (0.5 % w/w). Inhalation exposure is assessed quantitatively with Surface Disinfection Model 1 (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 105), which considers the exposure during mixing and loading of (liquid) biocidal product as well as during application. As only low amounts of product are handled via a scoop or comparable tools and a.s. the degree of powder formation is expected to be generally low for granules, inhalation exposure towards dust is expected to be negligible. However, the mixing and loading of KMPS granules (50 % w/w) by manual dosing was assessed separately (please refer to scenario 2.1.2) to account for the exposure towards the concentrated product. Dermal exposure is assessed semi-quantitatively considering the in-use concentration of KMPS.			
	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.5 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 105)		220 min per shift
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	Surface Disinfection Model 1 (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 105)	indicative value: inhalation	22.9 mg/m³

Calculations for Scenario 2.2.3

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (aerosol)**	**Estimated dermal exposure**
Scenario 2.2.3	1/none	0.11 mg/m³	0.5 % (w/w)

Further information and considerations on scenario 2.2.3: Not relevant.

3.4.6 Scenario 2.2.4: Application – Spraying

Description of Scenario 2.2.4: : Application – Spraying			
Professionals spray treatment solution at low pressure onto surfaces in industrial areas. The in-use concentration of KMPS is 5 g/L (0.5 % w/w). Inhalation exposure is assessed quantitatively with Spraying Model 1 (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 115), which considers the exposure during mixing and loading of biocidal product as well as during application. As only low amounts of product are handled via a scoop or comparable tools and as the degree of powder formation is expected to be generally low for granules, inhalation exposure towards dust is expected to be negligible. However, the mixing and loading of KMPS granules (50 % w/w) by manual dosing was assessed separately (please refer to scenario 2.1.2) to account for the exposure towards the concentrated product. Dermal exposure is assessed semi-quantitatively considering the in-use concentration of KMPS.			
	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.5 % (w/w)
	Duration and frequency of events (Recommendation 6, HEAdhoc, ver.3, p. 7)		120 min per day
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	Spraying Model 1 (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 105)	Indicative value: inhalation	104 mg/m³
Tier 2	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment (RPE4):	25 % penetration

Calculations for Scenario 2.2.4

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (aerosol)**	**Estimated dermal exposure**
Scenario 2.2.4	1/none	0.52 mg/m³	0.5 % (w/w)
Scenario 2.2.4	2/RPE4	0.13 mg/m³	0.5 % (w/w)

Further information and considerations on scenario 2.2.4: Not relevant.

3.4.7 Scenario 2.3.1: Post-application – Handling of empty containers

Description of Scenario 2.3.1: Post-application – Handling of empty containers
After the application, empty containers are stored and finally disposed of. Exposure during these tasks is considered negligible due to the small amounts of remaining KMPS.

3.4.8 Scenario 2.3.2: Post-Application – Disposal of treatment solution

Description of Scenario 2.3.2: Post-application – Disposal of treatment solution			
After usage, professionals pour the treatment solution from the vessel (e.g. dipping bath, bucket, spray equipment) into the drain. The vessel and mops are rinsed with water. The maximum in-use concentration of KMPS is 5 g/L (0.5 % w/w). Inhalation exposure is assessed quantitatively with Mixing and Loading Model 7, loading liquids (HEEG opinion 1, 2008). Dermal exposure is assessed semi-quantitatively considering the in-use concentration of KMPS.			
	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.5 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1 , 2015, p. 107)		10 min per day
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	Loading liquids (Mixing and loading model 7, HEEG Opinion 1, 2008)	indicative value: inhalation	0.94 mg/m³

Calculations for Scenario 2.3.2

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (aerosol)**	**Estimated dermal exposure**
Scenario 2.3.2	1/none	0.005 mg/m³	0.5 % (w/w)

Further information and considerations on scenario 2.3.2
Not relevant.

3.4.9 Combined scenarios

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Furthermore, corrosion/irritation by KMPS is an effect occurring immediately due to direct chemical reactivity. Any potential systemic toxic effect is considered secondary to local corrosion.

Thus, combined scenarios and adding up of exposure for the different scenarios/work tasks related to each intended use are not considered relevant.

Nevertheless, the relevant scenarios/work tasks for each professional use in PT2 are summarized in the following table to provide an overview on relevant work tasks per intended use.

Use #1: PT2 – Disinfection of swimming pools (professional use)			
Scenario/ work task	**KMPS concentration**	**inhalation exposure (dust or aerosol)**	**dermal exposure**
Mixing & loading of granules – manual placing [2.1.1]	50 % (w/w)	Tier-1/no RPE: 0.860 mg/m³ Tier-2/RPE10: 0.086 mg/m³ Tier-3/RPE4: 0.063 mg/m³	50 % (w/w)
Application – Pool disinfection [2.2.1]	0.013 % (w/w) (maintenance dose) 0.050 % (w/w) (shock dosing)	n.r. (automated dosing, no exposure)	
Post-application – Handling of empty containers [2.3.1]	max. 50 % (w/w)	n.r. (negligible)	
Use #2: PT2 – Dipping of equipment (professional use)			
Scenario/ work task	**KMPS concentration**	**inhalation exposure (dust or aerosol)**	**dermal exposure**
Mixing & loading of granules – manual dosing [2.1.2]	50 % (w/w)	n.r. (negligible)	50 % (w/w)
Application – Dipping of equipment [2.2.2]	0.5 % (w/w)	0.001 mg/m³	0.5 % (w/w)
Post-application – Handling of empty containers [2.3.1]	max. 50 % (w/w)	n.r. (negligible)	
Post-application – Disposal of treatment solution [2.3.2]	max. 0.5 % (w/w)	0.005 mg/m³	max. 0.5 % (w/w)
Use #3: PT2 – Surface disinfection of industrial areas by wiping with mop (professional use)			
Scenario/ work task	**KMPS concentration**	**inhalation exposure (dust or aerosol)**	**dermal exposure**

Mixing & loading of granules – manual dosing [2.1.2]	50 % (w/w)	n.r. (negligible)	50 % (w/w)
Application – Wiping [2.2.3]	0.5 % (w/w)	Tier-1/no RPE: 0.11 mg/m³	0.5 % (w/w)
Post-application – Handling of empty containers [2.3.1]	max. 50 % (w/w)	n.r. (negligible)	
Post-application – Disposal of treatment solution [2.3.2]	max. 0.5 % (w/w)	0.005 mg/m³	max. 0.5 % (w/w)
Use #4: PT2 – Surface disinfection of industrial areas by manual spraying (low pressure) (professional use)			
Scenario/ work task	**KMPS concentration**	**inhalation exposure (dust or aerosol)**	**dermal exposure**
Mixing & loading of granules – manual dosing [2.1.2]	50 % (w/w)	n.r. (negligible)	50 % (w/w)
Application – Spraying [2.2.4]	0.5 % (w/w)	Tier-1/no RPE: 0.52 mg/m³ Tier-2/RPE4: 0.13 mg/m³	0.5 % (w/w)
Post-application – Handling of empty containers [2.3.1]	max. 50 % (w/w)	n.r. (negligible)	
Post-application – Disposal of treatment solution [2.3.2]	max. 0.5 % (w/w)	0.005 mg/m³	max. 0.5 % (w/w)

n.r.: not relevant

3.5 NON-PROFESSIONAL EXPOSURE

3.5.1 Scenario 3.1: Mixing and loading of KMPS tabs – manual dosing

Description of Scenario 3.1: mixing and loading of KMPS tabs – manual dosing		
Non-professionals dose the product (50 % KMPS) directly into the pool water. Products for use by non-professional users are formulated as tabs (50 % KMPS), thus limiting the potential of dust formation to approximately zero. Consequently, inhalation exposure towards dust during mixing and loading is considered to be negligible. Of note, according to ConsExpo Disinfectant Factsheet, Sections 2.2.3 and 6.4, no inhalation exposure occurs for the non-professional user during mixing and loading of tablets. Thus, only a semi-quantitative exposure assessment is performed for the dermal route considering the concentration of KMPS in the product.		
	Parameters	**Value**
Tier 1	KMPS concentration tabs	50 % (w/w)
	Duration and frequency of events (ConsExpo Disinfectant Factsheet)	once a day/4 months per year

Calculations for Scenario 3.1

Summary table: local exposure from non-professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (dust)**	**Estimated dermal exposure**
Scenario 3.1	1/none	not relevant	50 % (w/w)

Further information and considerations on scenario 3.1

The active substance KMPS as well as the theoretical product (50 % KMPS) is classified as Skin Corr. 1. The semi-quantitative assessment of dermal exposure towards a product containing 50 % KMPS leads to exceeding of the generic concentration limit for skin irritation. Thus, a qualitative local risk assessment is performed as discussed in Part C, Chapter 12.

3.5.2 Scenario 3.2: Application of KMPS for pool disinfection

Description of Scenario 3.2: Application of KMPS for pool disinfection
Non-professional users dose the product (50 % KMPS tabs) directly into the pool water. Hence, no additional application phase for the use of KMPS for swimming pool disinfection exists.

3.5.3 Scenario 3.3: Post-application – Handling of empty containers

Description of Scenario 3.3: Post-application – Handling of empty containers
After the application, empty containers are storage and finally disposed. Exposure during these tasks is considered negligible due to the small amounts of remaining KMPS.

3.5.4 Combined scenarios

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Furthermore, corrosion/irritation by KMPS is an effect occurring immediately due to direct chemical reactivity. Any potential systemic toxic effect is considered secondary to local corrosion.

Thus, combined scenarios and adding up of exposure for the different scenarios/work tasks related to each intended use are not considered relevant.

Nevertheless, the relevant scenarios/work tasks for the non-professional use in PT2 is summarized in the following table to provide an overview on relevant work tasks per intended use.

Use #5: PT2 - Disinfection of swimming pools (non-professional use)			
Scenario/ work task	**KMPS concentration**	**inhalation exposure (dust or aerosol)**	**dermal exposure**
Mixing & loading of tabs – manual dosing [3.1]	50 % (w/w)	n.r. (negligible)	max. 50 % (w/w)
Application – Pool disinfection [3.2]	0.013 % (w/w) (maintenance dose) 0.050 % (w/w) (shock dosing)	n.r. (no exposure)	
Post-application – Handling of empty containers [3.3]	max. 50 % (w/w)	n.r. (negligible)	

n.r.: not relevan

3.6 SECONDARY EXPOSURE EXCLUDING DIETARY EXPOSURE

3.6.1 Scenario 4.1: Professional bystander during mixing & loading of KMPS granules – manual placing

Description of Scenario 4.1: Professional bystander during mixing & loading of KMPS granules – manual placing			
Professional bystanders might be present during manual placing of KMPS granules (50 % w/w) into a dosing container. This bystander might be exposed towards KMPS dust by the inhalation route. Inhalation exposure during mixing and loading is assessed quantitatively using the Advanced Reach Tool (ART). As the product itself is of hypothetical nature, as a Tier 1 approach, worst case assumptions and default-values were used in order to derive a worst worst-case exposure assumption. However, as Tier 3, a more realistic worst-case scenario was calculated to reflect a more probable use of the product. Dermal exposure of professional bystanders is considered negligible. This scenario is only considered relevant for the use: Use #1: PT2 – Disinfection of swimming pools (professional use)			
	Parameters		**Value**
Tier 1	KMPS concentration granules		50 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1 , 2015, p. 107)		10 min per day
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	ART (Advanced Reach Tool, full shift, 75th Percentile, inter-quartile confidence interval)[1]:		0.86 mg/m³
Tier 2	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment: RPE10	10 % penetration
Tier 3	ART (Advanced Reach Tool, full shift, 75th Percentile, inter-quartile confidence interval)[1]:		0.25 mg/m³
	RPE	Respiratory protection equipment: RPE4	25 % penetration

1. For details on the calculation, please refer to Scenario 2.1.1.

Calculations for scenario 4.1

Summary table: secondary local exposure of professional bystanders		
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (dust)**
Scenario 4.1	1/none	0.860 mg/m³
	2/RPE10	0.086 mg/m³
	3/RPE4	0.063 mg/m³

Further information and considerations on scenario 4.1

The active substance KMPS as well as the theoretical product (50 % KMPS) is classified as Skin Corr. 1 and considered to cause respiratory tract irritation when inhaled. The quantitative Tier-1 assessment leads to exceeding of the AEC_{inhal}. Thus, a qualitative local risk assessment is performed for the professional bystander during mixing & loading tasks (see Part C, Chapter 12).

3.6.2 Scenario 4.2: Professional bystander during dipping

Description of Scenario 4.2: Professional bystander during dipping			
Professional bystanders might be present during dipping of equipment. This bystander might be exposed towards KMPS aerosol by the inhalation route. Inhalation exposure is assessed quantitatively with Dipping Model 4 (Biocides Human Health Exposure Methodology, vers. 1, 2015, pp. 106-7), which considers the exposure during mixing and loading of biocidal product as well as during application. As only low amounts of product are handled via a scoop or comparable tools and as the degree of powder formation is expected to be generally low for granules, inhalation exposure towards dust is expected to be negligible. Dermal exposure of professional bystanders is considered not relevant due to the rapid degradation of KMPS to potassium and sulphate.			
	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.5 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 106-7)		30 min per day
	Dipping Model 4 (Biocides Human Health Exposure Methodology, vers. 1, 2015, pp. 106-7	indicative value: inhalation	0.2 mg/m³

Calculations for scenario 4.2

Summary table: secondary local exposure of professional bystanders		
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (aerosol)**
Scenario 4.2	Tier-1/no PPE	0.001 mg/m³

Further information and considerations on scenario 4.2
Not relevant.

3.6.3 Scenario 4.3: Professional bystander during wiping

Description of Scenario 4.3: Professional bystander during wiping			
Professional bystanders might be present during wiping of surfaces. This bystander might be exposed towards KMPS aerosol by the inhalation route. Inhalation exposure is assessed quantitatively with Surface Disinfection Model 1 (Biocides Human Health Exposure Methodology, vers. 1, 2015, pp. 105), which considers the exposure during mixing and loading of (liquid) biocidal product as well as during application. As only low amounts of product are handled via a scoop or comparable tools and as the degree of powder formation is expected to be generally low for granules, inhalation exposure towards dust is expected to be negligible. Dermal exposure of professional bystanders is considered not relevant due to the rapid degradation of KMPS to potassium and sulphate.			
	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.5 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 105)		220 min per shift
	Surface Disinfection Model 1 (Biocides Human Health Exposure Methodology, vers.1, 2015, p. 105)	indicative value: inhalation	22.9 mg/m³
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no

Calculations for scenario 4.3

Summary table: secondary local exposure of professional bystanders		
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (aerosol)**
Scenario 4.3	1/no PPE	0.11 mg/m³

Further information and considerations on scenario 4.3
Not relevant.

3.6.4 Scenario 4.4: Professional bystander during spraying

Description of Scenario 4.4: Professional bystander during spraying			
Professional bystanders might be present during surface disinfection by spraying. This bystander might be exposed towards KMPS aerosol by the inhalation route. Inhalation exposure is assessed quantitatively with Spraying Model 1 (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 115), which considers the exposure during mixing and loading of biocidal product as well as during application. As only low amounts of product are handled via a scoop or comparable tools and as the degree of powder formation is expected to be generally low for granules, inhalation exposure towards dust is expected to be negligible. Dermal exposure of professional bystanders is considered not relevant due to the rapid degradation of KMPS to potassium and sulphate.			
	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.5 % (w/w)
	Duration and frequency of events (Recommendation 6, HEAdhoc, ver.3, p. 7)		120 min per day
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	Spraying Model 1 (Biocides Human Health Exposure Methodology, vers.1, 2015)	Indicative value: inhalation	104 mg/m³
Tier 2	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment: RPE4	25 % penetration

Calculations for scenario 4.4

Summary table: secondary local exposure of professional bystanders		
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure**
Scenario 4.4	1/none	0.52 mg/m³
	2/RPE4	0.13 mg/m³

Further information and considerations on scenario 4.4
The active substance KMPS as well as the theoretical product (50 % KMPS) is classified as Skin Corr. 1 and considered to cause respiratory tract irritation when inhaled. The quantitative Tier-1 assessment leads to exceeding of the AEC_{inhal}. Thus, a qualitative local risk assessment is performed for the professional bystander during spraying tasks (see Part C, Chapter 12).

3.6.5 Scenario 4.5: Secondary exposure of a swim instructor

Description of Scenario 4.5: Secondary exposure of a swim instructor		
Swim instructors might be exposed via the inhalation route to vapours arising from the swimming pool surface when water is disinfected. However, after contact with water, KMPS rapidly dissociates into potassium and sulphate, i.e. ionic species which do not evaporate. Exposure towards KMPS aerosols (e.g. splashes and water turbulences) is considered negligible. The in-use concentration of KMPS is 130 mg/L (0.013 % w/w) for maintenance dose and 500 mg/L (0.050 % w/w) for shock dosing. Of note, shock dosing of pools is performed outside of opening hours and/or overnight. Consequently, the pool is not used during this special water treatment and presence of personnel in the swimming hall is not expected. Thus, only dermal exposure to splashes is considered relevant, which is assessed semi-quantitatively considering the in-use concentration (maintenance dose) of KMPS.		
	Parameters	**Value**
Tier 1	KMPS in-use concentration (maintenance dose)	0.013 % (w/w)
	KMPS in-use concentration (shock dosing)	0.050 % (w/w)
	Duration and frequency of events	max. 8 h per day

Calculations for scenario 4.5

Summary table: secondary local exposure of professional bystanders (swim instructor)			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure**	**Estimated dermal exposure (aerosol)**
Scenario 4.5	Tier-1/no PPE	not relevant	0.013 % (w/w)

Further information and considerations on scenario 4.5
Not relevant.

3.6.6 Scenario 4.6: Secondary exposure of swimmers in pool

Description of Scenario 4.6: Secondary exposure of swimmers in pool		
Swimmers are exposed towards pool water containing KMPS. Relevant exposure occurs via the dermal route and the oral route (i.e. accidental swallowing of pool water). The in-use concentration of KMPS is 130 mg/L (0.013 % w/w) for maintenance dose and 500 mg/L (0.050 % w/w) for shock dosing. Of note, shock dosing of pools is performed outside of opening hours and/or overnight. Consequently, the pool is not used during this special water treatment and presence of personnel in the swimming hall is not expected. Exposure towards vapour is considered negligible, as KMPS in aqueous solutions dissociates rapidly into potassium and sulphate, i.e. ionic species which do not evaporate. Exposure towards KMPS aerosols (e.g. splashes and water turbulences) is considered negligible. Thus, only oral and dermal exposure to KMPS in pool water is considered relevant, which is assessed semi-quantitatively considering the in-use concentration (maintenance dose) of KMPS. This scenario is considered relevant for the following uses: ☐ Use #1: PT2 – Disinfection of swimming pool (professional use) ☐ Use #5: PT2 – Disinfection of swimming pool (non-professional use)		
	Parameters	**Value**
Tier 1	KMPS in-use concentration (maintenance dose)	0.013 % (w/w)
	KMPS in-use concentration (shock dosing)	0.050 % (w/w)
	Duration and frequency of events (ConsExpo Disinfectant Products Factsheet, pp. 87-91)	baby: 30 min once a week child: 60 min 2 times a week adult (competitive swimmer): 120 min 5 times a week

Calculations for scenario 4.6

Summary table: secondary local exposure of swimmers in pools (general public)				
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (vapour and aerosol)**	**Estimated dermal exposure**	**Estimated oral exposure**
Scenario 4.6	Tier-1/no PPE	not relevant	0.013 % (w/w)	0.013 % (w/w)

Further information and considerations on scenario 4.6

Not relevant.

3.6.7 Combined scenarios

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Furthermore, corrosion/irritation by KMPS is an effect occurring immediately due to direct chemical reactivity. Any potential systemic toxic effect is considered secondary to local corrosion.

Thus, combined scenarios for secondary exposure are not considered relevant.

PT2 - Disinfectants and algaecides not intended for direct application to humans or animals ☐

PT3 - Veterinary hygiene ☐

3.7 IDENTIFICATION OF MAIN PATHS OF HUMAN EXPOSURE TOWARDS ACTIVE SUBSTANCE FROM ITS USE IN BIOCIDAL PRODUCT

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	yes	no	n.a.	yes	no	no
Dermal	n.a.	yes	no	n.a.	no	no	no
Oral	n.a.	no	no	n.a.	no	no	no

n.a.: not applicable (no industrial uses foreseen)

3.8 LIST OF SCENARIOS

Different applications of KMPS as a disinfectant in the intended uses within PT3 are described below.

Use #1: PT3 – Terminal disinfection of animal houses using a low pressure sprayer (professional use)

Representative product: Theoretical product (50 % KMPS), formulated as granules.

General description of use: The product is delivered in containers containing max. 5-10 kg. Granules are dosed manually with a scoop or comparable tool into the reservoir of the spray equipment containing some water. The granules are dissolved by gentle manual stirring with an adequate tool, and the reservoir is filled up to a mark with water.
The in-use concentration of KMPS is 8 g/L (0.8 % w/w). The KMPS solution is sprayed onto

walls, floors, etc.
The terminal disinfection of animal houses by spraying is performed only few times a year after depopulation and thorough cleaning of the animal house. The frequency of application varies with the type of animal house. The disinfected surfaces are left to dry before repopulation of the animal house.

After the application, remaining treatment solution is poured into the drain or into slurry/manure.

Empty containers are stored and finally disposed of. Exposure during handling of empty containers is considered negligible.

Use #2: PT3 – Foot dips (professional use)

Representative product: Theoretical product (50 % KMPS), formulated as granules.
General description of use: The product is delivered in containers containing max. 5-10 kg. Granules are dosed manually with a scoop or comparable tool into a vessel containing some water. The granules are dissolved by gentle manual stirring with an adequate tool, and the vessel is filled up to a mark with water. The in-use concentration of KMPS is 8 g/L (0.8 % w/w).
Foot dips are placed at all main farm entrances and at entrances to farm buildings together with brushes. One brush is used to remove organic matter prior to disinfection and one brush is used within the foot dip to wash the boot with the disinfection solution.

After the application, treatment solution is disposed of by pouring into the drain. The solution is replaced weekly or when heavily soiled.

Empty containers are disposed of. Exposure during handling of empty containers is considered negligible.

Each exposure scenario is composed of different phases/processes/work tasks, which are presented in the table below.

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1. Primary exposure of industrials			
No industrial uses are foreseen.			
2. Primary exposure of professionals			
2.1	Mixing & loading of granules – manual dosing	Primary exposure of professionals during manual dosing and dissolving of KMPS granules (50 % KMPS).	professionals
2.2.1	Application - Spraying	Primary exposure of professionals during manual spraying of animal houses at low pressure.	professionals
2.2.2	Application – Foot dips	Primary exposure of professionals during disinfection of boots in foot dips.	professionals
2.3.1	Post-application – Handling empty containers	Primary exposure during handling of empty containers.	professionals
2.3.2	Post-application – Disposal of treatment solution	Primary exposure of professionals during disposal of treatment solution (emptying of spray equipment, foot dip).	professionals
3. Primary exposure of non-professionals			
No non-professional uses are foreseen.			
4. Secondary exposure			
4.1	Secondary exposure: Bystander during spraying	Secondary inhalation exposure of bystanders during terminal disinfection of animal houses using a low pressure sprayer.	professional bystander

3.9 INDUSTRIAL EXPOSURE

No industrial use of KMPS as biocidal product in PT3 is foreseen.

3.10 PROFESSIONAL EXPOSURE

3.10.1 Scenario 2.1: Mixing and loading of KMPS granules – manual dosing

Description of Scenario 2.1: Mixing and loading of KMPS granules – manual dosing			
Professionals measure and dissolve KMPS granules (50 % KMPS) by filling the product with a scoop (or comparable tool) into a vessel (e.g. reservoir of spray equipment, dipping bath) containing some water. Granules are dissolved by manual stirring with an adequate tool, and the vessel is filled up with water to a mark. Inhalation exposure towards dust is expected to be negligible as only low amounts of product are handled via a scoop or comparable tools and as the degree of powder formation is expected to be generally low for granules. Dermal exposure is assessed semi-quantitatively considering the concentration of KMPS in the product.			
	Parameters		**Value**
Tier 1	KMPS concentration granules		50 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1 , 2015, p. 107)		10 min per day
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
Tier 2	PPE/RPE	Dermal protection: yes	Coverall and gloves

Calculations for Scenario 2.1

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (dust)**	**Estimated dermal exposure**
Scenario 2.1.2	1/none	n.r. (negligible)	50 % (w/w)
	2/coverall and gloves	n.r. (negligible)	<<50 % (w/w)

Further information and considerations on scenario 2.1

The active substance KMPS as well as the theoretical product (50 % KMPS) is classified as Skin Corr. 1. The semi-quantitative assessment of dermal exposure towards granules containing 50 % KMPS leads to exceeding of the generic concentration limit for skin irritation. Thus, a qualitative local risk assessment is performed (see Part C, Chapter 12).

3.10.2 Scenario 2.2.1: Application – Spraying

Description of Scenario 2.2.1: Application – Spraying			
Professionals spray treatment solution at low pressure onto surfaces in animal houses. The in-use concentration of KMPS is 8 g/L (0.8 % w/w). Inhalation exposure is assessed quantitatively with Spraying Model 2 (Biocides Human Health Exposure Methodology, vers.1, 2015, p. 109), which considers the exposure during mixing and loading of biocidal product as well as during application. As only low amounts of product are handled via a scoop or comparable tools and as the degree of powder formation is expected to be generally low for granules, inhalation exposure towards dust is expected to be negligible. However, the mixing and loading of KMPS granules (50 % w/w) by manual dosing was assessed separately (please refer to scenario 2.1) to account for the exposure towards the concentrated product. Dermal exposure is assessed semi-quantitatively considering the in-use concentration of KMPS. Disinfection by spraying is expected to be performed about six times a year (according to Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 109; TAB, vers. 1.2, 2016, TOX 16).			
	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.8 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 109; TAB, vers. 1.2, 2016, TOX 16)		120 min 6 times per year
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	Spraying Model 2 (Biocides Human Health Exposure Methodology, vers.1, 2015, p. 109)	Indicative value: inhalation	76 mg/m³
Tier 2	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment (RPE4)	25 % penetration

Calculations for Scenario 2.2.1

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (aerosol)**	**Estimated dermal exposure**
Scenario 2.2.1	1/none	0.61 mg/m³	0.8 % (w/w)
	2/RPE4	0.15 mg/m³	0.8 % (w/w)

Further information and considerations on scenario 2.2.1
Not relevant.

3.10.3 Scenario 2.2.2: Application – Foot dips

Description of Scenario 2.2.2: Application – Foot dips			
Professionals clean their boots at the farm entrances. First, organic matter is removed with a brush, then boots are scrubbed in the foot bath with the disinfectant solution. The in-use concentration of KMPS is 8 g/L (0.8 % w/w). According to the Biocides Human Health Exposure Methodology (vers. 1, 2015, p. 114), for the use "Disinfection foot bath for rubber boots" only dermal exposure is relevant. Dermal exposure is assessed semi-quantitatively considering the in-use concentration of KMPS.			
	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.8 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 114)		30 sec per day, 104 times a year
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no

Calculations for scenario 2.2.2

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure**	**Estimated dermal exposure**
Scenario 2.2.2	1/none	not relevant	0.8 % (w/w)

Further information and considerations on scenario 2.2.2: Not relevant.

3.10.4 Scenario 2.3.1: Post-application – Handling of empty containers

Description of Scenario 2.3.1; Post-application – Handling of empty containers
After the application, empty containers are stored and finally disposed of. Exposure during these tasks is considered negligible due to the small amounts of remaining KMPS.

3.10.5 Scenario 2.3.2: Post-Application – Disposal of treatment solution

Description of Scenario 2.3.2: Post-Application – Disposal of treatment solution			
After usage, professionals pour the treatment solution from the vessel (e.g. dipping bath, bucket, spray equipment) into the drain or into slurry/manure. The vessel and mops are rinsed with water. The maximum in-use concentration of KMPS is 8 g/L (0.8 % w/w). Inhalation exposure is assessed quantitatively with Mixing and Loading Model 7, loading liquids (HEEG opinion 1, 2008). Dermal exposure is assessed semi-quantitatively considering the in-use concentration of KMPS.			
	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.8 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1 , 2015, p. 107)		10 min per day
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	Loading liquids (Mixing and loading model 7, HEEG Opinion 1, 2008)	indicative value: inhalation	0.94 mg/m³

Calculations for scenario 2.3.2

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (aerosol)**	**Estimated dermal exposure**
Scenario 2.3.2	1/none	0.008 mg/m³	0.8 % (w/w)

Further information and considerations on scenario 2.3.2
Not relevant.

3.10.6 Combined scenarios

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Furthermore, corrosion/irritation by KMPS is an effect occurring immediately due to direct chemical reactivity. Any potential systemic toxic effect is considered secondary to local corrosion.

Thus, combined scenarios and adding up of exposure for the different scenarios/work tasks related to each intended use are not considered relevant.

Nevertheless, the relevant scenarios/work tasks for each professional use in PT3 are summarized in the following table to provide an overview on relevant work tasks per intended use.

Use #1: PT3 – Terminal disinfection of animal houses using a low pressure sprayer) (professional use)			
Scenario/ work task	**KMPS concentration**	**inhalation exposure (dust or aerosol)**	**dermal exposure**
Mixing & loading of granules – manual dosing [2.1]	50 % (w/w)	n.r. (negligible)	50 % (w/w)
Application – Spraying [2.2.1]	0.8% (w/w)	Tier-1/no PPE: 0.61 mg/m³ Tier-2/RPE4: 0.15 mg/m³	0.8 % (w/w)
Post-application – Handling of empty containers [2.3.1]	max. 50 % (w/w)	n.r. (negligible)	
Post-application – Disposal of treatment solution [2.3.2]	max. 0.8 % (w/w)	0.008 mg/m³	max. 0.8 % w/w
Use #2: PT3 – Foot dips (professional use)			
Scenario/ work task	**KMPS concentration**	**inhalation exposure (dust or aerosol)**	**dermal exposure**
Mixing & loading of granules – manual	50 % (w/w)	n.r. (negligible)	50 % (w/w)

dosing [2.1]			
Application – Foot dips [2.2.2]	0.8 % (w/w)	n.r. (negligible)	0.8 % (w/w)
Post-application – Handling of empty containers [2.3.1]	max. 50 % (w/w)	n.r. (negligible)	
Post-application – Disposal of treatment solution [2.3.2]	max. (0.8 % w/w)	0.008 mg/m³	max. 0.8 % w/w

n.r.: not relevant

3.11 NON-PROFESSIONAL EXPOSURE

No non-professional uses of KMPS as biocidal product in PT3 are foreseen.

3.12 SECONDARY EXPOSURE EXCLUDING DIETARY EXPOSURE

The intended uses in PT3 are in the professional setting only. The areas in which KMPS is applied are considered to be restricted to professional users, and it is unlikely that non-professionals are present during the application of KMPS in the intended uses.

Consequently, secondary exposure of the general public is not considered relevant.

3.12.1 Scenario 4.1: Professional bystander during spraying

Description of Scenario 4.2: Professional bystander during spraying			
Professional bystanders might be present during spraying of animal houses. These bystanders might be exposed towards KMPS aerosol by the inhalation route. Inhalation exposure is assessed quantitatively with Spraying Model 2 (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 109), which considers the exposure during mixing and loading of biocidal product as well as during application. As only low amounts of product are handled via a scoop or comparable tools and as the degree of powder formation is expected to be generally low for granules, inhalation exposure towards dust is expected to be negligible.			
	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.8 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 109; TAB, vers. 1.2, 2016, TOX 16)		120 min 6 times per year
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	Spraying Model 2 (Biocides Human Health Exposure Methodology, vers.1, 2015, p. 109)	Indicative value: inhalation	76 mg/m³
Tier 2	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment: RPE4	25 % penetration

Calculations for scenario 4.1

Summary table: secondary local exposure of professional bystanders		
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure**
Scenario 4.1	1/none	0.61 mg/m³
	2/RPE20	0.15 mg/m³

Further information and considerations on scenario 4.1
Not relevant.

3.12.2 Combined scenarios

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Furthermore, corrosion/irritation by KMPS is an effect occurring immediately due to direct chemical reactivity. Any potential systemic toxic effect is considered secondary to local corrosion.

Thus, combined scenarios for secondary exposure are not considered relevant.

PT3 – Veterinary hygiene ☐

PT4 – Food and feed area ☐

3.13 IDENTIFICATION OF MAIN PATHS OF HUMAN EXPOSURE TOWARDS ACTIVE SUBSTANCE FROM ITS USE IN BIOCIDAL PRODUCT

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	yes	no	n.a.	yes	no	no
Dermal	n.a.	yes	no	n.a.	no	no	no
Oral	n.a.	no	no	n.a.	no	no	no

n.a.: not applicable (no industrial uses foreseen)
Different applications of KMPS as a disinfectant in the intended uses within PT4 are

described below.

3.14 LIST OF SCENARIOS

Use #1: PT4 – Disinfection of food and feeding areas by wiping with mop (professional use)

Representative product: Theoretical product (50 % KMPS), formulated as granules.
General description of use: The product is delivered in 5-10 kg containers. Granules are dosed manually with a scoop or comparable tool into a bucket containing some water. The granules are dissolved by gentle manual stirring with an adequate tool, and the bucket is filled up to a mark with water. The in-use concentration of KMPS is 5 g/L.
Kitchen surfaces or objects are wiped with flat mop or cloth by professionals.
After the application, treatment solution is disposed of by pouring into the drain.

Empty containers are disposed of. Exposure during handling of empty containers is considered negligible.

Use #2: PT4 – Disinfection of food and feeding areas by manual spraying (low pressure) (professional use)

Representative product: Theoretical product (50 % KMPS), formulated as granules.

General description of use: The product is delivered in 5-10 kg containers. Granules are dosed manually with a scoop or comparable tool into the reservoir of the spray equipment containing some water. The granules are dissolved by gentle manual stirring with an adequate tool, and the reservoir is filled up to a mark with water. The in-use concentration of KMPS is 5 g/L.
The treatment solution is by low pressure sprayers. After the application, treatment solution is disposed of by pouring into the drain.

Empty containers are disposed of. Exposure during handling of empty containers is considered negligible.

Each exposure scenario is composed of different phases/processes/work tasks, which are presented in the table below.

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1. Primary exposure of industrials			
No industrial uses are foreseen.			
2. Primary exposure of professionals			
2.1	Mixing & loading of granules – manual dosing	Primary exposure of professionals during manual dosing and dissolving of KMPS granules (50 % KMPS).	professionals
2.2.1	Application - Wiping	Primary exposure of professionals during wiping of surfaces in food and feed areas with a mop.	professionals
2.2.2	Application - Spraying	Primary exposure of professionals during manual spraying of KMPS solution onto surfaces in food and feed areas at low pressure.	professionals
2.3.1	Post-application – Handling empty containers	Primary exposure during handling of empty containers.	professionals
2.3.2	Post-application – Disposal of treatment solution	Primary exposure of professionals during disposal of treatment solution (emptying of bucket, spray equipment).	professionals
3. Primary exposure of non-professionals			
No non-professional uses are foreseen.			
4. Secondary exposure			
4.1	Secondary exposure: Bystander during wiping	Secondary inhalation exposure of bystanders during surface disinfection by wiping with mop.	professional bystander
4.2	Secondary exposure: Bystander during spraying	Secondary inhalation exposure of bystanders during surface disinfection by manual spraying.	professional bystander

3.15 INDUSTRIAL EXPOSURE

No industrial use of KMPS as biocidal product in PT4 is foreseen.

3.16 PROFESSIONAL EXPOSURE

3.16.1 Scenario 2.1: Mixing and loading of KMPS granules – manual dosing

Description of Scenario 2.1: Mixing and loading of KMPS granules – manual dosing			
Professionals measure and dissolve KMPS granules (50 % KMPS) by filling the product with a scoop (or comparable tool) into a vessel (bucket, reservoir of spray equipment) containing some water. Granules are dissolved by manual stirring with an adequate tool, and the vessel is filled up with water to a mark. Inhalation exposure towards dust is expected to be negligible as only low amounts of product are handled via a scoop or comparable tools and as the degree of powder formation is expected to be generally low for granules. Dermal exposure is assessed semi-quantitatively considering the concentration of KMPS in the product.			
Tier 1	KMPS concentration granules		50 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 107)		10 min per day
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
Tier 2	PPE/RPE	Dermal protection	Coverall and gloves

Calculations for Scenario 2.1

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (dust)**	**Estimated dermal exposure**
Scenario 2.1.2	1/none	n.r. (negligible)	50 % (w/w)
	2/coverall and gloves	n.r. (negligible)	<<50 % (w/w)

Further information and considerations on scenario 2.1

The active substance KMPS as well as the theoretical product (50 % KMPS) is classified as Skin Corr. 1. The semi-quantitative assessment of dermal exposure towards granules containing 50 % KMPS leads to exceeding of the generic concentration limit for skin irritation. Thus, a qualitative local risk assessment was performed (see Part C, Chapter 12).

3.16.2 Scenario 2.2.1: Application – Wiping

Description of Scenario 2.2.1: Application – Wiping			
Professionals wipe surfaces and objects in food and feed areas with a flat mop or cloth. The in-use concentration of KMPS is 5 g/L (0.5 % w/w). Inhalation exposure is assessed quantitatively with Surface Disinfection Model 1 (Biocides Human Health Exposure Methodology, vers.1, 2015, p. 105), which considers the exposure during mixing and loading of (liquid) biocidal product as well as during application. As only low amounts of product are handled via a scoop or comparable tools and as the degree of powder formation is expected to be generally low for granules, inhalation exposure towards dust is expected to be negligible. However, the mixing and loading of KMPS granules (50 % w/w) by manual dosing was assessed separately (please refer to scenario 2.1) to account for the exposure towards the concentrated product. Dermal exposure is assessed semi-quantitatively considering the in-use concentration of KMPS.			
	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.5 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 105)		220 min per shift
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	Surface Disinfection Model 1 (Biocides Human Health Exposure Methodology, vers.1, 2015, p. 105)	indicative value: inhalation	22.9 mg/m³

Calculations for Scenario 2.2.1

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (aerosol)**	**Estimated dermal exposure**
Scenario 2.2.1	1/none	0.11 mg/m³	0.5 % (w/w)

Further information and considerations on scenario 2.2.1
Not relevant.

3.16.3 Scenario 2.2.2: Application – Spraying

Description of Scenario 2.2.2: Application – Spraying			
Professionals spray treatment solution at low pressure onto surfaces in food and feed areas. The in-use concentration of KMPS is 5 g/L (0.5 % w/w). Inhalation exposure is assessed quantitatively with Spraying Model 1 (Biocides Human Health Exposure Methodology, vers.1, 2015, p. 115), which considers the exposure during mixing and loading of biocidal product as well as during application. As only low amounts of product are handled via a scoop or comparable tools and as the degree of powder formation is expected to be generally low for granules, inhalation exposure towards dust is expected to be negligible. However, the mixing and loading of KMPS granules (50 % w/w) by manual dosing was assessed separately (please refer to scenario 2.1) to account for the exposure towards the concentrated product. Dermal exposure is assessed semi-quantitatively considering the in-use concentration of KMPS.			
	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.5 % (w/w)
	Duration and frequency of events (Recommendation 6, HEAdhoc, ver.3, p. 7)		120 min per day
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	Spraying Model 1 (Biocides Human Health Exposure Methodology, vers.1, 2015, p. 115/105)	Indicative value: inhalation	104 mg/m³
Tier 2	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment: RPE4	25 % penetration

Calculations for Scenario 2.2.2

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure**	**Estimated dermal exposure**
Scenario 2.2.2	1/none	0.52 mg/m³	0.5 % (w/w)
	2/ RPE4	0.13 mg/m³	0.5 % (w/w)

Further information and considerations on scenario 2.2.2
Not relevant.

3.16.4 Scenario 2.3.1: Post-application – Handling of empty containers

Description of Scenario 2.3.1: Post-application – Handling of empty containers
After the application, empty containers are stored and finally disposed of. Exposure during these tasks is considered negligible due to the small amounts of remaining KMPS.

3.16.5 Scenario 2.3.2: Post-Application – Disposal of treatment solution

Description of Scenario 2.3.2: Post-Application – Disposal of treatment solution

After usage, professionals pour the treatment solution from the vessel (e.g. bucket, spray equipment) into the drain. The vessel and mops are rinsed with water. The maximum in-use concentration of KMPS is 5 g/L (0.5 % w/w).

Inhalation exposure is assessed quantitatively with Mixing and Loading Model 7, loading liquids (HEEG opinion 1, 2008).

Dermal exposure is assessed semi-quantitatively considering the in-use concentration of KMPS.

	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.5 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 107)		10 min per day
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	Loading liquids (Mixing and loading model 7, HEEG Opinion 1, 2008)	indicative value: inhalation	0.94 mg/m³

Calculations for Scenario 2.3.2

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (aerosol)**	**Estimated dermal exposure**
Scenario 2.3.2	1/none	0.005 mg/m³	0.5 % (w/w)

Further information and considerations on scenario 2.3.2
Not relevant.

3.16.6 Combined scenarios

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Furthermore, corrosion/irritation by KMPS is an effect occurring immediately due to direct chemical reactivity. Any potential systemic toxic effect is considered secondary to local corrosion.

Thus, combined scenarios and adding up of exposure for the different scenarios/work tasks related to each intended use are not considered relevant.

Nevertheless, the relevant scenarios/work tasks for each professional use in PT4 are summarized in the following table to provide an overview on relevant work tasks per intended use.

Use #1: PT4 - Disinfection of food and feeding areas by wiping with mop (professional use)			
Scenario/ work task	**KMPS concentration**	**inhalation exposure (dust or aerosol)**	**dermal exposure**
Mixing & loading of granules – manual dosing [2.1]	50 % (w/w)	n.r. (negligible)	50 % (w/w)
Application – Wiping [2.2.1]	0.5 % (w/w)	Tier-1/no RPE: 0.11 mg/m³	0.5 % (w/w)
Post-application – Handling of empty containers [2.3.1]	max. 50 % (w/w)	n.r. (negligible)	
Post-application – Disposal of treatment solution [2.3.2]	max. 0.5 % (w/w)	0.005 mg/m³	max. 0.5 % (w/w)
Use #2: PT4 - Disinfection of food and feeding areas by manual spraying (low pressure) (professional use)			
Scenario/ work task	**KMPS concentration**	**inhalation exposure (dust or aerosol)**	**dermal exposure**
Mixing & loading of granules – manual dosing [2.1.2]	50 % (w/w)	n.r. (negligible)	50 % (w/w)
Application – Spraying [2.2.2]	0.5 % (w/w)	Tier-1/no PPE: 0.52 mg/m³ Tier-2/RPE4: 0.13 mg/m³	0.5 % (w/w)
Post-application – Handling of	max. 50 % (w/w)	n.r. (negligible)	

empty containers [2.3.1]			
Post-application – Disposal of treatment solution [2.3.2]	max. 0.5 % (w/w)	0.005 mg/m³	max. 0.5 % (w/w)

n.r.: not relevant

3.17 NON-PROFESSIONAL EXPOSURE

No non-professional use of KMPS as biocidal product in PT4 is foreseen.

3.18 SECONDARY EXPOSURE EXCLUDING DIETARY EXPOSURE

The intended uses in PT4 are in the professional setting only. The areas in which KMPS is applied are considered to be restricted to professional users, and it is unlikely that non-professionals are present during the application of KMPS in the intended uses.
Consequently, secondary exposure of the general public is not considered relevant.

3.18.1 Scenario 4.1: Professional bystander during wiping

Description of Scenario 4.1: Professional bystander during wiping			
Professional bystanders might be present during wiping of surfaces. This bystander might be exposed towards KMPS aerosol by the inhalation route. Inhalation exposure is assessed quantitatively with Surface Disinfection Model 1 (Biocides Human Health Exposure Methodology, vers. 1, 2015, pp. 105), which considers the exposure during mixing and loading of (liquid) biocidal product as well as during application. As only low amounts of product are handled via a scoop or comparable tools and as the degree of powder formation is expected to be generally low for granules, inhalation exposure towards dust is expected to be negligible. Dermal exposure of professional bystanders is considered not relevant due to the rapid degradation of KMPS to potassium and sulphate.			
	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.5 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 105)		220 min per shift
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	Surface Disinfection Model 1 (Biocides Human Health Exposure Methodology, vers.1, 2015, p. 105)	indicative value: inhalation	22.9 mg/m³

Calculations for scenario 4.1

Summary table: secondary local exposure of professional bystanders		
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (aerosol)**
Scenario 4.1	1/no PPE	0.11 mg/m³

Further information and considerations on scenario 4.1
Not relevant.

3.18.2 Scenario 4.2: Professional bystander during spraying

Description of Scenario 4.2: **Professional bystander during spraying**			
Professional bystanders might be present during surface disinfection by spraying. This bystander might be exposed towards KMPS aerosol by the inhalation route. Inhalation exposure is assessed quantitatively with Spraying Model 1 (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 115), which considers the exposure during mixing and loading of biocidal product as well as during application. As only low amounts of product are handled via a scoop or comparable tools and as the degree of powder formation is expected to be generally low for granules, inhalation exposure towards dust is expected to be negligible. Dermal exposure of professional bystanders is considered not relevant due to the rapid degradation of KMPS to potassium and sulphate.			
	Parameters		**Value**
Tier 1	KMPS in-use concentration		0.5 % (w/w)
	Duration and frequency of events (Recommendation 6, HEAdhoc, ver.3, p. 7)		120 min per day
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	Spraying Model 1 (Biocides Human Health Exposure Methodology, vers.1, 2015, p. 115/105)	Indicative value: inhalation	104 mg/m³
Tier 2	PPE/RPE	Respiratory protection equipment: RPE4	25 % penetration

Calculations for scenario 4.2

Summary table: secondary local exposure of professional bystanders		
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (aerosol)**
Scenario 4.2	1/none	0.52 mg/m³
Scenario 4.2	2/ RPE20	0.13 mg/m³

Further information and considerations on scenario 4.2
Not relevant.

3.18.3 Combined scenarios

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Furthermore, corrosion/irritation by KMPS is an effect occurring immediately due to direct chemical reactivity. Any potential systemic toxic effect is considered secondary to local corrosion.

Thus, combined scenarios for secondary exposure are not considered relevant.

PT4 – Food and feed area ☐

PT5 – Drinking water ☐

3.19 IDENTIFICATION OF MAIN PATHS OF HUMAN EXPOSURE TOWARDS ACTIVE SUBSTANCE FROM ITS USE IN BIOCIDAL PRODUCT

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	yes	no	n.a.	yes	no	no
Dermal	n.a.	yes	no	n.a.	no	no	no
Oral	n.a.	no	no	n.a.	no	no	no

n.a.: not applicable (no industrial uses foreseen)

Different applications of KMPS as a disinfectant in the intended uses within PT5 are described below.

3.20 LIST OF SCENARIOS

Use #1: PT5 – Continuous water sanitation by dosing the header tank or application via a dosing system (professional use)

Representative product: Theoretical product (50 % KMPS), formulated as granules.
General description of use: The product is delivered in 5-10 kg containers. Granules are dosed manually into the dose header tank or via a dosing system into the water pipe system. No exposure occurs during application. The in-use concentration of KMPS is 0.8 g/L.

After the application, empty containers are stored and finally disposed of. Exposure during handling of empty containers is considered negligible.

The treated water is used as animal drinking water.

Each exposure scenario is composed of different phases/processes/work tasks, which are presented in the table below.

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1. Primary exposure of industrials			
No industrial uses are foreseen.			
2. Primary exposure of professionals			
2.1	Mixing & loading of granules – manual placing	Primary exposure of professionals during manual placing of KMPS granules (50 % KMPS) into dose header tank or dosing system.	professionals
2.2	Application – Water disinfection	The product is added directly into the dose header tank or dosing system; no additional application phase exists.	professionals
2.3	Post-application – Handling empty containers	Primary exposure during handling of empty containers.	professionals
3. Primary exposure of non-professionals			
No non-professional uses are foreseen.			
4. Secondary exposure			
4.1	Secondary exposure: Bystander during mixing & loading of granules – manual placing	Secondary inhalation exposure of professional bystanders during manual placing of KMPS granules (50 % KMPS).	professional bystanders
4.2	Secondary exposure: Dermal contact to treated water	Secondary dermal exposure of professionals when in contact with treated animal drinking water.	professionals

3.21 INDUSTRIAL EXPOSURE

No industrial use of KMPS as biocidal product in PT5 is foreseen.

3.22 PROFESSIONAL EXPOSURE

3.22.1 Scenario 2.1: Mixing and loading of KMPS granules – manual placing

Description of Scenario 2.1: Mixing and loading of KMPS granules – manual placing			
Professionals place KMPS granules (50 % KMPS) into the dose header tank or dosing system. Inhalation exposure during mixing and loading is assessed quantitatively using the Advanced Reach Tool (ART). As the product itself is of hypothetical nature, as a Tier 1 approach, worst case assumptions and default-values were used in order to derive a worst worst-case exposure assumption. However, as Tier 3, a more realistic worst-case scenario was calculated to reflect a more probable use of the product. Dermal exposure is assessed semi-quantitatively considering the concentration of KMPS in the product.			
	Parameters		**Value**
Tier 1	***Dermal exposure***		
	KMPS concentration granules		50 % (w/w)
	Inhalation exposure		
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1 , 2015, p. 107)		10 min per day
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	ART (Advanced Reach Tool, full shift, 75th Percentile, inter-quartile confidence interval)[1.]:		0.86 mg/m³
Tier 2	PPE/RPE	Dermal protection:	Coverall and gloves
		Respiratory protection equipment: RPE10	10 % penetration
Tier 3	Is the work performed indoors, outdoors or in a spray room or downward laminar flow booth?[5]		<u>Choose site:</u> Indoors <u>What is the room size of the work area?</u> 100 m³ <u>What is the ventilation rate of the general ventilation system in the work area?</u> 3 Air changes per hour
	ART (Advanced Reach Tool, full shift, 75th Percentile, inter-quartile confidence interval)[1.]:		0.25 mg/m³
	RPE	Respiratory protection equipment: RPE4	25 % penetration

1. For details on the calculation parameters, please refer to subsection 8.4.1, Scenario 2.1.1.

Calculations for Scenario 2.1

Summary table: local exposure from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure**	**Estimated dermal exposure**
Scenario 2.1	1/none	0.860 mg/m³	50 % (w/w)
	2/RPE10	0.086 mg/m³	<<50 % (w/w)
	3/RPE4	0.063 mg/m³	<<50 % (w/w)

Further information and considerations on scenario 2.1

The active substance KMPS as well as the theoretical product (50 % KMPS) is classified as Skin Corr. 1. The semi-quantitative assessment of dermal exposure towards granules containing 50 % KMPS leads to exceeding of the generic concentration limit for skin irritation. Thus, a qualitative local risk assessment is performed (see Part C, Chapter 12).

3.22.2 Scenario 2.2: Application – Water disinfection

Description of Scenario 2.2: **Application – Water disinfection**
The product (50 % KMPS granules) is loaded directly into the dose header tank or storage system. Hence, no additional application phase for the use of KMPS for continuous water sanitation exists.

3.22.3 Scenario 2.3: Post-application – Handling of empty containers

Description of Scenario 2.3: **Post-application – Handling of empty containers**
After the application, empty containers are stored and finally disposed of. Exposure during these tasks is considered negligible due to the small amounts of remaining KMPS.

3.22.4 Combined scenarios

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Furthermore, corrosion/irritation by KMPS is an effect occurring immediately due to direct chemical reactivity. Any potential systemic toxic effect is considered secondary to local corrosion.

Thus, combined scenarios and adding up of exposure for the different scenarios/work tasks related to the intended use are not considered relevant.

However, the relevant scenarios/work tasks for the professional use in PT5 are summarized in the following table to provide an overview on relevant work tasks for the intended use.

Use #1: PT5 – Continuous water sanitation by dosing the header tank or application via a dosing system (professional use)			
Scenario/ work task	**KMPS concentration**	**inhalation exposure (dust or aerosol)**	**dermal exposure**
Mixing & loading of granules – manual placing [2.1]	50 % (w/w)	Tier-1/no RPE: 0.860 mg/m³ Tier-2/RPE10: 0.086 mg/m³ Tier-3/RPE4: 0.063 mg/m	50 % (w/w)
Application – Water disinfection [2.2]	0.08 % (w/w)	n.r. (automated dosing, no exposure)	
Post-application – Handling of empty containers [2.3]	max. 50 % (w/w)	n.r. (negligible)	

n.r.: not relevant

3.23 NON-PROFESSIONAL EXPOSURE

No non-professional use of KMPS as biocidal product in PT5 is foreseen.

3.24 SECONDARY EXPOSURE EXCLUDING DIETARY EXPOSURE

3.24.1 Scenario 4.1: Professional bystander during mixing & loading of KMPS granules – manual placing

Description of Scenario 4.1: Professional bystander during mixing & loading of KMPS granules – manual placing			
Professional bystanders might be present during manual placing of KMPS granules (50 % w/w) into the dose header tank or dosing system. This bystander might be exposed towards KMPS dust by the inhalation route. Inhalation exposure during mixing and loading is assessed quantitatively using the Advanced Reach Tool (ART). As the product itself is of hypothetical nature, as a Tier 1 approach, worst case assumptions and default-values were used in order to derive a worst worst-case exposure assumption. However, as Tier 3, a more realistic worst-case scenario was calculated to reflect a more probable use of the product. Dermal exposure of professional bystanders is considered not relevant due to the rapid degradation of KMPS to potassium and sulphate.			
	Parameters		**Value**
Tier 1	***Inhalation exposure***		
	KMPS concentration granules		50 % (w/w)
	Duration and frequency of events (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 107)		10 min per day
	PPE/RPE	Dermal protection:	no
		Respiratory protection equipment:	no
	ART (Advanced Reach Tool, full shift, 75th Percentile, inter-quartile confidence interval)[1.]:		0.86 mg/m³
Tier 2	PPE/RPE	Respiratory protection equipment: RPE10	10 % penetration
Tier 3	ART (Advanced Reach Tool, full shift, 75th Percentile, inter-quartile confidence interval)[1.]:		0.25 mg/m³
	RPE	Respiratory protection equipment: RPE4	25 % penetration

1. For details on the calculation parameters, please refer to subsection 8.4.1, Scenario 2.1.1.

Calculations for scenario 4.1

Summary table: secondary local exposure of professional bystanders		
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure (dust)**
Scenario 4.1	1/none	0.860 mg/m³
	2/RPE10	0.086 mg/m³
	3/RPE4	0.063 mg/m³

Further information and considerations on scenario 4.1
Not relevant.

3.24.2 Scenario 4.2: Dermal contact to treated water

Description of Scenario 4.2: Dermal contact to treated water		
Professionals might be dermally exposed towards KMPS when in contact with the treated animal drinking water (0.08 % w/w). Exposure towards vapour is considered negligible, as KMPS in aqueous solutions dissociates rapidly into potassium and sulphate, i.e. ionic species which do not evaporate. Exposure towards KMPS aerosols (e.g. splashes and water turbulences) is considered negligible. Thus, only dermal exposure to splashes is considered relevant, which is assessed semi-quantitatively considering the in-use concentration of KMPS.		
	Parameters	**Value**
Tier 1	KMPS concentration	0.08 % (w/w)

Calculations for scenario 4.2

Summary table: secondary local exposure of professionals		
Exposure scenario	**Tier/PPE**	**Estimated dermal exposure (aerosol)**
Scenario 4.2	Tier-1/no PPE	0.08 % (w/w)

Further information and considerations on scenario 4.2:
Not relevant.

3.24.3 Combined scenarios

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Furthermore, corrosion/irritation by KMPS is an effect occurring immediately due to direct chemical reactivity. Any potential systemic toxic effect is

considered secondary to local corrosion.

Thus, combined scenarios for secondary exposure are not considered relevant.

PT5 – Drinking water ☐

3.25 DIETARY EXPOSURE

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation. Only the breakdown products K^+ and SO_4^{2-} ions will remain to become systemically available, and are thus the only relevant species for toxicokinetic and metabolic considerations.

The breakdown products of KMPS, i.e. K^+ and SO_4^{2-} ions are chemically and biologically not further degradable because they constitute simple basic structures of inorganic nature. Furthermore, both ions are physiological essential elements of all living organisms. Detailed information on absorption, distribution and excretion of potassium ions (Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on the tolerable upper intake levels of Potassium; FAO/WHO expert consultation on Diet, Nutrition and Prevention of Chronic diseases, see Doc. No. 592-003) as well as sulphate ions (Morris and Levy, J. Toxicol.-Clin.Toxicol. 1983, 20:107-114, see Doc. No. 592-002 and EFSA Journal 2019;17(10):5868) are available, which are summarized briefly in chapter A.3.1.

As both breakdown products (i.e. potassium ions and sulphate ions) constitute physiologically essential metabolites in the human body which are efficiently excreted via the urine after oral uptake, no assessment of systemic livestock and dietary exposure is deemed necessary for intended uses in PT3, PT4 and PT5.

3.25.1 Information of non-biocidal use of the active substance

Non-biocidal uses of KMPS comprise those as a chemical substance, as registered according to the requirements of the REACH Regulation (1907/2006).

Evaluated exposure scenarios in the Chemical Safety Assessments include:

ES1 - Industrial use, Formulation of preparations
ES2 - Consumer use, Denture cleaner
ES3 - Professional use, Water treatment chemicals
ES4 - Consumer use, Water treatment chemicals
ES5 - Industrial use, Metal Treatment Products
ES6 - Industrial use, Chemical synthesis, Processing aid
ES7 - Industrial use, Chemical synthesis, Intermediate
ES8 - Industrial use, Manufacture of pulp, paper and paper products
ES9 - Industrial use, Processing aid, Water treatment chemicals
ES10 - Industrial use, Wool treatment

Registered uses include:

1 Formulation (Denture Cleaner)
2 Formulation (Recreational water: pool and spa)
3 Professional use (Recreational water: pool and spa)
4 Formulation (Chemical synthesis)
5 Industrial Use (Chemical synthesis)
6 Formulation (Metal surface treatment)
7 Industrial use (Metal surface treatment)
8 Formulation (Construction)
9 Professional use (Construction)
10 Formulation (Pulp and paper)
11 Industrial use (Pulp and paper)
12 Formulation (Wool treatment)
13 Industrial use (Wool treatment)
14 Formulation (Waste treatment)
15 Industrial use (Waste treatment)
16 Formulation (Cleaning and bleaching agents)
17 Consumer use (Denture Cleaner)
18 Consumer use (Recreational water: pool and spa)
19 Consumer use (Cleaning and bleaching agents)

PTs 2, 3, 4, 5 ☐

3.26 EXPOSURE ASSOCIATED WITH PRODUCTION, FORMULATION AND DISPOSAL OF THE BIOCIDAL PRODUCT

Production/formulation of the biocidal product
The production/formulation of the biocidal product is done in accordance with local and national occupational health and safety regulations. Typical formulation practices for biocidal products are similar to those for non-biocidal products, which are fully described in the Chemical Safety Report and exposure scenarios developed in accordance with the requirements of the REACH Regulation.

The production of biocidal products is typically done in a closed system. The raw materials are fed into a vessel equipped with a mixer, with engineering measures taken to prevent emission into the working environment. Workers use adequate PPE during processes in which exposure of workers cannot be excluded, such as sampling for quality control. The workers are trained professionals.

From the vessels the finished product is packaged prior to storage and transport. The exposure of industrial workers is therefore minimal.

Environmental exposure
In case of spillages, the biocidal product is taken up with inert material (sand, earth, chemical absorbent, etc.) and collected in dedicated properly labelled drums. It is disposed of as chemical waste in accordance with local and national laws and regulations.

Disposal of the biocidal product
The disposal of the products and solutions should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Surplus and non-recyclable products should be disposed via a licensed

waste disposal contractor. Waste packaging should be disposed or recycled.

3.27 COMBINED RESIDENTIAL SCENARIOS

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Furthermore, corrosion/irritation by KMPS is an effect occurring immediately due to direct chemical reactivity. Any potential systemic toxic effect is considered secondary to local corrosion.

Thus, combined residential scenarios are not considered relevant.

PTs 2, 3, 4, 5 ☐

4 ENVIRONMENTAL EXPOSURE ASSESSMENT

General information

Assessed PT	PT 2
Assessed scenarios	Scenario 2a: Disinfection of public swimming pools - maintenance treatment with chronic emissions - maintenance treatment with acute emissions Scenario 2b: Disinfection of private swimming pools - maintenance treatment with chronic emissions, Southern European countries (Tier 1) - maintenance treatment with chronic emissions, Northern European countries (Tier 2) - maintenance treatment with peak emissions, Southern European countries (Tier 1) - maintenance treatment with peak emissions, Northern European countries (Tier 2) Scenario 2c: Surface disinfection of industrial areas Scenario 2d: Disinfection of equipment by dipping - Disinfection of other instruments - Pre-disinfection dipping
ESD(s) used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), 2001 Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, 2011 Technical Agreements for Biocides, Environment (ENV), November 2021
Approach	Scenario 2a-2d: Average consumption
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, October 2017
Groundwater simulation	All scenarios: No
Confidential Annexes	No
Life cycle steps assessed	Scenario 2a-2d: Production: No Formulation No Use: Yes Service life: No
Remarks	-

Assessed PT	PT 3
Assessed scenarios	Scenario 3a: Terminal disinfection of animal houses by low pressure sprayers Scenario 3b: Foot dips
ESD(s) used	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, 2011
Approach	Scenario 3a and 3b: Average consumption
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, October 2017
Groundwater simulation	All scenarios: No
Confidential Annexes	No
Life cycle steps assessed	Scenario 3a and 3b: Production: No Formulation No Use: Yes Service life: No
Remarks	-

Assessed PT	PT 4
Assessed scenarios	Scenario 4: Surface disinfection of food and feed areas - Disinfection of slaughterhouses and butcheries - Disinfection of large scale catering kitchens
ESD(s) used	Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas, 2011
Approach	Scenario 4: Average consumption
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, October 2017
Groundwater simulation	All scenarios: No
Confidential Annexes	No
Lifce cycle steps assessed	Scenario 4: Production: No Formulation No Use: Yes Service life: No
Remarks	-

Assessed PT	PT 5
Assessed scenarios	Scenario 5: Disinfection of animal drinking water
ESD(s) used	Covered by the scenarios for the uses in PT3

Approach	Covered by the scenarios for the uses in PT3
Distribution in the environment	Covered by the scenarios for the uses in PT3
Groundwater simulation	Covered by the scenarios for the uses in PT3
Confidential Annexes	No
Lifce cycle steps assessed	Covered by the scenarios for the uses in PT3
Remarks	The use of KMPS in PT5 is considered covered by the scenarios for the uses in PT3.

Biocidal product specific data

There are no biocidal product specific data.

According to the Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, October 2017, emission and exposure resulting from all stages of the life cycle of a product have to be assessed in the exposure and risk assessments (so-called cradle-to-grave approach).

This includes the following life stages:

Production of the active substance
Information on emission of KMPS into the environment and its exposure during production of the KMPS containing product is provided in Section 3.26.

Formulation of the product
Information on emission of KMPS into the environment and its exposure during formulation of the KMPS containing product is provided in Section 3.26.

Application of the product
Emission of KMPS into the environment and its exposure after application of the KMPS containing product is assessed in the following section.

Service life of product
Not applicable for the described uses of KMPS containing products.

Recovery of disposal of the product
Recovery and disposal are not considered because no guidance document is available for the assessment of these lifecycle steps.

4.1 EMISSION ESTIMATION

Additional information for the emission estimation

Degradation in the sewer system

According to TAB ENV 39 (November, 2021), degradation in the sewer system should be considered for substances rapidly reacting with organic matter. KMPS rapidly decomposes by oxidising the organic compounds and has a short half-life. Thus, degradation in the sewer system can be taken into account for the emission estimation. In line with the TAB (November, 2021), calculations are performed according to the ESD for PT5 (2003), i.e. assuming an average wastewater temperature of 12 °C and a sewer residence time of 1 hour. The half-life of 0.844 hour was considered.

The amount of KMPS that is actually emitted to the STP after 1 hour residence time in the sewer system ($Elocal_{water,degr.}$) was calculated assuming first order kinetic and using the following equation:

$$Elocal_{water,degr.} = Elocal_{water} * e^{(-k_{sewer} * t_{sewer})}$$

with

$Elocal_{water,degr.}$: Local emission to STP considering degradation in the sewer system [kg/d]

$Elocal_{water}$: Local emission to sewer system as calculated in the emission scenario [kg/d]

k_{sewer}: Degradation rate constant in the sewer system [h^{-1}], i.e. $ln(2)/DT_{50}$ (DT_{50} = 0.844 hour at 12 °C; k = 0.821 h^{-1} at 12 °C)

t_{sewer}: Residence time in the sewer system [h], i.e. 1 h (ESD for PT5, 2003)

Since taking into account degradation in the sewer system is an agreed approach, only PEC and PEC/PNEC values considering degradation in the sewer system are presented for the emission pathway via STP.

Degradation in slurry/manure

When the biocidal product is used in veterinary hygiene (PT3), KMPS may be emitted via slurry/manure. Since slurry/manure is stored prior to land application, degradation of KMPS will occur due to abundant presence of organic substances. As a worst case it is assumed that the last emission to slurry/manure takes places 12 hours prior to land application. Due to the rapid degradation of KMPS in slurry/manure with half-lives at 12 °C of only 0.844 hour, there will be no relevant residues left when slurry/manure is applied to land. Only 5.3E-03 % of emitted KMPS will be left after 12 hours assuming first order degradation kinetic (e^{-k*t}). Thus, an emission via slurry/manure will lead to negligible environmental concentrations due to the very rapid degradation of KMPS. Nevertheless, for sake of completeness, calculations are presented for this emission pathway, taking degradation in slurry/manure into account according to the following equation:

$$M_{t1(degr).} = M_{t0} * e^{(-k_{slurry/manure} * t_{slurry/manure})}$$

with

$M_{t1(degr.)}$: Total amount of substance present at time 1, considering degradation in

slurry/manure [kg]

M_{t0}: Total amount of substance present at time 0 as calculated in the emission scenario [kg]

$k_{slurrry/manure}$: Degradation rate constant in slurry/manure [h^{-1}], i.e. ln(2)/DT_{50} (DT_{50} = 0.844 hour at 12 °C; k=0.821 h^{-1} at 12 °C)

$t_{slurry/manure}$: Residence time in slurry/manure [h], i.e. 12 h

4.1.1 PT2a Disinfection of public swimming pools

For the disinfection of public swimming pools, 500 mg KMPS/L is recommended as shock dosing concentration and 130 mg KMPS/L as maintenance level concentration.

KMPS is emitted into the environment via the facility drain.

Emission estimation was performed in line with the TAB ENV 51 (December, 2019) assessing emission estimation from public swimming pools. The scenario differentiates between a chronic situation (chronic emission) and acute situation (peak emission). Nevertheless, acute emissions will not occur after shock dosing concentration as shock disinfection means high dose disinfection and is applied at the beginning of a pool season or in cases where high microbial load was generated. After shock disinfection it would be not advisable to change the whole water body because – in this case – the prior shock disinfection would not have been needed. As people are only allowed to (re)use the pool when the level of disinfectant has reached the maintenance concentration, chronic emissions were not calculated for shock dosing concentration. At the end, only maintenance level concentration is assessed for both chronic and peak emissions.

The input parameters for the emission estimation as described in TAB ENV 51 (December, 2019) are listed in the table below. Only 1/3 of the pool water is released per day when considering peak emission.

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 2a: Disinfection of public swimming pools				
Water surface	$AREA_{swim}$	440	m²	TAB ENV 51
Average depth of water	$DEPTH_{swim}$	1.8	m	TAB ENV 51
Fraction released to STP	F_{rel}	1	-	TAB ENV 51
Concentration of the active substance in swimming water	$C_{proc\ continuous}$	0.130	kg/m³	Information provided by the applicant
Emission period	Ep_{acute} $Ep_{chronic}$	3 1	d	TAB ENV 51
Number of visitors per day	N_{visit}	400	-	TAB ENV 51
Water replaced by visitor	V_{repl}	0.05	m³	TAB ENV 51

Calculations for disinfection of public swimming pools

Local emissions to waste water are calculated with the following equations:

$Elocal_{water\ acute} = AREA_{swim} * DEPTH_{swim} * C_{proc} / (F_{rel} / Ep_{acute})$

$Elocal_{water\ chronic} = N_{visit} * V_{repl} * C_{proc} / Ep_{chronic}$

Resulting local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$)**	**Value**	**Unit**
Emission rate to waste water, acute emission	$Elocal_{water\ acute}$	34.32	kg/d
Emission rate to waste water, chronic emission	$Elocal_{water\ chronic}$	2.60	kg/d
Emission rate at the STP, acute emission*	$Elocal_{STP\ acute}$	15.1	kg/d
Emission rate at the STP, chronic emission*	$Elocal_{STP\ chronic}$	1.14	kg/d

* Local emission to STP was calculated taking into account degradation of KMPS in the sewer (see section 4.1).

4.1.2 PT2b Disinfection of private swimming pools

Emission estimation for the disinfection of private pools was performed in line with the document "PT02 - Private pool scenarios - Permanent installed pools" embedded under TAB ENV 44 (December, 2019) that provides emission scenarios for the disinfection of permanent installed pools connected to the STP. Two scenarios are available: chronic (releases to wastewater following the cleaning of the filtration system) and peak release estimation (releases to wastewater due to the preparation for wintering). The following has been agreed for the active substance approval:

- Tier 1: consider 550 pools (Southern Europe)
  Tier 2: consider 100 pools (Northern Europe)
  If the substance fails Tier 1, a statement would need to be provided in the CAR that for product authorisation in Southern European countries the assessment needs to be refined.
- For the approval of active substances, it is acceptable to assess only the releases to municipal STP and consider application to permanent installed pools.
- A market share of 0.5 should be used for active substances (beside substances which mode of action is based on chlorine) as first tier.
- An annual release fraction of 33 % of pool content before overwintering (peak emission) should be used in general for permanent pools.
- For the time period for peak emissions, a value of 60 days should be used. In the scenario however in order to simplify the calculations a value of 10 pools per day (for Southern countries) and 2 pools per day (for Northern countries) emitting during 60 days should be used.

For the disinfection of public swimming pools, 500 mg KMPS/L is recommended as shock dosing concentration and 130 mg KMPS/L as maintenance level concentration. Likewise

for the disinfection of public swimming pools, an emission of pool water with the shock disinfection concentration of 500 mg/L will not occur (see explanation for scenario 2a). Consequently, the emission estimation is based on the maintenance concentration of 130 mg/L.

For this reason, the four scenarios in PT2b are:

- maintenance treatment with peak emissions, Southern European countries (Tier 1)
- maintenance treatment with peak emissions, Northern European countries (Tier 2)
- maintenance treatment with chronic emissions, Southern European countries (Tier 1)
- maintenance treatment with chronic emissions, Northern European countries (Tier 2)

The input parameters for the emission estimation are listed in the tables below.

Input parameters for calculating the local emission of biocide used as disinfectant in private pool by applying a chronic emission scenario				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 2b: Disinfection of private swimming pools				
Private pool volume	V_{pool}	48	m³	TAB ENV 44
Number of private pools per STP	N_{pool} (Tier 1) N_{pool} (Tier 2)	550 100	-	TAB ENV 44
Fraction chronically released to STP	F_{chro_rel}	0.0143	-	TAB ENV 44
Application rate of active substance in the pool water	Q_{appl}	0.130	g/L	Information provided by the applicant
Market share	F_{market}	0.5	-	TAB ENV 44

Input parameters for calculating the local emission of biocide used as disinfectant in private pool by applying a peak emission scenario				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 2b: Disinfection of private swimming pools				
Private pool volume	V_{pool}	48	m³	TAB ENV 44
Number of private pools per STP	N_{pool} (Tier 1) N_{pool} (Tier 2)	10 2	-	TAB ENV 44
Fraction acutely released to STP	F_{acut_rel}	0.33	-	TAB ENV 44
Application rate of active substance in the pool water	Q_{appl}	0.130	g/L	Information provided by the applicant
Fraction of active substance released to wastewater	F_{water}	1	-	TAB ENV 44
Market share	F_{market}	0.5	-	TAB ENV 44

Calculations for disinfection of private swimming pools

Local emissions to waste water for chronic emission scenario are calculated with the following equations:

$N_{pool\_chro\_rel} = N_{pool} * F_{market}$

$Elocal_{water} = V_{pool} * N_{pool\_chro\_rel} * F_{chro\_rel} * Q_{appl}$

Local emissions to waste water for peak emission scenario are calculated with the following equations:

$N_{pool\_acut\_rel} = N_{pool} * F_{market}$

$Elocal_{water} = V_{pool} * N_{pool\_acut\_rel} * F_{water} * F_{acut\_rel} * Q_{appl}$

Resulting local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$)**	**Value**	**Unit**
Emission rate to waste water, acute emission	$Elocal_{water\ acute}$	10.30 (Tier 1) 2.06 (Tier 2)	kg/d
Emission rate to waste water, chronic emission	$Elocal_{water\ chronic}$	24.54 (Tier 1) 4.46 (Tier 2)	kg/d
Emission rate at the STP, acute emission*	$Elocal_{STP\ acute}$	4.53 (Tier 1) 0.906 (Tier 2)	kg/d
Emission rate at the STP, chronic emission*	$Elocal_{STP\ chronic}$	10.79 (Tier 1) 1.963 (Tier 2)	kg/d

* Local emission to STP was calculated taking into account degradation of KMPS in the sewer (see section 4.1).

4.1.3 PT2c Surface disinfection of industrial areas

For surface disinfection of industrial areas by wiping with mop or by manual spraying (low pressure), a dosing rate of 5 g KMPS per litre water (corresponding to a 1 % product solution of theoretical biocidal product) is recommended.

KMPS is emitted into the environment via the facility drain.

The release rate has been estimated using the ESD for PT2 (2011) - emission scenario for calculating releases of disinfectants used in industrial areas. The scenario does not differentiate between different application methods and thus, emission estimation covers disinfection by wiping and manual spraying.

The input parameters for the emission estimation are listed in the table below.

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 2c: Surface disinfection of industrial areas				
Application rate of biocidal product (spraying solution)	V_{form}	0.1	L/m^2	TAB ENV 26

Concentration of active substance in the product	C_{form}	5	g/L	Information provided by the applicant
Surface area to be disinfected	$AREA_{surface}$	1000	m^2	Default ESD PT02
Number of application per day	N_{appl}	1	d^{-1}	Default ESD PT02
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0	-	Default ESD PT02
Fraction released to waste water	F_{water}	1	-	Default ESD PT02

Calculations for disinfection of industrial areas

Local emissions to waste water (without pre-treatment) are calculated with the following equation:

$Elocal_{water} = V_{form} * C_{form} * AREA_{surface} * N_{appl} * (1 - F_{dis}) * F_{water} / 1000$

Resulting local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$)**	**Value**	**Unit**
Emission rate to waste water	$Elocal_{water}$	0.500	kg/d
Emission rate at the STP*	$Elocal_{STP}$	0.220	kg/d

* Local emission to STP was calculated taking into account degradation of KMPS in the sewer (see section 4.1).

4.1.4 PT2d Surface disinfection of equipment by dipping

For the disinfection of equipment by dipping, a dosing rate of 5 g KMPS per litre water (corresponding to a 1 % product solution of theoretical biocidal product) is recommended.

KMPS is emitted into the environment via the facility drain.

As instruments are disinfected in dipping baths, two different scenarios are considered. It is stated in the ESD PT2 (2001) that "In all out-patient departments instruments are disinfected locally in baths which are regularly disposed of into the sewer". Therefore, emission scenario for calculating the releases of disinfectants used in hospitals for disinfection of other contaminated instruments was used. The scenario assumes a default of 100 replacements of 250 kg active substance per year, with negligible volatilisation and the possibility to correct for degradation. Moreover, disinfection of medical equipment by dipping is described in TAB ENV 45 (December, 2019). This scenario has thus also been used in the following assessment, using the default values agreed at WG-I-2015.

Surface disinfection of equipment by dipping - other instruments

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 2d: Surface disinfection of equipment by dipping - other instruments				
Amount of active substance	$Qyear_{disinf}$	250	kg/y	Default ESD PT02
Emission days, i.e. replacements	$T_{emission}$	100	y^{-1}	Default ESD PT02
Rate constant for chemical conversion	$kdeg_{disinf}$	0.11	day^{-1}	Hydrolysis rate, based on a DT_{50} of 145 h at pH 7 and 20 °C
Average time a disinfection solution is in use	T_{repl}	4	day	Default ESD PT02

Calculations for disinfection of equipment

Local emissions to waste water for disinfection of equipment by dipping are calculated with the following equation:

T_{repl} = INT (365 / $T_{emission}$ + 0.5)

$Elocal_{water}$ (= Q_{repl}) = $Qyear_{disinf}$ / $T_{emission}$ * e $^{-kdegdisinf * Trepl}$

Resulting local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$)**	**Value**	**Unit**
Emission rate to waste water	$Elocal_{water}$	1.61	kg/d
Emission rate at the STP*	$Elocal_{STP}$	0.708	kg/d

* Local emission to STP was calculated taking into account degradation of KMPS in the sewer (see section 4.1).

The local emission to the sewer per day of replacement of the dip solution was calculated to be 1.61 kg/d (intermittent release: 100 replacements per year). Decomposition of KMPS in the dipping solution during disinfection was taken into account by considering the decomposition rate obtained in the hydrolysis study ([redacted] (2007) Doc. No. 119-003, A7.1.1.1.1/01). However, by selecting the decomposition rate obtained in the hydrolysis study (pH 7, 20 °C), a worst case approach was chosen: The hydrolysis study was conducted under sterile conditions. Therefore, decomposition of KMPS in the hydrolysis test solutions was only due to hydrolysis and/or disproportionation. Conditions in the dipping basin, however, are not sterile because instruments which are soiled with organic contaminants are dipped into the solution. A simulation test investigating the depletion of KMPS in synthetic pool water ([redacted] (2007) Doc. No. 711-002, A7.1.1.1.1/02) indicated that the decomposition of KMPS is much faster in the presence of organic contaminants than under clean conditions. In the presence of organic contaminants KMPS is consumed in oxidation reactions. The DT_{50} value in contaminated synthetic pool water was determined to be approximately 3 hours at 29 °C. Therefore, it can be concluded that the decomposition in the dipping solution is much faster than in sterile hydrolysis solution resulting in a lower $Elocal_{water}$.

Surface disinfection of equipment by dipping - pre-disinfection dipping

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 2d: Surface disinfection of equipment by dipping - pre-disinfection dipping				
Working concentration of active ingredient	C_{disinf}	5.00E+03	mg/L	Information provided by the applicant
Volume of solution in dipping bath	$Q_{dipping\_bath}$	10	L	TAB ENV 26
Maximum number of dipping bath per day	$N_{dipping\_bath}$	30	day^{-1}	TAB ENV 26
Fraction released to wastewater	F_{water}	1	-	TAB ENV 26

Calculations for disinfection of equipment

Local emissions to waste water for disinfection of equipment by dipping are calculated with the following equation:

$Elocal_{water} = C_{disinf} * Q_{dipping\_bath} * F_{water} * N_{dipping\_bath} * 10^{-6}$

Resulting local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$)**	**Value**	**Unit**
Emission rate to waste water	$Elocal_{water}$	1.50	kg/d
Emission rate at the STP*	$Elocal_{STP}$	0.660	kg/d

* Local emission to STP was calculated taking into account degradation of KMPS in the sewer (see section 4.1).

4.1.5 PT3a Terminal disinfection of animal houses

For the terminal disinfection of animal houses, the active substance concentration in the product of 8 g KMPS/L and application rate of 300 mL/m² is recommended.

KMPS can be theoretically emitted into the environment via STP into surface water and sediment and via application of slurry/manure or sewage sludge to soil.

The local emission was calculated using the ESD for PT3 (2011) - Emission scenario for calculating the release of disinfectants used for disinfection of animal housings by using the calculation sheet provided by ECHA. The following worst case scenarios were identified:

- turkeys (subcategory 16) for emission to standard STP,
- ducks (subcategory 17) for emission via slurry/manure and application onto arable land, and
- ducks (subcategory 17) for emission via slurry/manure and application onto grassland.

The estimated emission rates were used as input parameter for the exposure assessment.

Degradation of KMPS during disinfection was not taken into account.

Emission to waste water

The input parameters provided for animal subcategory 16 (turkeys) as worst case for the emission to waste water and the resulting calculation of $Elocal_{waste\ water}$ are listed in the tables below. Default values and values chosen from the pick lists for the emission estimation were taken from the ESD for PT3 (2011), Tables 1a, 7, 8, 9 and 10.

Disinfection of turkey housings is performed after each fattening cycle (182 d), when the animals have been housed out, the litter/manure has been removed and the housing cleaned.

It should be noted that farms are not always connected to a municipal STP but have their own on-site STP. These on-site STPs are not able to cope with such amounts of chemicals which results from their use as biocides in animal housings. Therefore, in case of an on-site STP the only possible emission pathway is via slurry/manure.

Input parameters for calculating the local emission to STP				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 3a: Terminal disinfection of animal houses				
Type of housing/manure storage	cat-subcat (i1)	16	-	ESD PT3, Table 7
Type of biocide	bioctype (i2)	1	-	ESD PT3, Table 7
Type of application	appway (i3)	1	-	ESD PT3, Table 7
Relevant emission stream	stream (i4)	2	-	ESD PT3, Table 7
Area of the housing for application	$AREA_{i1}$	8040	m^2	ESD PT3, Table 8
Content of active ingredient in formulation (product)	Fbioc	8	g/L	Information provided by the applicant
Amount of (undiluted) product prescribed to be used per m^2	$Vprod_{i1,i2,i3}$	0.3	L/m^2	Information provided by the applicant
Dilution factor (for preparation of the working solution from the formulation (product))	F_{dil}	1	-	Information provided by the applicant
Fraction of active ingredient released to STP	$F_{stp\_i1,i2,i3,i4}$	0.2	-	ESD PT3, Table 10
Fraction of active ingredient released to air	F_{air}	0	-	ESD PT3, Table 1a
Number of disinfectant applications in one year	Napp-bioc	2	-	ESD PT3, Table 9
Amount of active ingredient to be used for one application	$Qai\text{-}prescr_{i1,i2,i3}$	19.3	kg	ESD PT3, Table 1c (intermediate calculations)

Calculations of emission to waste water for disinfection of animal houses

Local emissions to waste water for disinfection of animal houses are calculated with the following equations:

$Qai\text{-}prescr_{i1,i2,i3} = 10^{-3} * Fbioc * Vprod_{i1,i2,i3} * F_{dil} * AREA_{i1}$

$Qai\text{-}stp_{i1,i2,i3,i4} = Elocal_{waste\ water} = F_{stp\_i1,i2,i3,i4} * Qai\text{-}prescr_{i1,i2,i3}$

Resulting local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$)**	**Value**	**Unit**
Emission from one application to a standard STP or an on-site waste water treatment plant	$Qai\text{-}stp_{i1,i2,i3,i4} = Elocal_{waste\ water}$	3.86	kg/d
Local emission to STP*	$Elocal_{STP}$	1.70	kg/d

* Local emission to STP was calculated taking into account degradation of KMPS in the sewer (see section 4.1).

Emission to arable land via slurry/manure application

The input parameters for animal subcategory 17 (ducks) as worst case for emission to arable land via slurry/manure application are listed in the tables below. Default values and values chosen from the pick lists for the emission estimation were taken from the ESD for PT3 (2011), Tables 7, 8, 9, 10, 11, 12 and 13.

Disinfection of duck housings is performed after each fattening cycle (28 d), after the animals have been housed out and the housing has been cleaned.

Input parameters for calculating the local emission to arable land via slurry/manure application				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 3a: Terminal disinfection of animal houses				
Type of housing/manure storage	cat-subcat (i1)	17	-	ESD PT3, Table 7
Type of biocide	bioctype (i2)	1	-	ESD PT3, Table 7
Type of application	appway (i3)	1	-	ESD PT3, Table 7
Relevant emission stream	stream (i4)	1	-	ESD PT3, Table 7
Area of the housing for application	$AREA_{i1}$	4880	m^2	ESD PT3, Table 8
Content of active ingredient in formulation (product)	Fbioc	8	g/L	Information provided by the applicant
Amount of (undiluted) product prescribed to be used per m^2	$Vprod_{i1,i2,i3}$	0.3	L/m^2	Information provided by the applicant
Dilution factor (for preparation of the working solution from the formulation (product))	F_{dil}	1	-	Information provided by the applicant
Fraction of active ingredient	$F_{slurry/manure\_i1,i2,i3,i4}$	0.5	-	TAB ENV 168

released to slurry/manure				
Fraction of active ingredient released to air	F_{air}	0	-	ESD PT3, Table 7
Number of disinfectant applications in one year	Napp-bioc	13	-	ESD PT3, Table 9
Biocide application interval	Tbioc-int	28	d	ESD PT3, Table 9
Number of manure applications for arable land	Nlapp-arab	1	-	ESD PT3, Table 1a
Manure application time interval for arable land	Tar-int,10	365	d	Addendum to ESD PT 18 stables (TAB ENV 212)
Number of animals in housing for every relevant category/subcategory i1	$Nanimal_{i1}$	10000	-	ESD PT3, Table 8
Amount of nitrogen per animal for every relevant category/subcategory i1	$Qnitrog_{i1}$	0.00274	kg/d	ESD PT3, Table 11
Nitrogen immission standard for one year on arable land	$Q_{N,arable\_land}$	170	kg/ha	ESD PT3, Table 13
Mixing depth with soil, arable land	$DEPTH_{arable\_land}$	0.20	m	ESD PT3, Table 1a
Density of wet bulk soil	$RHOsoil_{wet}$	1700	kg/m^3	ESD PT3, Table 1a

Calculations of emission to slurry/manure for disinfection of animal housing

Parameter	**Symbol**	**Value**	**Unit**	**Origin**
Intermediate calculations				
Number of biocide applications during storage period for application on arable land	$Napp\text{-}manure_{ar}$	1	-	Addendum to ESD PT 18 stables (TAB ENV 212)
Amount of active ingredient to be used for one application	$Qai\text{-}prescr_{i1,i2,i3}$	11.71	kg	O
$Qai\text{-}prescr_{i1,i2,i3} = 10^{-3} * Fbioc * Vprod_{i1,i2,i3} * F_{dil} * AREA_{i1}$				
Amount of active ingredient in slurry/manure after one application	$Qai_{manure/slurry}$	5.86	kg	O
$Qai_{manure/slurry} = F_{slurry/manure\_i1,i2,i3,i4} * Qai\text{-}prescr_{i1,i2,i3}$				
Amount of active substance in manure/slurry after the relevant number of biocidal product applications for the manure application to arable land	$Qai_{manure/slurry\text{-}ar}$	5.86	kg	O
$Qai_{manure/slurry\text{-}ar} = Qai_{manure/slurry} * Napp\text{-}manure_{ar}$				
Amount of active ingredient in slurry/manure after the last biocide application before the slurry/manure application to arable land considering degradation in slurry/manure	$Qai_{manure/slurry\text{-}ar\text{-}deg}$	3.07E-04	kg	O (see section "Degradation in slurry/manure")

$Qai_{manure/slurry\text{-}ar\text{-}deg} = Qai_{manure/slurry\text{-}ar} * EXP^{(-k \cdot t1)}$				
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to arable land	$Qnitrog\text{-}arab_{i1,i4}$	767.2	kg	Addendum to ESD PT 18 stables (TAB ENV 212)
$Qnitrog\text{-}arab_{i1,i4} = Nanimal_{i1} * Qnitrog_{i1} * Tbioc\text{-}int$				

Resulting local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$)**	**Value**	**Unit**
Local emission to soil	Amount of active ingredient in slurry/manure after the last biocide application before the slurry/manure application to arable land considering degradation in slurry/manure ($Qai_{manure/slurry\text{-}ar\text{-}deg}$)	3.07E-04	kg

Emission to grassland via slurry (liquid manure) application

The input parameters for animal subcategory 17 (ducks) as worst case for emission to grassland via slurry/manure application are listed in the tables below. Default values and values chosen from the pick lists for the emission estimation were taken from the ESD for PT3 (2011), Tables 7, 8, 9, 10, 11, 12 and 13.

Disinfection of duck housings is performed after each fattening cycle (28 d), after the animals have been housed out and the housing has been cleaned.

Input parameters for calculating the local emission to grassland via slurry/manure application				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 3a: Terminal disinfection of animal houses				
Type of housing/manure storage	cat-subcat (i1)	17	-	ESD PT3, Table 7
Type of biocide	bioctype (i2)	1	-	ESD PT3, Table 7
Type of application	appway (i3)	1	-	ESD PT3, Table 7
Relevant emission stream	stream (i4)	3	-	ESD PT3, Table 7
Area of the housing for application	$AREA_{i1}$	4880	m^2	ESD PT3, Table 8
Content of active ingredient in formulation (product)	Fbioc	8	g/L	Information provided by the applicant
Amount of (undiluted) product prescribed to be used per m^2	$Vprod_{i1,i2,i3}$	0.3	L/m^2	Information provided by the applicant
Dilution factor (for preparation of the working solution from the formulation (product))	F_{dil}	1	-	Information provided by the applicant
Fraction of active ingredient released to slurry/manure	$F_{slurry/manure\_i1,i2,i3,i4}$	0.5	-	TAB ENV 168

Fraction of active ingredient released to air	F_{air}	0	-	ESD PT3, Table 7
Number of disinfectant applications in one year	Napp-bioc	13	-	ESD PT3, Table 9
Biocide application interval	Tbioc-int	28	d	ESD PT3, Table 9
Number of manure applications for grassland	Nlapp-grass	4	-	ESD PT3, Table 1a
Manure application time interval for grassland	Tgr-int	53	d	ESD PT3, Table 12
Number of animals in housing for every relevant category/subcategory i1	$Nanimal_{i1}$	10000	-	ESD PT3, Table 8
Amount of nitrogen per animal for every relevant category/subcategory i1	$Qnitrog_{i1}$	0.00274	kg/d	ESD PT3, Table 11
Nitrogen immission standard for one year on grassland	$Q_{N,grassland}$	170	kg/ha	ESD PT3, Table 13
Mixing depth with soil, grassland	$DEPTH_{grassland}$	0.05	m	ESD PT3, Table 1a
Density of wet bulk soil	$RHOsoil_{wet}$	1700	kg/m^3	ESD PT3, Table 1a

Calculations of emission to slurry/manure for disinfection of animal housing

Parameter	**Symbol**	**Value**	**Unit**	**Origin**
Intermediate calculations				
Number of biocide applications during storage period for application on grassland	$Napp\text{-}manure_{gr}$	1.89	-	O, Addendum to ESD PT 18 stables (TAB ENV 212)
$Napp\text{-}manure_{gr}$ 1. $Napp\text{-}manure_{gr}$ = Tgr-int / Tbioc-int 2. If Nlapp-grass * $Napp\text{-}manure_{gr}$ > Napp-bioc, then $Napp\text{-}manure_{gr}$ = Napp-bioc / Nlapp-grass				
Amount of active ingredient to be used for one application	$Qai\text{-}prescr_{i1,i2,i3}$	11.71	kg	O
$Qai\text{-}prescr_{i1,i2,i3} = 10^{-3} * Fbioc * Vprod_{i1,i2,i3} * F_{dil} * AREA_{i1}$				
Amount of active ingredient in slurry/manure after one application	$Qai_{manure/slurry}$	5.86	kg	O
$Qai_{manure/slurry} = F_{slurry/manure\_i1,i2,i3,i4} * Qai\text{-}prescr_{i1,i2,i3}$				
Amount of active substance in manure/slurry after the relevant number of biocidal product applications for the manure application to grassland	$Qai_{manure/slurry\text{-}gr}$	11.08	kg	O
$Qai_{manure/slurry\text{-}gr} = Qai_{manure/slurry} * Napp\text{-}manure_{gr}$				

Amount of active ingredient in slurry/manure after the last biocide application before the slurry/manure application to grassland considering degradation in slurry/manure	$Qai_{manure/slurry-gr-deg}$	5.82E-04	kg	O (see section "Degradation in slurry/manure")
$Qai_{manure/slurry-gr-deg} = Qai_{manure/slurry-gr} * EXP^{(-k \cdot t1)}$				
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland	$Qnitrog\text{-}grass_{i1,i4}$	1452.2	kg	O
$Qnitrog\text{-}grass_{i1,i4} = Nanimal_{i1} * Qnitrog_{i1} * Tgr\text{-}int$				

Resulting local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$)**	**Value**	**Unit**
Local emission to soil	Amount of active ingredient in slurry/manure after the last biocide application before the slurry/manure application to grassland considering degradation in slurry/manure ($Qai_{manure/slurry-gr-deg}$)	5.82E-04	kg

4.1.6 PT3b Disinfection of footwear

For the disinfection of footwear, a dilution of the theoretical product is used containing 8 g KMPS/L.

KMPS can be theoretically emitted into the environment via STP into surface water and sediment and via application of slurry/manure or sewage sludge to soil.

The local emission was calculated using the ESD for PT3 (2011) - Emission scenario for calculating the release of disinfectants used for veterinary hygiene: footwear by using the calculation sheet provided by ECHA. The worst case for emission to STP is the removal of one tub filling per day, independent from housing type and animal category. Veal calves (subcategory 3) was identified as worst case for emission via slurry/manure.

Degradation of KMPS during disinfection was not taken into account.

Emission to waste water

The input parameters provided for the emission to waste water and the resulting calculation of $Elocal_{waste\ water}$ are listed in the tables below. Default values and values chosen from the pick lists for the emission estimation were taken from the ESD for PT3 (2011), Tables 4a, 7 and 10.
It should be noted that farms are not always connected to a municipal STP but have their own on-site STP. These on-site STPs are not able to cope with such amounts of chemicals

which results from their use as biocides in animal housings. Therefore, in case of an on-site STP the only possible emission pathway is via slurry/manure.

Input parameters for calculating the local emission to STP				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 3b: Disinfection of footwear				
Type of housing/manure storage	cat-subcat (i1)	1 - 18	-	ESD PT3, Table 7
Type of biocide	bioctype (i2)	1	-	ESD PT3, Table 7
Type of application	appway (i3)	3	-	ESD PT3, Table 7
Relevant emission stream	stream (i4)	2	-	ESD PT3, Table 7
Volume of the reservoir (tub)	$Vreserv_{i1,i2,i3}$	10	L	ESD PT3, Table 4a
Content of active ingredient in formulation (product)	Fbioc	8	g/L	Information provided by the applicant
Dilution factor (for preparation of the working solution from the formulation (product))	F_{dil}	1	-	Information provided by the applicant
Fraction of active ingredient released to STP	$F_{stp\_i1,i2,i3,i4}$	1	-	ESD PT3, Table 4a
Number of applications (tub fillings) in one year	Napp-bioc	365	-	ESD PT3, Table 4a
Time interval between two applications (tub fillings)	Tbioc-int	1	d	ESD PT3, Table 4a
Amount of active ingredient to be used for one application	$Qai\text{-}prescr_{i1,i2,i3}$	0.08	kg	ESD PT3, Table 4c (intermediate calculations)

Calculations of emission to waste water for disinfection of footwear

Local emissions to waste water for disinfection of footwear are calculated with the following equations:

$Qai\text{-}prescr_{i1,i2,i3} = 10^{-3} * Fbioc * Vreserv_{i1,i2,i3} * F_{dil}$

$Qai\text{-}stp_{i1,i2,i3,i4} = Elocal_{waste\ water} = F_{stp\_i1,i2,i3,i4} * Qai\text{-}prescr_{i1,i2,i3}$

Resulting local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$)**	**Value**	**Unit**
Emission from one application to a standard STP or an on-site waste water treatment plant	$Qai\text{-}stp_{i1,i2,i3,i4} = Elocal_{waste\ water}$	0.080	kg/d
Local emission to STP*	$Elocal_{STP}$	3.52E-02	kg/d

* Local emission to STP was calculated taking into account degradation of KMPS in the sewer (see Section 4.1).

Emission to slurry/manure

The input parameters for animal subcategory 3 (veal calves) as worst case for for the emission to slurry are listed in the table below. Default values and values chosen from the pick lists for the emission estimation were taken from the ESD for PT3 (2011), Tables 4a, 7, 8, 11, 12 and 13.

Input parameters for calculating the local emission to grassland and arable land via slurry/manure application				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 3b: Disinfection of footwear				
Type of housing/manure storage	cat-subcat (i1)	3	-	ESD PT3, Table 7
Type of biocide	bioctype (i2)	1	-	ESD PT3, Table 7
Type of application	appway (i3)	3	-	ESD PT3, Table 7
Relevant emission stream	stream (i4)	3	-	ESD PT3, Table 7
Volume of the reservoir (tub)	$Vreserv_{i1,i2,i3}$	10	L	ESD PT3, Table 4a
Content of active ingredient in formulation (product)	Fbioc	8	g/L	Information provided by the applicant
Dilution factor (for preparation of the working solution from the formulation (product))	F_{dil}	1	-	Information provided by the applicant
Fraction of active ingredient released to slurry/manure	$F_{slurry/manure\_i1,i2,i3,i4}$	1	-	ESD PT3, Table 4a
Number of disinfectant applications in one year	Napp-bioc	365	-	ESD PT3, Table 4a
Biocide application interval	Tbioc-int	1	d	ESD PT3, Table 4a
Number of manure applications for grassland	Nlapp-grass	4	-	ESD PT3, Table 4a
Number of manure applications for arable land	Nlapp-arab	1	-	ESD PT3, Table 4a
Manure application time interval for grassland	Tgr-int	53	d	ESD PT3, Table 12
Manure application time interval for arable land	Tar-int,10	365	d	Addendum to ESD PT 18 stables (TAB ENV 212)
Number of animals in housing for every relevant category/subcategory i1	$Nanimal_{i1}$	80	-	ESD PT3, Table 8
Amount of nitrogen per animal for every relevant category/subcategory i1	$Qnitrog_{i1}$	0.02382	kg/d	ESD PT3, Table 11
Nitrogen immission standard for one year on	$Q_{N,grassland}$	170	kg/ha	ESD PT3, Table 13

grassland				
Nitrogen immission standard for one year on arable land	$Q_{N,arable\_land}$	170	kg/ha	ESD PT3, Table 13
Mixing depth with soil, grassland	$DEPTH_{grassland}$	0.05	m	ESD PT3, Table 4a
Mixing depth with soil, arable land	$DEPTH_{arable\_land}$	0.20	m	ESD PT3, Table 4a
Density of wet bulk soil	$RHOsoil_{wet}$	1700	kg/m^3	ESD PT3, Table 4a

Calculations of emission to slurry/manure for disinfection of footwear

Parameter	**Symbol**	**Value**	**Unit**	**Origin**
Intermediate calculations				
Number of biocide applications during manure storage period for application on arable land	$Napp\text{-}manure_{ar}$	1	-	O, Addendum to ESD PT 18 stables (TAB ENV 212)
Number of biocide applications during manure storage period for application on grassland	$Napp\text{-}manure_{gr}$	53	-	O, Addendum to ESD PT 18 stables (TAB ENV 212)
$Napp\text{-}manure_{gr}$ 1. $Napp\text{-}manure_{gr}$ = Tgr-int / Tbioc-int 2. If Nlapp-grass * $Napp\text{-}manure_{gr}$ > Napp-bioc, then $Napp\text{-}manure_{gr}$ = Napp-bioc / Nlapp-grass				
Amount of active ingredient to be used for one application	$Qai\text{-}prescr_{i1,i2,i3}$	0.08	kg	O
$Qai\text{-}prescr_{i1,i2,i3} = 10^{-3} * Fbioc * Vreserv_{i1,i2,i3} * F_{dil}$				
Amount of active ingredient in slurry/manure after one application	$Qai_{manure/slurry}$	0.08	kg	O
$Qai_{manure/slurry} = F_{slurry/manure\_i1,i2,i3,i4} * Qai\text{-}prescr_{i1,i2,i3}$				
Amount of active substance in manure/slurry after the relevant number of biocidal product applications for the manure application to grassland	$Qai_{manure/slurry\text{-}gr}$	4.24	kg	O
$Qai_{manure/slurry\text{-}gr} = Qai_{manure/slurry} * Napp\text{-}manure_{gr}$				
Amount of active substance in manure/slurry after the relevant number of biocidal product applications for the manure application to arable land	$Qai_{manure/slurry\text{-}ar}$	0.08	kg	O
$Qai_{manure/slurry\text{-}ar} = Qai_{manure/slurry} * Napp\text{-}manure_{ar}$				
Amount of active ingredient in slurry/manure after the	$Qai_{manure/slurry\text{-}gr\text{-}deg}$	2.22E-04	kg	O (see section "Degradation in

last biocide application before the slurry/manure application to grassland considering degradation in slurry/manure				slurry/manure")
$Qai_{manure/slurry-gr-deg} = Qai_{manure/slurry-gr} * EXP^{(-k \cdot t1)}$				
Amount of active ingredient in slurry/manure after the last biocide application before the slurry/manure application to arable land considering degradation in slurry/manure	$Qai_{manure/slurry-ar-deg}$	4.20E-06	kg	O (see section "Degradation in slurry/manure")
$Qai_{manure/slurry-ar-deg} = Qai_{manure/slurry-ar} * EXP^{(-k \cdot t1)}$				
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland	$Qnitrog\text{-}grass_{i1,i4}$	101	kg	O
$Qnitrog\text{-}grass_{i1,i4} = Nanimal_{i1} * Qnitrog_{i1} * Tgr\text{-}int$				
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to arable land	$Qnitrog\text{-}arab_{i1,i4}$	1.9	kg	Addendum to ESD PT 18 stables (TAB ENV 212)
$Qnitrog\text{-}arab_{i1,i4} = Nanimal_{i1} * Qnitrog_{i1} * Tbioc\text{-}int$				

Resulting local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$)**	**Value**	**Unit**
Local emission to soil	Amount of active ingredient in slurry/manure after the last biocide application before the slurry/manure application to grassland considering degradation in slurry/manure ($Qai_{manure/slurry-gr-deg}$)	2.22E-04	kg
	Amount of active ingredient in slurry/manure after the last biocide application before the slurry/manure application to arable land considering degradation in slurry/manure ($Qai_{manure/slurry-ar-deg}$)	4.20E-06	kg

4.1.7 PT4 Surface disinfection of food and feed areas

For the disinfection of food and feeding areas by spraying or wiping, the use of a 1 % solution of the theoretical product is recommended corresponding to a KMPS concentration of 5 g/L in the spraying solution.

The uses that are attributed to PT 4 concern disinfection of food and feed areas e.g. surfaces in kitchens

- by spraying
- by wiping with mop and bucket (disinfection of floors)
- by wiping with cloth and bucket (disinfection of other surface than floors)

KMPS is emitted into the environment via the facility drain.

A scenario for the assessment of applications in industrial kitchens and meat processing industry is available in the ESD PT4 (2011). The amount of KMPS released after surface disinfection in e.g. kitchen was estimated on the basis of the amount of KMPS applied per m² of the surface area to be disinfected. Residues of the disinfectant are released into the facility drain with rinsing water.

The input parameters for the emission estimation and the resulting calculation of the local emission to wastewater ($Elocal_{water}$) are given in the tables below. Default values for the emission estimation were taken from the ESD for PT4, Table 10 on page 24.

Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 4: Surface disinfection of food and feed areas				
Application rate of the biocidal product	$Qb.p._{appl}$	0.1	L/m²	TAB ENV 26
Concentration of the active substance in biocidal product	Cform	5	g/L	Information provided by the applicant
Application rate of the active substance	$Qa.i._{appl}$	0.5	g/m²	$Qb.p._{appl}$ * Cform
Surface area to be disinfected Slaughterhouses Large scale catering kitchens	$AREA_{surface}$	 10000 2000	m²	Default ESD PT04
Number of applications per day	N_{appl}	1	d^{-1}	Default ESD PT04
Fraction of substance disintegrated during or after application (before release to the sewer system)	F_{dis}	0	-	Default ESD PT04
Fraction of substance eliminated due to onsite pre-treatment of wastewater	F_{elim}	0	-	Default ESD PT04
Fraction released to wastewater	F_{water}	1	-	Default ESD PT04

Calculations for surface disinfection of food and feed areas

Local emissions to wastewater for disinfection of food and feed areas are calculated with the following equation:

$Elocal_{water} = Qa.i._{appl} * AREA_{surface} * N_{appl} * (1 - F_{dis}) * (1 – F_{elim}) * F_{water} / 1000$

Resulting local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$)**	**Value**	**Unit**
Emission rate to waste water, slaughterhouses	$Elocal_{water}$	5.00	kg/d
Emission rate to waste water, large scale catering kitchens	$Elocal_{water}$	1.00	kg/d
Emission rate at the STP, slaughterhouses and butcheries*	$Elocal_{STP}$	2.20	kg/d
Emission rate at the STP, large scale catering kitchens*	$Elocal_{STP}$	0.44	kg/d

* Local emission to STP was calculated taking into account degradation of KMPS in the sewer (see section 4.1).

4.1.8 PT5 Disinfection of animal drinking water

The only use of KMPS attributed to PT5 is disinfection of animal drinking water. For disinfection of animal drinking water or water systems, the use of a 0.08 % solution is recommended (corresponding to 0.8 g/L KMPS). After the intake of disinfected drinking water by animals, KMPS is most likely be metabolised in the animal's body due to its rapid reaction with organic substances. Thus, it can be expected that no residues of KMPS will be excreted. However, if residues of KMPS are excreted, they would be released into the manure/slurry where a fast reaction with the organic material would occur.

The risk assessment for the use of KMPS in PT5 is therefore covered by the risk assessments performed for the uses in PT3. Please refer to Section 4.1.5 and 4.1.6 for PT3.

4.2 FATE AND DISTRIBUTION IN EXPOSED ENVIRONMENTAL COMPARTMENTS

Identification of relevant receiving compartments based on the exposure pathway								
Scenario	**Fresh-water**	**Sedi-ment**	**Sea-water**	**Seawater sediment**	**STP**	**Air**	**Soil**	**Ground-water**
PT2a, public swimming pool, chronic release	+	+	-	-	+	+	+	+
PT2a, public swimming pool, acute release	+	+	-	-	+	+	+	+
PT2b, private swimming pools, chronic release, S-EU	+	+	-	-	+	+	+	+
PT2b, private swimming pools, chronic release, N-EU	+	+	-	-	+	+	+	+
PT2b, private swimming pools, acute release, S-EU	+	+	-	-	+	+	+	+
PT2b, private swimming pools, acute release, N-EU	+	+	-	-	+	+	+	+
PT2c, surface disinfection of industrial areas	+	+	-	-	+	+	+	+
PT2d, disinfection of equipment by dipping, other instruments	+	+	-	-	+	+	+	+
PT2d, disinfection of equipment by dipping, pre-disinfection dipping	+	+	-	-	+	+	+	+
PT3a, disinfection of animal housing, STP	+	+	-	-	+	+	+	+
PT3a, disinfection of animal housing, slurry/manure // arable land	-	-	-	-	-	-	+	+
PT3a, disinfection of animal housing, slurry/manure // grassland	-	-	-	-	-	-	+	+
PT3b, disinfection of footwear, STP	+	+	-	-	+	+	+	+
PT3b, disinfection of footwear, slurry/manure // arable land	-	-	-	-	-	-	+	+
PT3b, disinfection of footwear, slurry/manure // grassland	-	-	-	-	-	-	+	+
PT4a, disinfection of slaughterhouses and butcheries	+	+	-	-	+	+	+	+
PT4b, disinfection of large catering kitchens	+	+	-	-	+	+	+	+
PT5, disinfection of animal drinking water	+	+	-	-	+	+	+	+

In the study on the "Depletion of Potassium Monopersulfate in Synthetic Pool Water" ([redacted] (2007) Doc. No. 711-002, A7.1.1.1.1/02), it was shown that the decomposition of KMPS in water is very dependent on the presence of oxidizable contaminants. The addition of a 'body fluid analog' to the synthetic pool water used in this laboratory test reduced the half-life for decomposition of KMPS from ca. 120 hours (synthetic pool water without 'body fluid analog') to ca. 3 hours. This is explained by the consumption of $KHSO_5$ in many different oxidation reactions with reduced amine substrate components of the added 'body fluid analog', according to the general reaction:

$KHSO_5 + X \rightarrow KHSO_4 + X = O$

It can be assumed that KMPS is degraded at similar rates in natural waters, such as pond and river water. The higher the concentration of oxidizable organic substrate is in the water, the faster KMPS will be degraded. Such oxidizing reactions can also occur in soil due to the high content of oxidizable agents in soil.

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	614.76	g/mol	
Vapour pressure (at 20°C)	$1.2 \cdot 10^{-4}$	Pa	
Water solubility (at 20°C)	$3.64 \cdot 10^{5}$	mg/L	
Henry's law constant (at 20°C)	$2.04 \cdot 10^{-7}$	$Pa \cdot m^3 \cdot mol^{-1}$	
Log10 Octanol/water partition coefficient	-3.90	-	Calculated value
DT_{50} for degradation in STP	0.844	hr (at 12 ºC)	Geometric mean value
DT_{50} for degradation in manure/slurry	0.844	hr (at 12 ºC)	Geometric mean value
DT_{50} for hydrolysis in surface water	6.04	day (at 20 ºC)	Corresponds to 145 h
DT_{50} for degradation in soil	<1	hr (at 12 ºC)	
DT_{50} for degradation in air	96	hr	

The distribution and degree of removal of KMPS in the STP is determined by the processes oxidisation of organic compounds, hydrolysis and disproportionation. Biodegradation, adsorption onto sludge, removal due to sludge withdrawal and volatilisation, on the contrary, do not play a role in the decomposition and distribution of the inorganic compound KMPS.

Simple Treat 4.0 calculates the following distribution of KMPS in the STP:

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
	All scenarios	
Air	5.892E-08	Calculated with SimpleTreat 4.0
Water	7.382	
Sludge	9.40E-04	
Degraded in STP	92.62	

4.3 CALCULATED PEC VALUES

The appropriate approaches and algorithms stated in the Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, October 2017 (together with default values for environmental compartments, etc.) were used to develop PEC values. In Section 4.2 emission via STP or via slurry/manure were concluded to be the only relevant primary routes of environmental exposure for KMPS in all scenarios considered. Consequently, the daily emission to the STP was the key input parameter to calculate PEC values in case of emission via STP. In case of emission via slurry/manure, the concentration in the slurry/manure as well as the amont of nitrogen in slurry/manure are relevant parameters for PEC calculation.

4.3.1 PEC in STP, surface water, and sediment

The calculated $PEC_{STP,}$ PEC_{water} and PEC_{sed} for all sub-product types where emission to the STP occurs are given in the summary table on calculated PEC values in Section 4.3.5.

KMPS might reach the surface water either via the effluent stream of the STP or via run-off from agricultural land where sewage sludge was applied.

STP effluent stream: The effluent of the STP is diluted in the surface water. According to the Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, October 2017, complete mixing of the effluent in the surface water is assumed.

The standard dilution factor of 10 to the effluent concentration of an STP was used for the PEC_{water} calculation.

Run-off from agricultural land after sewage sludge application: This emission pathway was considered only qualitatively. KMPS rapidly decomposes when getting in contact with organic substances, which are present in large amounts in sewage sludge and soil. Furthermore, adsorption of the inorganic compound KMPS to sewage sludge is negligible. Therefore, the amount of KMPS that might enter the surface water via run-off from agricultural land, where sludge was applied is negligible.

Freshwater sediment (PEC_{sed}): The PEC in bulk sediment is derived from the corresponding water-body concentration, assuming thermodynamic partition equilibrium, following the calculation given in the Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, October 2017 (Equation 53).

4.3.2 PEC in air

Volatilisation from the sewage treatment was considered although volatilisation for the inorganic compound KMPS is expected negligible. The PEC_{air} values are reported in the

summary table on calculated PEC values in Section 4.3.5.

4.3.3 PEC in soil

Soil might be exposed to KMPS either by sewage sludge from the STP or by dry and wet depositions of KMPS from the atmosphere. The use for disinfection of animal housing, disinfection of footwear and disinfection of drinking water can in theory also result in soil exposure following application of contaminated slurry/manure.

Sewage sludge: According to the Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, October 2017, sewage sludge is assumed to be applied for 10 consecutive years. For calculation of PEC_{soil}, equation 66 was considered, taking into account the DT_{50} of 0.844 hr (see input table above).

Slurry/manure: The ESD for PT3 principally foresees to calculate two PECsoil values relating to both the nitrogen and the phosphorus content of manure/slurry. However, the differences between the two PECs are small. Since the PEC/PNEC values calculated with reference to the nitrogen content are far below the trigger value of 1 the PEC/PNEC values based on phosphorous content would not give raise to any concern. In addition, considering the phosphorus content is only relevant for one European member state. Therefore, it is justified to reflect only the nitrogen scenario, which is relevant for all European countries.

Due to the rapid decomposition of KMPS in soil (read-across from decomposition in sewage sludge) and application intervals of slurry/manure onto agricultural of at least 53 days only the initial PEC (PIEC) was calculated and the provided PECsoil values equal these PIEC values.

Air: According to the Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, October 2017, atmospheric deposition is assumed to be a continuous flux throughout the year (the deposition flux is averaged over a year in the calculation). Deposition from air to soil is only a minor exposure pathway but was nevertheless included in the calculations (for the emissions to waste water/STP).

4.3.4 PEC in groundwater

For inorganic rapidly reacting substances (e.g. substances reacting with organic matter such as e.g. hydrogen peroxide) no groundwater exposure assessment is needed in line with the TAB ENV 208 (November 2021) since it is very unlikely that substance will reach groundwater. Since KMPS is also a peroxide and likewise rapidly reacting than hydrogen peroxide, a quantitative groundwater assessment is not required.

4.3.5 Summary of calculated PEC values

The calculated PEC values are summarized in the table below.

Summary table on calculated PEC values						
Scenario	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**$PEC_{soil/STP}$**	**$PEC_{soil/slurry}$**	**PEC_{air}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/ kg_{wwt}]	[mg/ kg_{wwt}]	[mg/m^2]
PT2a, public swimming pool, chronic release	4.22E-02	4.22E-03	3.31E-03	4.01E-08	n.r	1.87E-03
PT2a, public swimming pool, acute release	5.57E-01	5.57E-02	4.37E-02	5.29E-07	n.r	2.47E-12
PT2b, private swimming pools, chronic release, S-EU	3.98E-01	3.98E-02	3.13E-02	3.78E-07	n.r	1.77E-12
PT2b, private swimming pools, chronic release, N-EU	7.24E-02	7.24E-03	5.68E-03	6.87E-08	n.r	3.21E-13
PT2b, private swimming pools, acute release, S-EU	1.67E-01	1.67E-02	1.31E-02	1.59E-07	n.r	7.42E-13
PT2b, private swimming pools, acute release, N-EU	3.34E-02	3.34E-03	2.62E-03	3.17E-08	n.r	1.48E-13
PT2c, surface disinfection of industrial areas	8.12E-03	8.12E-04	6.37E-04	7.70E-09	n.r	3.60E-14
PT2d, disinfection of equipment by dipping, other instruments	2.61E-02	2.61E-03	2.05E-03	2.48E-08	n.r	1.16E-13
PT2d, disinfection of equipment by dipping, pre-disinfection dipping	2.43E-02	2.43E-03	1.91E-03	2.31E-08	n.r	1.08E-13
PT3a, disinfection of animal housing, STP	6.26E-02	6.26E-03	4.92E-03	5.95E-08	n.r	2.78E-13
PT3a, disinfection of animal housing, slurry/manure // arable land	n.r	n.r	n.r	n.r	2.00E-05	n.r

PT3a, disinfection of animal housing, slurry/manure // grassland	n.r	n.r	n.r	n.r	2.00E-05	n.r
PT3b, disinfection of footwear, STP	1.30E-03	1.30E-04	1.02E-04	1.23E-09	n.r	5.76E-15
PT3b, disinfection of footwear, slurry/manure // arable land	n.r	n.r	n.r	n.r	1.10E-04	n.r
PT3b, disinfection of footwear, slurry/manure // grassland	n.r	n.r	n.r	n.r	1.10E-04	n.r
PT4a, disinfection of slaughterhouses and butcheries	8.12E-02	8.12E-03	6.37E-03	7.70E-08	n.r	3.60E-13
PT4b, disinfection of large catering kitchens	1.62E-02	1.62E-03	1.27E-03	1.54E-08	n.r	7.21E-14
PT5, disinfection of animal drinking water	Covered by PT 3 scenarios					

4.4 PRIMARY AND SECONDARY POISONING

Primary poisoning
Not relevant for the product types concerned.

Secondary poisoning

This point is not relevant because KMPS does not bioaccumulate. It is an inorganic salt with ionic structure, which is readily soluble in water and dissociates completely. The estimated log Pow value is below 0.30 at 20 °C (calculated value -3.90). Furthermore, KMPS is not a surface active substance (surface tension measured: 72.9 mN/m at 23 °C) and it breaks down to inorganic salts (potassium and sulphate ions) of ubiquitous nature.

It can therefore be excluded that KMPS should concentrate in the food chain.

5 ASSESSMENT OF EFFECTS ON HUMAN HEALTH FOR THE PRODUCT

5.1 PRODUCT

For the purpose of the human health risk assessment (HHRA), a theoretical product containing 50 % KMPS and 50 % of inert, non-toxic and non-classified substances is considered. Theoretical product is formulated as water soluble granules.
The real-life products marketed usually contain around 50 % of KMPS and various co-formulants (e.g. salts, stabilisers, pH-adjusters). However, as the individual product composition varies for different producers, a potential influence of the co-formulants should be assessed during product authorisation and is not considered relevant for the purpose of HHRA in the context of active substance approval.
As inert, non-toxic and non-classified co-formulants are considered for the theoretical product (50 % KMPS), no substances of concern are to be considered for the risk assessments.

No studies are available for the theoretical product (50 % KMPS). However, as it is defined to consist only of KMPS itself (50 % w/w) and chemically inert, non-toxic and non-classified substances, the toxicological profile of the theoretical product (KMPS 50 % w/w) can easily be deduced from the available data on the active substance (i.e. 100 % KMPS) as summarized above in Chapter 3. For this reason, no study data is deemed necessary for the theoretical product.

The following table provides details on the in-use concentrations for the different uses and PTs.

Use	in-use concentration	
	mg KMPS/L	% KMPS (w/w)
PT2 - Disinfectants and algaecides not intended for direct application to humans or animals		
Use #1: PT2 – Disinfection of swimming pools – professional use	130 (maintenance dose) 500 (shock-dosing)	0.013(maintenance dose) 0.050 (shock-dosing)
Use #2: PT2 – Dipping of equipment – professional use	5000	0.5
Use #3: PT2 – Surface disinfection of industrial areas by wiping with mop – professional use	5000	0.5
Use #4: PT2 – Surface disinfection of industrial areas by manual spraying (low pressure) – professional use	5000	0.5
Use #5: PT2 – Disinfection of swimming pools – non-professional use	130 (maintainance dose) 500 (shock-dosing)	0.013 (maintainance dose) 0.050 (shock-dosing)
PT3 – Veterinary hygiene		
Use #1: PT3 – Terminal disinfection of animal houses using a low pressure	8000	0.8

sprayer – professional use		
Use #2: PT3 – Foot dips – professional use	8000	0.8
PT4 – Food and feed area		
Use #1: PT4 – Disinfection of food and feeding areas by wiping with mop – professional use	5000	0.5
Use #2: PT4 - Disinfection of food and feeding areas by manual spraying (low pressure) – professional use	5000	0.5
PT5 – Drinking water		
Use #1: Continuous water sanitation by dosing the header tank or application via a dosing system – professional use	800	0.08

5.2 DERMAL ABSORPTION

No dermal absorption study with the active substance KMPS or the theoretical product (50 % KMPS) was performed.

Value(s) used in the Risk Assessment – Dermal absorption	
Value(s)*	not relevant
Justification for the selected value(s)	Please see the following justification on data waiving for more information.

Data waiving	
Information requirement	Dermal absorption
Justification	No value for the dermal absorption of KMPS (100 %) or the theoretical product (50 % KMPS) was determined. Due to the high reactivity of KMPS and its immediate dissociation into potassium and sulphate ions when in contact with wet tissues, dermal absorption of KMPS itself is not considered relevant. Regarding the breakdown products, i.e. potassium and sulphate ions, dermal absorption is not considered relevant as ions are unlikely to penetrate the dermal barrier. Moreover, both breakdown products are physiologically relevant metabolites and not toxic *per se* even when becoming systemically available. KMPS exerts only local effects (i.e. corrosion) due to direct chemical reactivity, and potential systemic effects are considered secondary to this local mode of action. Consequently, only a local risk assessment needs to be performed and values relevant for a systemic risk assessment such as dermal absorption are not deemed necessary.

5.3 ACUTE TOXICITY

No acute toxicity studies were performed with the theoretical product (50 % KMPS). However, the available information on KMPS (100 %) can be used to deduce the acute toxicity profile of the theoretical product (please see below).

5.3.1 Overall conclusion on acute toxicity

Value used in the Risk Assessment – Acute toxicity	
Value(s)	Acutely toxic via the oral route, category 4. Not acutely toxic via the dermal route. Not acutely toxic via the inhalation route.
Justification for the selected value	Based on intrinsic properties of individual components (i.e. 50 % KMPS) of the theoretical product and calculate ATE for the theoretical product based on content of KMPS alone.
Classification for the product according to CLP	According to the criteria of Regulation (EC) 1272/2008 the theoretical product (50 % KMPS) warrants classification as Acute Tox. 4, H302 (Harmful if swallowed).

Data waiving	
Information requirement	Acute oral toxicity
Justification	Studies on the potential acute oral toxicity of the theoretical product (50 % KMPS) are not required. Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. For the theoretical product (50 % KMPS), the composition is known. It contains 50 % KMPS and 50 % of inert, non-toxic and non-classified substances. According to the criteria of Regulation (EC) 1272/2008, KMPS (100 %) warrants classification as Acute Tox. 4, H302 (Harmful if swallowed), while it is not classified with regard to acute dermal and inhalation toxicity. There is no indication of synergistic effects between any of the components of theoretical biocide product. Consequently, classification of the mixture can be proposed according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal product itself is not required. According to chapter 3.1.3.6 "Classification of mixtures based on ingredients of the mixture (Additivity formula)" of the CLP Regulation, the ATE of the mixture (ATE_{mix}) is determined by calculation from the ATE values for all relevant

	ingredients according to the following formula and using the LD_{50}/LC_{50}-values as provided for the respective components for oral, dermal or inhalation toxicity: $$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$$ where: C_i = concentration of ingredient i (% w/w or % v/v) i = the individual ingredient from 1 to n n = the number of ingredients ATE_i = Acute Toxicity Estimate of ingredient i. The only component in the theoretical product relevant for acute toxicity is KMPS at a concentration of 50 % (w/w). For KMPS (100 %), the following values apply: $LD_{50, oral}$ = 500 mg/kg bw $LD_{50, dermal}$ > 2000 mg/kg bw $LC_{50, inhalation}$ > 5 mg/L. Thus, the following values are calculated for the theoretical product (50 % KMPS): oral route: ATE_{mix} =1000 mg/kg bw dermal route: ATE_{mix} > 4000 mg/kg bw inhalation route: ATE_{mix} > 10 mg/L According to the rules laid down in Regulation (EC) 1272/2008, the theoretical product (50 % KMPS) warrants classification as Acute Tox. (oral) 4, H302 (Harmful if swallowed). It does not warrant classification with respect to acute dermal and inhalation toxicity.

5.4 CORROSION AND IRRITATION

5.4.1 Skin corrosion and irritation

No data on skin corrosion and irritation is available for the theoretical product (50 % KMPS). However, the available information on KMPS (100 %) can be used to deduce the skin corrosion and irritation profile of the theoretical product (please see below).

5.4.2 Serious eye damage and eye irritation

No data on eye damage and eye irritation is available for the theoretical product (50 % KMPS). However, the available information on KMPS

(100 %) can be used to deduce the eye damage and eye irritation profile of the theoretical product (please see below).

5.4.3 Respiratory tract irritation

No data on respiratory tract irritation is available for the theoretical product (50 % KMPS). However, the available information on KMPS (100 %) can be used to deduce the respiratory tract irritation profile of the theoretical product (please see below).

5.4.4 Overall conclusion on corrosion and irritation

Conclusion used in the Risk Assessment – Corrosion and irritation	
Value(s) or Conclusion(s)	Corrosive to skin. The generic concentration limit (1%) is considered when assessing the risk for local dermal effects of KMPS aqueous solutions. Aqueous solutions containing more than the generic concentration limit for skin irritation (1%) are considered to be irritating to skin. Corrosive to eyes. Corrosive to respiratory tract.
Justification for the selected value/ conclusion	Based on intrinsic properties of individual components (i.e. 50 % KMPS) of the theoretical product.
Classification of the product according to CLP	According to the criteria of Regulation (EC) 1272/2008, the theoretical product (50 % KMPS) warrants classification as Skin Corr. 1, H314 (Causes severe skin burns and eye damage) and Eye Dam. 1, H318 (Causes serious eye damage) and labelling with EUH071 (Corrosive to the respiratory tract).

Data waiving	
Information requirement	Skin irritation. Eye irritation. Respiratory tract irritation.
Justification	Studies on the potential skin irritation of the theoretical product (50 % KMPS) are not required. Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. For the theoretical product (50 % KMPS), the composition is known. It contains 50 % KMPS and 50 % of inert, non-toxic and non-classified substances. According to the criteria of Regulation (EC) 1272/2008, KMPS (100 %) warrants classification as Skin Corr. 1, H314 (Causes severe skin burns and eye damage) and Eye Dam. 1, H318 (Causes serious eye damage). Considering the CLP Regulation, classification of the theoretical product can be determined by calculation based on the generic concentration limits set out in Table 3.2.3 of the regulation for skin corrosion/irritation effects and in Table 3.3.3 for eye damage/irritation. According to the rules laid down in Regulation (EC) 1272/2008, the theoretical product (50 % KMPS) warrants classification

	as Skin Corr. 1, H314 (Causes severe skin burns and eye damage) and Eye Dam. 1, H318 (Causes serious eye damage) and labelling with EUH071 (Corrosive to the respiratory tract).

5.5 SENSITISATION

5.5.1 Skin sensitisation

No data on skin sensitisation is available for the theoretical product (50 % KMPS). However, the available information on KMPS (100 %) can be used to deduce the skin sensitisation profile of the theoretical product (please see below).

5.5.2 Respiratory sensitisation

No data on respiratory sensitisation is available for the theoretical product (50 % KMPS). However, the available information on KMPS (100 %) can be used to deduce the respiratory sensitisation profile of the theoretical product (please see below).

5.5.3 Overall conclusion on sensitisation

Conclusion used in the Risk Assessment – Sensitisation	
Conclusion(s)	Not sensitising to skin. Not sensitising to respiratory tract.
Justification for the conclusion(s)	Based on intrinsic properties of individual components (i.e. 50 % KMPS) of the theoretical product.
Classification of the product according to CLP	According to the criteria of Regulation (EC) 1272/2008, the theoretical product (50 % KMPS) does not warrant classification with respect to skin sensitisation or respiratory sensitisation. As KMPS contains impurity dipotassium peroxodisulphate ($K_2S_20_8$) which has a harmonised classification as Skin Sensitiser 1, H317 and Respiratory Sensitiser 1, H334 and is present in a concentration greater than that specified in Table 3.4.6 of Annex I of Regulation (EC) 1272/2008 the theoretical product shall be labelled with EUH208 "Contains dipotassium peroxodisulphate (CAS 7727-21-1). May produce an allergic reaction."

Data waiving	
Information requirement	Skin sensitization

Justification	Studies on the potential skin sensitisation of the theoretical product (50 % KMPS) are not required. Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. For the theoretical product (50 % KMPS), the composition is known. It contains 50 % KMPS and 50 % of inert, non-toxic and non-classified substances. According to the criteria of Regulation (EC) 1272/2008, KMPS (100 %) does not warrant classification as skin or respiratory sensitiser. Thereafter according to the criteria of Regulation (EC) 1272/2008, the theoretical product (50 % KMPS) does not warrant classification with respect to skin or respiratory sensitisation.

5.6 OTHER

KMPS (100 %) is proposed to be classified as STOT RE 1, H372 ("Causes damage to eyes through prolonged or repeated exposure") due to local effects seen in the acute inhalation toxicity study. The generic concentration limit for triggering classification of the mixture as STOT RE 1 is ≥ 10 %. The theoretical product is 50 % KMPS, and it has to be classified as STOT RE 1, H372 ("Causes damage to eyes through prolonged or repeated exposure".

6 ENVIRONMENTAL EFFECTS ASSESSMENT FOR THE PRODUCT

6.1 ATMOSPHERE

The ecotoxicological properties of the product may be derived from the properties of the active substance and other components of the product. Information on the ecotoxicity of the active substance is presented in Part A, Section 4.2. There are no compounds of concern in the formulated products that adversively affect the conclusions of the risk assessment for the active substance in the product, therefore no further assessment is needed.

6.2 STP

The ecotoxicological properties of the product may be derived from the properties of the active substance and other components of the product. Information on the ecotoxicity of the active substance is presented in Part A, Section 4.2. There are no compounds of concern in the formulated products that adversively affect the conclusions of the risk assessment for the active substance in the product, therefore no further assessment is needed.

6.3 AQUATIC COMPARTMENT

The ecotoxicological properties of the product may be derived from the properties of the active substance and other components of the product. Information on the ecotoxicity of the active substance is presented in Part A, Section 4.2. There are no compounds of concern in the formulated products that adversively affect the conclusions of the risk assessment for the active substance in the product, therefore no further assessment is needed.

6.4 TERRESTRIAL COMPARTMENT

The ecotoxicological properties of the product may be derived from the properties of the active substance and other components of the product. Information on the ecotoxicity of the active substance is presented in Part A, Section 4.2. There are no compounds of concern in the formulated products that adversively affect the conclusions of the risk assessment for the active substance in the product, therefore no further assessment is needed.

6.5 PRIMARY AND SECONDARY POISONING

The ecotoxicological properties of the product may be derived from the properties of the active substance and other components of the product. Information on the ecotoxicity of the active substance is presented in Part A, Section 4.2. There are no compounds of concern in the formulated products that adversively affect the conclusions of the risk assessment for the active substance in the product, therefore no further assessment is needed.

Part C Risk characterisation of the biocidal product(s)

1 RISK CHARACTERISATION FOR HUMAN HEALTH

For a user-friendly handling of the data in this CAR, the following chapter is divided per PT:
Blue bars and arrows highlight the "start" (🡻) and the "end" (🡹) of the assessment for each PT in this chapter.

PTs 2, 3, 4, 5 🡻

1.1 CRITICAL ENDPOINTS

1.1.1 Systemic effects

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. No true systemic effects were observed in the studies presented above, and any potential systemic toxic effect is considered secondary to local corrosion.

1.1.2 Local effects

Route	Effect	Study[2] (performed with the active substance)	Classification	Hazard category[1]
Dermal	Skin corrosion	Acute dermal irritation/corrosion study [redacted] (1983, Doc. No. 565-001)	Skin corrosion 1, H314 (Causes severe skin burns and eye damage)	High
Eye	Eye irritation	Acute eye irritation study [redacted] (1985, Doc. No. 566-002)	Serious eye damage 1, H318 (Causes serious eye damage)	High
Eye	Eye damage	Subacute inhalation toxicity [redacted] (1981, Doc. No. 531-001)	STOT RE 1, H372 (Causes damage to eyes through prolonged or repeated exposure)	Medium
Respiratory	Respiratory tract irritation	Acute inhalation toxicity [redacted] (1980, Doc. No. 523-001)	EUH071 (Corrosive to the repiratory tract)	High

1 *According to the Guidance on the Biocidal Products Regulation, Volume III Human Health – Assessment & Evaluation (Parts B+C), Version 4.0, December 2017.*

2 *Studies with the representative product are not available. The studies indicated in this column were performed with the active substance. Briefly, the results are as follows: the active substance is corrosive to the skin and eye. However, the active substance is not acute toxic via the inhalation route. Indeed, it is not classified for acute inhalation toxicity.*

1.1.3 Absorption

No value for the oral, dermal or inhalation absorption of KMPS was determined. Due to the high reactivity of KMPS and its immediate dissociation into potassium and sulphate ions when in contact with wet tissues, absorption values for KMPS itself are not considered relevant.

Breakdown products of KMPS, i.e. potassium and sulphate ions, constitute physiologically essential metabolites in the human body, which can efficiently be excreted, and are not toxic *per se* even when becoming systemically available.

KMPS exerts only local effects (i.e. corrosion) due to direct chemical reactivity, and potential systemic effects are considered secondary to this local mode of action. Consequently, only a local risk assessment needs to be performed and values relevant for a systemic risk assessment such as oral, dermal or inhalation absorption values are not deemed necessary.

1.2 REFERENCE VALUES

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Any potential systemic toxic effect is considered secondary to local

corrosion. Thus, deduction of AEL, ADI and ARfD values is not required and only local reference values have been derived, which are considered to cover also potential systemic effects. During WG I 2023, the members agreed that $NOAEC_{dermal}$ of 1 % and $NOAEC_{oral}$ of 2% should be removed from the CAR. The NOAEC values were considered unnecessary due to the risk management measures that will be applied due to the classification of KMPS for corrosive properties. Therefore, only $AEC_{inhalation}$ has been derived.

Uncertainties and assessment factors

Inhalation AEC		
Uncertainty	**AF**	**Justification**
Interspecies variability	2.5	Default interspecies toxicodynamic AF of 2.5 for local respiratory effects (according to Guidance on BPR, Vol. III, Part B+C, p. 241)
Intraspecies variability	3.2	The mode of action of KMPS is direct chemical reactivity without influence of local metabolism (kinetics), thus application of an intraspecies toxicokinetic AF is not deemed necessary. For precautionary reasons, an intra-species toxicodynamic AF of 3.2 is applied nonetheless.
Route to route extrapolation	1	not applicable
Time duration extrapolation	1	Local effects occur immediately and are considered to be concentration dependent.
NOAEL to LOAEL extrapolation	1	not applicable
Dose response	1	not applicable
Severity of key health effects	1	not applicable
Overall AF	**8**	

1.2.1 Reference values to be used in Risk Characterisation

The following table gives an overview of studies relevant for AEC deduction.

Reference	Study	NOAEC (LOAEC)	AF	Correction for oral absorption	Reference value
$AEC_{inhalation}$					
[redacted] (1981), Doc. No. 531-001, Document IIIA, Section 6, 6.3.3/01	14-day inhalation study in rat (KMPS tested as aerosol dust)	NOAEC: 1.4 mg/m³ (0.0014 mg/L) LOAEC: 10.1 mg/m³ (0.0101 mg/L)	8	not relevant	$AEC_{inhalation}$ 0.175 mg/m³ (0.000175 mg/L)

Rational for the deduction of reference values

$AEC_{inhalation}$

A valid sub-acute 14-day inhalation study in rat is available for KMPS and the NOAEC from this study (i.e. 1.4 mg/m³) is taken as point of departure for AEC deduction. In this study, KMPS was applied as dust aerosol, which is considered a worst case. Thus, the $AEC_{inhalation}$

derived covers also the risk from exposure to KMPS aerosol from aqueous solutions.

An inter-species toxicodynamic factor of 2.5 was applied to account for differences in the respiratory tract of rats and humans.

KMPS exerts only local irritating/corrosive effects at the port of entry (i.e. skin, eye, upper respiratory or GI tract) which depend only on the concentration of the KMPS solution. Any potential systemic effects are considered secondary to that local mode of action.

Moreover, these local effects are based on the direct chemical reactivity of the substance (for example, the mucus layer of the epithelial cells, or the epithelial cells themselves) without metabolism and are considered to be independent of individual intra-species variances. Thus, the effects of KMPS neither rely on nor require toxicodynamic or -kinetic correction factors to scale the results.

However, for precautionary reasons, an intra-species toxicodynamic assessment factor of 3.2 was applied additionally.

Corrosion can be considered a threshold effect which depends on the concentration of the KMPS solution only. Consequently, extrapolation to medium- or long-term values is not deemed necessary, and only one reference value was derived indicative of short-, medium- and long-term exposure.

Summing up, an overall assessment factor of 8 is applied to derive the $AEC_{inhalation}$ from the NOAEC of 1.4 mg/m³:

$$AEC_{inhalation} = 1.4 \text{ mg/m}^3/8 = 0.175 \text{ mg/m}^3$$

The $AEC_{inhalation}$ value concerns the active substance as manufactured.

1.2.2 Maximum residue limits or equivalent

KMPS is highly reactive and will react with any organic material at the site of first contact. Residues of this reaction are potassium and sulphate ions, which are physiological metabolites. Thus, no MRLs need to be defined.
KMPS is not authorised as active substance in plant protection products but a default MRL of 0.01 mg/kg has been set according to Art 18(1)(b) Reg (EU) No 396/2005. Per default the residue definition is set for the parent substance KMPS. However, due to the fast dissociation into potassium and sulfate, an MRL for KMPS seems not feasible. Therefore, the default MRL set under Reg (EU) No 396/2005 is not considered relevant for the evaluation of the active substance under the biocidal regulation.

1.3 INDUSTRIAL USES

No industrial uses for KMPS in PTs 2, 3, 4, and 5 are foreseen.

PTs 2, 3, 4, 5

PT2 - Disinfectants and algaecides not intended for direct application to humans or animals

1.4 PROFESSIONAL USES

1.4.1 Systemic effects

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Any potential systemic toxic effect is considered secondary to local corrosion. Thus, only a local exposure and risk assessment is performed for KMPS which is considered to cover also potential secondary systemic effects.

1.4.2 Local effects

For all intended uses, the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017) is followed for the local assessment of the theoretical product (50 % KMPS) as well as for the relevant diluted in-use solutions.

For the dermal route of exposure, a qualitative assessment is performed.

For the inhalation route of exposure, a quantitative assessment (Tier-1 and Tier-2) is performed. Additionally, a qualitative assessment is performed for secondary exposure scenarios in case the quantitative assessment for the inhalation route indicated an unacceptable risk.

For the oral route of exposure, a qualitative assessment is performed for KMPS where relevant.

The results of the risk assessment for local effects for the intended professional uses of KMPS in PT2 are provided in the table below.

Scenario/ work task	**Tier/PPE**	**Inhalation exposure** mg/m³	**AEC_{inhal}** mg/m³	**% AEC_{inhal}**	**Acceptable** (yes/no)
Mixing & loading of granules – manual placing [2.1.1]	1/none	0.86	0.175	491	no
	2/RPE10	0.086	0.175	49	yes
	3/RPE4	0.063	0.175	36	yes
Application – Pool disinfection [2.2.1]	1/none	n.r. (automated dosing)	0.175	n.r.	yes
Post-application – Handling empty containers [2.3.1]	1/none	n.r. (negligible)	0.175	n.r.	yes
Mixing & loading of granules – manual dosing [2.1.2]	1/none	n.r. (negligible)	0.175	n.r.	yes
Application – Dipping of equipment [2.2.2]	1/none	0.001	0.175	0.6	yes
Post-application – Handling empty containers [2.3.1]	1/none	n.r. (negligible)	0.175	n.r.	yes
Post-application – Disposal of treatment solution [2.3.2]	1/none	0.005	0.175	3	yes
Mixing & loading of granules – manual dosing [2.1.2]	1/none	n.r. (negligible)	0.175	n.r.	yes
Application – Wiping [2.2.3]	1/none	0.11	0.175	65	yes

Post-application – Handling empty containers [2.3.1]	1/none	n.r. (negligible)	0.175	n.r.	yes
Post-application – Disposal of treatment solution [2.3.2]	1/none	0.005	0.175	3	yes
Mixing & loading of granules – manual dosing [2.1.2]	1/none	n.r. (negligible)	0.175	n.r.	yes
Application – Spraying [2.2.4]	1/none	0.52	0.175	297	no
	2/RPE4	0.13	0.175	74	yes
Post-application – Handling empty containers [2.3.1]	1/none	n.r. (negligible)	0.175	n.r.	yes
Post-application – Disposal of treatment solution [2.3.2]	1/none	0.005	0.175	3	yes

n.r.: not relevant

Qualitative local risk assessment for dermal and inhalation route – mixing and loading of KMPS granules by manual placing (50 % w/w)

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Conclusion on risk**
High	Skin Corr 1 (H314) Eye Dam 1 (H318) EUH071 STOT RE 1 (H372, eyes)	-	2	Professional users	M&L Manual placing of granules (50 % w/w KMPS) into dosing device	Skin Eye RT	M&L 10 minutes per day, daily	50 % w/w KMPS (dermal contact, hand to eye transfer, dusting)	**RMM** Labelling • Labelling according to CLP Formulation • Product formulation which reduces dusting (e.g. tablets, granules) Trained personnel • Trained workers • Containment as appropriate • Good standard of general ventilation • Regular cleaning of equipment and work area • Avoidance of contact with contaminated tools and objects **PPE** Hand protection:	**Acceptable** + Engineering controls; + Short duration; + Professionals using PPE; + Professionals following instructions for use; + Good standard of personal hygiene.

									Suitable chemical resistant safety gloves. Eye protection: Tightly fitting safety goggles Body protection: Body protection must be chosen based on level of activity and exposure. Respiratory protection: Suitable RPE.	

Qualitative local risk assessment for dermal and inhalation route – mixing and loading of KMPS granules by manual dosing (50 % w/w)

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Conclusion on risk**
High	Skin Corr 1 (H314) Eye Dam 1 (H318) EUH071 STOT RE 1 (H372, eyes)	-	2	Professional users	M&L Manual dosing of granules (50 % w/w KMPS) with scoop or comparable tool into a vessel (dipping bath, bucket, spraying equipment) containing some water	Skin Eye RT	M&L 10 minutes per day, daily	50 % w/w KMPS (dermal contact, hand to eye transfer, dusting)	**RMM** Labelling • Labelling according to CLP Formulation • Product formulation which reduces dusting (e.g. tablets, granules) Trained personnel • Trained workers • Containment as appropriate • Good standard of general ventilation • Regular cleaning of equipment	**Acceptable** + Engineering controls; + Short duration; + Small quantities used + Use of dosing scoop/tool minimizing dermal contact + Professionals using PPE; + Professionals following instructions for use; + Good standard of personal hygiene.

									and work area • Avoidance of contact with contaminated tools and objects • Use of dosing scoop/tool **PPE** Hand protection: Suitable chemical resistant safety gloves. Eye protection: Tightly fitting safety goggles Body protection: Body protection must be chosen based on level of activity and exposure. Respiratory protection: Suitable RPE.	

According to the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017), risk characterisation for local effects is not required when the active substance and/or co-formulants in a product are classified for local effects but are present at concentrations that do not trigger classification of the product according to the CLP criteria. The concentration of KMPS in the in-use dilutions is below the generic concentration limits for local irritant effects (i.e. < 1 % for skin and eye). However, eye protection (goggles) is required when RPE is needed for in-use dilutions due to the product's classification as STOT RE 1, H372 (eyes): Scenario Application - Spraying.

1.4.3 Conclusion

Use #1: PT2 - Disinfection of swimming pools (professional use)
Quantitative assessment of inhalation exposure using ART (Advanced Reach Tool) with worst case assumptions for the mixing and loading of granules by manual placing results in 491 % AEC_{inhal} (Tier-1). Application of respiratory protection equipment with a protection factor of 10 (RPE10; Tier-2) results in 49 % AEC_{inhal}. To further refine the assessment, ART with realistic worst-case assumptions (Tier-3) was used to show that realistically, the application of respiratory protection equipment with a protection factor of 4 will suffice to result in safe exposures (36 % AEC_{inhal}).
The dermal exposure towards KMPS granules (50 % KMPS) was assessed qualitatively. For the professional user, application of PPE (gloves, goggles, body protection) is assumed. The application, i.e. the dosing of KMPS into the pool water, is considered an automated process without exposure of workers, and is thus considered acceptable.
Inhalation and dermal exposure during handling of empty containers (post-application) is considered negligible.

Consequently, exposure during the use of KMPS for swimming pool disinfection by professionals is considered acceptable assuming the use of suitable PPE/RPE.

Use #2: PT2 – Dipping of equipment (professional use)
For the mixing and loading of granules by manual dosing with a dosing scoop/tool, inhalation exposure is considered negligible (small amounts, low dust generation).
The dermal exposure towards KMPS granules (50 % KMPS) was assessed qualitatively. For the professional user, application of PPE (gloves, goggles, body protection) is assumed.
Quantitative inhalation exposure assessment for the application by dipping results in 0.6 % AEC_{inhal}. Dermal exposure during dipping is below generic concentration limit for skin irritation, and thus considered acceptable.
Inhalation and dermal exposure during handling of empty containers (post-application) is considered negligible.
Quantitative inhalation exposure during post-application (disposal of treatment solution) results in 3 % AEC_{inhal}. Dermal exposure during disposal is below generic concentration limit for skin irritation, and thus considered acceptable.

Consequently, exposure during the use of KMPS for dipping of equipment by professionals is considered acceptable assuming the professional wearing suitable PPE/RPE.

Use #3: PT2 – Surface disinfection of industrial areas by wiping with mop (professional use)
For the mixing and loading of granules by manual dosing with a dosing scoop/tool, inhalation exposure is considered negligible (small amounts, low dust generation).
The dermal exposure towards KMPS granules (50 % KMPS) was assessed qualitatively. For the professional user, application of PPE (gloves, goggles, body protection) is assumed.
Quantitative inhalation exposure assessment for the application by wiping results in 65 % AEC_{inhal}. Dermal exposure during wiping is below generic concentration limit for skin irritation, and thus considered acceptable
Inhalation and dermal exposure during handling of empty containers (post-application) is considered negligible.

Quantitative inhalation exposure during post-application (disposal of treatment solution) results in 3 % AEC_{inhal}. Dermal exposure during disposal of treatment solution is below generic concentration limit for skin irritation, and thus considered acceptable.

Consequently, exposure during the use of KMPS for surface disinfection by wiping with mop by professionals is considered acceptable assuming the application of suitable PPE/RPE.

Use #4: PT2 – Surface disinfection of industrial areas by manual spraying (low pressure) (professional use)
For the mixing and loading of granules by manual dosing with a dosing scoop/tool, inhalation exposure is considered negligible (small amounts, low dust generation).
The dermal exposure towards KMPS granules (50 % KMPS) was assessed qualitatively. For the professional user, application of PPE (gloves, goggles, body protection) is assumed.
Quantitative inhalation exposure assessment for the application by spraying results in 297 % AEC_{inhal} (Tier-1). Application of respiratory protection equipment with a protection factor of 4 (RPE4; Tier-2) results in 74 % AEC_{inhal}. Goggles are required due to possible eye effects.
Dermal exposure during spraying is below generic concentration limit for skin irritation, and thus considered acceptable.
Inhalation and dermal exposure during handling of empty containers (post-application) is considered negligible.
Quantitative inhalation exposure during post-application (disposal of treatment solution) results in 3 % AEC_{inhal}. Dermal exposure during disposal of treatment solution is below generic concentration limit for skin irritation, and thus considered acceptable.

Consequently, exposure during the use of KMPS for surface disinfection by manual spraying by professionals is considered acceptable assuming the application of suitable PPE/RPE.

1.5 NON-PROFESSIONAL USERS

1.5.1 Systemic effects

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Any potential systemic toxic effect is considered secondary to local corrosion. Thus, only a local exposure and risk assessment is performed for KMPS which is considered to cover also potential secondary systemic effects.

1.5.2 Local effects

For all intended uses, Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017) is followed for the local assessment of the theoretical product (50 % KMPS) as well as for the relevant diluted in-use solutions.

For the oral route of qualitative assessment is performed for KMPS where relevant.

For the dermal route of exposure, qualitative assessment is performed.
For the inhalation route of exposure, a quantitative assessment (Tier-1) is performed.

The results of the (semi-)quantitative risk assessment for the intended non-professional uses of KMPS in PT2 are provided in the table below.

Scenario/ work task	**Tier/PPE**	**inhalation exposure** mg/m³	**AEC_{inhal}** mg/m³	**% AEC_{inhal}**	**acceptable** (yes/no)
Mixing & loading of tabs – manual dosing [3.1]	1/none	n.r. (negligible)	0.175	n.r.	yes
Application – Pool disinfection [3.2]	1/none	n.r.	0.175	n.r.	yes
Post-application – Handling empty containers [3.3]	1/none	n.r. (negligible)	0.175	n.r.	yes

n.r.: not relevant

Qualitative local risk assessment for dermal and inhalation route – mixing and loading of KMPS tabs by manual dosing (50 % w/w)

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed ?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM**	**Conclusion on risk**
High	Skin Corr 1 (H314) Eye Dam 1 (H318) EUH071 STOT RE 1 (H372, eyes)	-	2	Non-professional users	M&L Manual dosing of tabs (50 % w/w KMPS) with scoop or comparable tool into the pool water	Skin Eye RT	M&L once a day, for 4 months a year	50 % w/w KMPS (dermal contact, hand to eye transfer, dusting)	**Product integrated RMM** Labelling • Labelling according to CLP • Instructions for use and storage Formulation • Product formulation which reduces dusting (e.g. tablets) Packaging • Packaging reducing risk for dermal contact and dusting (e.g.water soluable granules) • Child proof closure • Small package size	**Acceptable** + Low frequency; + Short duration; + Non-professionals following instructions for use; + No children and infant exposure; + Low amount per event; + Washing of hands after use; + Washing of face/eye after accidental exposure + Products delivered with dosing scoop/tool

According to the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017), risk characterisation for local effects is not required when the active substance and/or co-formulants in a product are classified for local effects but are present at concentrations that do not trigger classification of the product according to the CLP criteria. The concentration of KMPS in the in-use dilution is below the generic concentration limits for local irritant effects (i.e. < 1 % for skin and eye).

Risk mitigation measures:

For the dermal route of exposure, a qualitative risk assessment was performed (according to Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017)).

For non-professional users the application of PPE shall not be assumed and product integrated RMM are required as stand-alone measures to restrict consumers' exposure.

As product integrated RMM are product (and company) specific, for the purpose of active substance authorization only a generic description is given. In the following, a non-exhaustive list with examples of product integrated RMMs for solid products is provided.

(1) Packaging control
   a. Child proof closure
   b. Small package size
   c. Packaging design facilitating precise dosing
   d. Dosing scoop or tool delivered with the product

(2) Formulation control
   a. Formulation facilitating exact dosing and reducing dust formation (e.g. granules or tablets)
   b. Water-reactive packaging to control dissolution of solid products
   c. Films covering part of the product to avoid direct contact

(3) Labelling instructions
   a. Labelling according to CLP criteria
   b. Appropriate and easy to understand instructions for safe use

1.5.3 Conclusion

Use #5: PT2 - Disinfection of swimming pools (non-professional use)
Inhalation exposure for the manual mixing and loading of KMPS tabs is considered negligible due to the product formulation which reduces dust formation.
The dermal exposure towards KMPS granules (50 % KMPS) was assessed qualitatively and results in exceeding the generic concentration limit for skin irritation of 1%. For the non-professional user, product integrated risk mitigation measures are to be applied (e.g. formulation reducing exposure, supply of dosing tools, small package sizes) as described in the qualitative risk assessment which reduce dermal exposure to an acceptable level.
Non-professional users dose the product directly into the pool water; thus the application is equal to the mixing and loading and not assessed separately.
Inhalation and dermal exposure during handling of empty containers (post-application) is considered negligible.

Consequently, exposure during the use of KMPS for swimming pool disinfection by non-professionals is considered acceptable.

1.6 SECONDARY (INDIRECT) EXPOSURE AS A RESULT OF USE

1.6.1 Systemic effects

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Any potential systemic toxic effect is considered secondary to local corrosion. Thus, only a local exposure and risk assessment is performed for KMPS which is considered to cover also potential secondary systemic effects.

1.6.2 Local effects

For all intended uses, the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017) is followed for the local assessment of the theoretical product (50 % KMPS) as well as for the relevant diluted in-use solutions.

Secondary exposure of professional or non-professional bystanders/non-users upon dermal contact with treated surfaces is considered to be irrelevant. Due to the high reactivity of KMPS, residues on surfaces degrade very rapidly. Decomposition to physiological potassium and sulphate ions takes place which are not expected to arise any concerns for human health.

Hence, residue formation and chronic secondary exposure is assumed to be negligible for aqueous solutions of KMPS and only inhalation exposure after application of KMPS is considered to be relevant for the assessment of secondary exposure.

An exception is the exposure of swimmers and swim instructors towards KMPS used for disinfection of pool water. Here, qualitative risk assessment is performed.

For the inhalation route of exposure, a (semi-)quantitative assessment (Tier-1 and Tier-2) is performed.

The results of the (semi-)quantitative risk assessment for the relevant secondary exposure scenarios in PT2 are provided in the table below.

Scenario/ work task	Tier/PPE	inhalation exposure mg/m³	AEC_{inhal} mg/m³	% AEC_{inhal}	acceptable (yes/no)
Secondary exposure: bystander during mixing & loading of granules – manual placing [4.1]	1/none	0.86	0.175	491	no
	2/RPE10	0.086	0.175	49	yes
	3/RPE4	0.063	0.175	36	yes
Secondary exposure: bystander during dipping [4.2]	1/none	0.001	0.175	0.6	yes
Secondary exposure: bystander during wiping [4.3]	1/none	0.11	0.175	65	yes
Secondary exposure: bystander during spraying [4.4]	1/none	0.52	0.175	297	no
	2/RPE4	0.13	0.175	74	yes
Secondary exposure: swim instructor [4.5]	1/none	n.r.	0.175	n.r.	yes
Secondary exposure: swimming in pool [4.6]	1/none	n.r.	0.175	n.r.	yes

n.r.: not relevant

According to the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017), risk characterisation for local effects is not required when the active substance and/or co-formulants in a product are classified for local effects but are present at concentrations that do not trigger classification of the product according to the CLP criteria. The concentration of KMPS in the in-use dilutions is below the generic concentration limits for local irritant effects (i.e. < 1 % for skin and eye). Even though, the local risk assessment was performed for secondary exposure to KMPS from PT proposed uses.

Inhalation exposure of bystanders during mixing, loading, wiping and spraying:
The inhalation exposure to KMPS for professional bystanders during manual placing of granules and during wiping and spraying exceeds the $AEC_{inhalation}$. Therefore the use of the same RPE was considered as for the professional performing these tasks, i.e. RPE 10 (Tier 2) or RPE4 (Tier 3) for the task of manual dosing and RPE4 for spraying. Eye protection (goggles) is required when RPE is needed due to the product's classification as STOT RE 1, H372 (eyes) (manual dosing and spraying). Since professional bystanders are professionals they are considered to follow the instructions for use and have the required RPE and goggles available.

1.6.3 Conclusion

Scenario 4.1: Secondary exposure: bystander during mixing & loading of granules – manual dosing
Quantitative inhalation exposure assessment for a professional bystander during mixing and loading of KMPS granules by manual placing results in 491 % AEC_{inhal}. A refined risk assessment was performed in addition: if a bystander is present during mixing and loading of KMPS granules by placing, the bystander has to apply the same set of PPE (goggles) and RPE (Tier 2: RPE10, Tier 3: RPE4) as the professional who handles the biocidal product. The use of required RPE reduces the bystander exposure on an acceptable level (Tier 2: 49 % $AEC_{inhal,}$ Tier 3: 36 % AEC_{inhal}). Taking that into account the refined quantitative risk assessment was performed.

Consequently, the exposure scenario is considered acceptable for the professional bystander during mixing and loading by manual placing (relevant for use #1: PT2 – Disinfection of swimming pools (professional use)).

Scenario 4.2: Secondary exposure: Bystander during dipping
Quantitative inhalation exposure assessment for a professional bystander during dipping of equipment results in 0.6 % AEC_{inhal}.

Consequently, the exposure scenario is considered acceptable for the professional bystander during dipping of equipment (relevant for use #2: PT2 – Dipping of equipment (professional use)).

Scenario 4.3: Secondary exposure: Bystander during wiping
Quantitative inhalation exposure assessment for a professional bystander during wiping of surfaces results in 65 % AEC_{inhal}.

Consequently, the exposure scenario is considered acceptable for the professional bystander during wiping of surfaces (relevant for use #3: PT2 – Surface disinfection of industrial areas by wiping with mop (professional use)).

Scenario 4.4: Secondary exposure: Bystander during spraying
Quantitative inhalation exposure assessment for a professional bystander during surface disinfection by spraying results in 297 % AEC_{inhal}.

Thus, if a professional bystander is present during spraying of KMPS for surface disinfection, the bystander has to apply the same set of PPE (goggles) and RPE (RPE4) as the professional who handles the biocidal product, which is considered acceptable for professional bystanders. The use of required RPE reduces the bystander exposure on an acceptable level (74 % AEC_{inhal}).

Consequently, the exposure scenario is considered acceptable for the professional bystander during spraying (relevant for use #4: PT2 – Surface disinfection of industrial areas by manual spraying (low pressure) (professional use)).

Scenario 4.5: Secondary exposure: Swim instructor
Quantitative inhalation exposure for a professional bystander (e.g. swim instructor) is considered negligible as KMPS dissociates rapidly into ionic species which do not evaporate from the pool water.
Qualitative dermal exposure assessment results in exposure below generic concentration limit for skin and eye irritation.
Oral exposure is considered not relevant for a swim instructor.

Consequently, the exposure scenario is considered acceptable for the professional bystander/swim instructor (relevant for use #1: PT2 – Disinfection of swimming pools (professional use)).

Scenario 4.5: Secondary exposure of swimmers in pool
Quantitative inhalation exposure for the general public is considered negligible as KMPS dissociates rapidly into ionic species which do not evaporate from the pool water.
Qualitative dermal and oral exposure assessment results in exposure below generic concentration limit for skin and eye irritation.

Consequently, the exposure scenario is considered acceptable for the general public exposed during swimming in public or private pools (relevant for use #1: PT2 – Disinfection of swimming pools (professional use) and use #5: PT2 – Disinfection of swimming pools (non-professional use)).

PT2 - Disinfectants and algaecides not intended for direct application to humans or animals

PT3 - Veterinary hygiene

1.7 PROFESSIONAL USES

1.7.1 Systemic effects

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Any potential systemic toxic effect is considered secondary to local corrosion. Thus, only a local exposure and risk assessment is performed for KMPS which is considered to cover also potential secondary systemic effects.

1.7.2 Local effects

For all intended uses, the Guidance on the BPR, Volume III Human Health – Assessment

& Evaluation (Parts B+C) (vers. 4.0, Dec. 2017) is followed for the local assessment of the theoretical product (50 % KMPS) as well as for the relevant diluted in-use solutions.

For the dermal route of exposure, a qualitative assessment is performed.

For the inhalation route of exposure, a quantitative assessment (Tier-1 and Tier-2) is performed.

The results of the (semi-)quantitative risk assessment for the local effects following the intended professional uses of KMPS in PT3 are provided in the table below.

Scenario/ work task	**Tier/PPE**	**inhalation exposure** mg/m³	**AEC_{inhal}** mg/m³	**% AEC_{inhal}**	**acceptable** (yes/no)
Mixing & loading of granules – manual dosing [2.1]	1/none	n.r. (negligible)	0.175	n.r.	yes
Application – Spraying [2.2.1]	1/none	0.61	0.175	347	no
	2/RPE4	0.152	0.175	87	yes
Post-application – Handling empty containers [2.3.1]	1/none	n.r. (negligible)	0.175	n.r.	yes
Post-application – Disposal of treatment solution [2.3.2]	1/none	0.008	0.175	14	yes
Mixing & loading of granules – manual dosing [2.1]	1/none	n.r. (negligible)	0.175	n.r.	yes
Application – Foot dips [2.2.2]	1/none	n.r.	0.175	n.r.	yes
Post-application – Handling empty containers [2.3.1]	1/none	n.r. (negligible)	0.175	n.r.	yes
Post-application – Disposal of treatment solution [2.3.2]	1/none	0.008	0.175	4	yes

n.r.: not relevant

Qualitative local risk assessment for dermal and inhalation route – mixing and loading of KMPS granules by manual dosing (50 % w/w)

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Conclusion on risk**
High	Skin Corr 1 (H314) Eye Dam 1 (H318) EUH071 STOT RE 1 (H372, eyes)	-	3	Professional users	M&L Manual dosing of granules (50 % w/w KMPS) with scoop or comparable tool into a vessel (spraying equipment, dipping bath) containing some water	Skin Eye RT	M&L 10 minutes per day, daily	50 % w/w KMPS (dermal contact, hand to eye transfer, dusting)	**RMM** Labelling • Labelling according to CLP Formulation • Product formulation which reduces dusting (e.g. tablets, granules) Trained personnel • Trained workers • Containment as appropriate • Good standard of general ventilation • Regular cleaning of equipment and work	**Acceptable** + Engineering controls; + Short duration; + Small quantities used + Use of dosing scoop/tool minimizing dermal contact + Professionals using PPE; + Professionals following instructions for use; + Good standard of personal hygiene.

									area • Avoidance of contact with contaminated tools and objects • Use of dosing scoop/tool **PPE** Hand protection: Suitable chemical resistant safety gloves. Eye protection: Tightly fitting safety goggles Body protection: Body protection must be chosen based on level of activity and exposure. Respiratory protection: Suitable RPE.	

However, according to the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017), risk characterisation for local effects is not required when the active substance and/or co-formulants in a product are classified for local effects but are present at concentrations that do not trigger classification of the product according to the CLP criteria. The concentration of KMPS in the in-use dilution (i.e. 0.8 % w/w) is below the generic concentration limits for local irritant effects (i.e. < 1 % for skin and eye). However, eye protection (goggles) is required when RPE is needed for in-use dilutions due to the product's classification as STOT RE 1, H372 (eyes): Scenario Application - Spraying.

1.7.3 Conclusion

Use #1: PT3 - Terminal disinfection of animal houses using a low pressure sprayer (professional use)

For the mixing and loading of granules by manual dosing with a dosing scoop/tool, inhalation exposure is considered negligible (small amounts, low dust generation).
The dermal exposure towards KMPS granules (50 % KMPS) was assessed quantitatively. For the professional user, application of PPE (gloves, goggles, body protection) is assumed.
Quantitative inhalation exposure assessment for the application by spraying results in 347 % AEC_{inhal} (Tier-1). Application of respiratory protection equipment with a protection factor of 4 (RPE4; Tier-2) results in 87 % AEC_{inhal}. Goggles are required due to possible eye effects.
Dermal exposure during spraying is below generic concentration limit for skin irritation, and thus considered acceptable.
Inhalation and dermal exposure during handling of empty containers (post-application) is considered negligible.
Quantitative inhalation exposure during post-application (disposal of treatment solution) results in 4 % AEC_{inhal}. Dermal exposure during disposal of treatment solution is below generic concentration limit for skin irritation, and thus considered acceptable.
Exposure of professional during the use of KMPS for animal house disinfection by spraying as well as disposal of treatment solution is considered acceptable assuming the application of suitable PPE.

Use #2: PT3 – Foot dips (professional use)

For the mixing and loading of granules by manual dosing with a dosing scoop/tool, inhalation exposure is considered negligible (small amounts, low dust generation). The dermal exposure towards KMPS granules (50 % KMPS) was assessed quantitatively. For the professional user, application of PPE (gloves, goggles, body protection) is assumed.
Inhalation exposure during application (i.e. disinfection of rubber boots by dipping) is considered not relevant (according to Human Health Exposure Methodology, vers. 1, 2015, p.114). Dermal exposure during dipping is below generic concentration limit for skin irritation, and thus considered acceptable..
Inhalation and dermal exposure during handling of empty containers (post-application) is considered negligible.
Quantitative inhalation exposure during post-application (disposal of treatment solution) results in 4 % AEC_{inhal}. Dermal exposure during disposal of treatment solution is below generic concentration limit for skin irritation, and thus considered acceptable..

Exposure of professional during the use of KMPS for foot dips by professionals as well as disposal of treatment solution is considered acceptable assuming the application of suitable PPE.

1.8 NON-PROFESSIONAL USERS

No non-professional uses for KMPS in PT3 are foreseen.

1.9 SECONDARY (INDIRECT) EXPOSURE AS A RESULT OF USE

1.9.1 Systemic effects

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Any potential systemic toxic effect is considered secondary to local corrosion. Thus, only a local exposure and risk assessment is performed for KMPS which is considered to cover also potential secondary systemic effects.

1.9.2 Local effects

For all intended uses, the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017) is followed for the local assessment of the theoretical product (50 % KMPS) as well as for the relevant diluted in-use solutions.

Secondary exposure of professional or non-professional bystanders/non-users upon dermal contact with treated surfaces is considered to be irrelevant. Due to the high reactivity of KMPS, residues on surfaces degrade very rapidly. Decomposition to physiological potassium and sulphate ions takes place which are not expected to arise any concerns for human health.

Hence, residue formation and chronic secondary exposure is assumed to be negligible for aqueous solutions of KMPS and only inhalation exposure after application of KMPS is considered to be relevant for the assessment of secondary exposure.

For the inhalation route of exposure, a quantitative assessment (Tier-1 and Tier-2) is performed.

The results of the (semi-)quantitative risk assessment for the relevant secondary exposure scenarios in PT3 are provided in the table below.

Task/ Scenario	**Tier/PPE**	**inhalation exposure** mg/m³	**AEC_{inhal}** mg/m³	**% AEC_{inhal}**	**acceptable** (yes/no)
Secondary exposure: bystander during spraying [4.1]	1/none	0.61	0.175	347	No
	2/RPE4	0.152	0.175	87	Yes

Inhalation exposure of bystanders during spraying:
The inhalation exposure to KMPS for professional bystanders during spraying exceeds the $AEC_{inhalation}$. Therefore the use of the same RPE was considered as for the professional performing this task, i.e. RPE 20 for spraying. Since professional bystanders are professionals they are considered to follow the instructions for use and have the required

RPE available.

1.9.3 Conclusion

Scenario 4.1: Secondary exposure: Bystander during spraying
Quantitative inhalation exposure assessment for a professional bystander during surface disinfection by spraying results in 347 % AEC_{inhal}.

Thus, if a bystander is present during spraying, the bystander has to apply the same set of PPE (goggles) and RPE (RPE4) as the professional who handles the biocidal product, which is considered acceptable for professional bystanders. The use of required RPE reduces the bystander exposure on an acceptable level (87 % AEC_{inhal}).

Consequently, the exposure scenario is considered acceptable for the professional bystander during spraying (relevant for use #1: PT3 – Terminal disinfection of animal houses using a low pressure sprayer (professional use)).

PT3 - Veterinary hygiene

PT4 – Food and feed area

1.10 PROFESSIONAL USES

1.10.1 Systemic effects

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Any potential systemic toxic effect is considered secondary to local corrosion. Thus, only a local exposure and risk assessment is performed for KMPS which is considered to cover also potential secondary systemic effects.

1.10.2 Local effects

For all intended uses, the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017) is followed for the local assessment of the theoretical product (50 % KMPS) as well as for the relevant diluted in-use solution.
For the dermal route of exposure, a qualitative assessment is performed.
For the inhalation route of exposure, a quantitative assessment (Tier-1 and Tier-2) is performed.
The results of the (semi-)quantitative risk assessment for the intended professional uses of KMPS in PT4 are provided in the table below.

Scenario/ work task	**Tier/PPE**	**inhalation exposure** mg/m³	**AEC_{inhal}** mg/m³	**% AEC_{inhal}**	**acceptable** (yes/no)
Mixing & loading of granules – manual dosing [2.1]	1/none	n.r. (negligible)	0.175	n.r.	yes
Application – Wiping [2.2.1]	1/none	0.11	0.175	65	yes
Post-application – Handling empty containers [2.3.1]	1/none	n.r. (negligible)	0.175	n.r.	yes
Post-application – Disposal of treatment solution [2.3.2]	1/none	0.005	0.175	3	yes
Mixing & loading of granules – manual dosing [2.1]	1/none	n.r. (negligible)	0.175	n.r.	yes
Application – Spraying [2.2.2]	1/none	0.52	0.175	297	no
	2/ RPE4	0.130	0.175	74	yes
Post-application – Handling empty containers [2.3.1]	1/none	n.r. (negligible)	0.175	n.r.	yes
Post-application – Disposal of treatment solution [2.3.2]	1/none	0.005	0.175	3	yes

n.r.: not relevant

Qualitative local risk assessment for dermal and inhalation route – mixing and loading of KMPS granules by manual dosing (50 % w/w)

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Conclusion on risk**
High	Skin Corr 1 (H314) Eye Dam 1 (H318) EUH071 STOT RE 1 (H372, eyes)	-	4	Professional users	M&L Manual dosing of granules (50 % w/w KMPS) with scoop or comparable tool into a vessel (bucket, spraying equipment) containing some water	Skin Eye RT	M&L 10 minutes per day, daily	50 % w/w KMPS (dermal contact, hand to eye transfer, dusting)	**RMM** Labelling • Labelling according to CLP Formulation • Product formulation which reduces dusting (e.g. tablets, granules) Trained personnel • Trained workers • Containment as appropriate • Good standard of general ventilation • Regular cleaning of equipment and work	**Acceptable** + Engineering controls; + Short duration; + Small quantities used + Use of dosing scoop/tool minimizing dermal contact + Professionals using PPE; + Professionals following instructions for use; + Good standard of personal hygiene.

									area • Avoidance of contact with contaminated tools and objects • Use of dosing scoop/tool **PPE** Hand protection: Suitable chemical resistant safety gloves. Eye protection: Tightly fitting safety goggles Body protection: Body protection must be chosen based on level of activity and exposure. Respiratory protection: Suitable RPE.	

According to the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017), risk characterisation for local effects is not required when the active substance and/or co-formulants in a product are classified for local effects but are present at concentrations that do not trigger classification of the product according to the CLP criteria. The concentration of KMPS in the in-use dilution is below the generic concentration limits for local irritant effects (i.e. < 1 % for skin and eye). However, eye protection (goggles) is required when RPE is needed for in-use dilutions due to the product's classification as STOT RE 1, H372 (eyes): Scenario Application - Spraying.

1.10.3 Conclusion

Use #1: PT4 – Disinfection of food and feeding areas by wiping with mop (professional use)

For the mixing and loading of granules by manual dosing with a dosing scoop/tool, inhalation exposure is considered negligible (small amounts, low dust generation). The dermal exposure towards KMPS granules (50 % KMPS) was assessed qualitatively. For the professional user, application of PPE (gloves, goggles, body protection) is assumed.
Quantitative inhalation exposure assessment for the application by wiping results in 65 % AEC_{inhal}. Dermal exposure during wiping is below generic concentration limit for skin irritation, and thus considered acceptable.
Inhalation and dermal exposure during handling of empty containers (post-application) is considered negligible.
Quantitative inhalation exposure during post-application (disposal of treatment solution) results in 3 % AEC_{inhal}. Dermal exposure during disposal of treatment solution is below generic concentration limit for skin irritation, and thus considered acceptable.

Consequently, exposure during the use of KMPS for surface disinfection by wiping by professionals is considered acceptable assuming the application of suitable PPE/RPE.

Use #2: PT4 – Disinfection of food and feeding areas by manual spraying (low pressure) (professional use)

For the mixing and loading of granules by manual dosing with a dosing scoop/tool, inhalation exposure is considered negligible (small amounts, low dust generation). The dermal exposure towards KMPS granules (50 % KMPS) was assessed qualitatively. For the professional user, application of PPE (gloves, goggles, body protection) is assumed.
Quantitative inhalation exposure assessment for the application by spraying results in 297 % AEC_{inhal} (Tier-1). Application of respiratory protection equipment with a protection factor of 4 (RPE4; Tier-2) results in 74 % AEC_{inhal}. Goggles are required due to possible eye effects.
Dermal exposure during spraying was is below generic concentration limit for skin irritation, and thus considered acceptable.
Inhalation and dermal exposure during handling of empty containers (post-application) is considered negligible.
Quantitative inhalation exposure during post-application (disposal of treatment solution) results in 3 % AEC_{inhal}. Dermal exposure during disposal of treatment solution is below generic concentration limit for skin irritation, and thus considered acceptable.

Consequently, exposure during the use of KMPS for surface disinfection by manual spraying by professionals is considered acceptable assuming the application of suitable PPE/RPE.

1.11 NON-PROFESSIONAL USERS

No non-professional uses for KMPS in PT4 are foreseen.

1.12 SECONDARY (INDIRECT) EXPOSURE AS A RESULT OF USE

1.12.1 Systemic effects

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Any potential systemic toxic effect is considered secondary to local corrosion. Thus, only a local exposure and risk assessment is performed for KMPS which is considered to cover also potential secondary systemic effects.

1.12.2 Local effects

For all intended uses, the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017) is followed for the local assessment of the theoretical product (50 % KMPS) as well as for the relevant diluted in-use solutions.

Secondary exposure of professional or non-professional bystanders/non-users upon dermal contact with treated surfaces is considered to be irrelevant. Due to the high reactivity of KMPS, residues on surfaces degrade very rapidly. Decomposition to physiological potassium and sulphate ions takes place which are not expected to arise any concerns for human health.

Hence, residue formation and chronic secondary exposure is assumed to be negligible for aqueous solutions of KMPS and only inhalation exposure after application of KMPS is considered to be relevant for the assessment of secondary exposure.

For the inhalation route of exposure, a quantitative assessment (Tier-1 and Tier 2) is performed. Additionally, a qualitative assessment is performed for secondary exposure scenarios in case the quantitative assessment leads formally to an unacceptable use.

The results of the (semi-)quantitative risk assessment for the relevant secondary exposure scenarios in PT4 are provided in the table below.

Task/ Scenario	Tier/PPE	inhalation exposure mg/m³	AEC_{inhal} mg/m³	% AEC_{inhal}	acceptable (yes/no)
4.1 Secondary exposure: bystander during wiping	1/none	0.11	0.175	65	Yes
4.2 Secondary exposure: bystander during spraying	1/none	0.52	0.175	297	no
	2/ RPE4	0.130	0.175	74	yes

n.r.: not relevant

Inhalation exposure of bystanders during spraying:
The inhalation exposure to KMPS for professional bystanders during wiping does not exceed the $AEC_{inhalation}$.

The inhalation exposure to KMPS for professional bystanders during spraying exceeds the $AEC_{inhalation}$. Therefore the use of the same RPE was considered as for the professional performing this task, i.e. RPE 10. Since professional bystanders are professionals they are considered to follow the instructions for use and have the required RPE available.

1.12.3 Conclusion

Scenario 4.1: Secondary exposure: Bystander during wiping
Quantitative inhalation exposure assessment for a professional bystander during wiping of surfaces results in 65 % AEC_{inhal}.

Consequently, the exposure scenario is considered acceptable for the professional bystander during wiping of surfaces (relevant for use #1: PT4 – Disinfection of food and feeding areas by wiping with mop (professional use)).

Scenario 4.4: Secondary exposure: Bystander during spraying
Quantitative inhalation exposure assessment for a professional bystander during surface disinfection by spraying results in 297 % AEC_{inhal}.

Thus, if a bystander is present during spraying, the bystander has to apply the same set of PPE (goggles) and RPE (RPE4) as the professional who handles the biocidal product, which is considered acceptable for professional bystanders. The use of required RPE reduces the bystander exposure on an acceptable level (74 % AEC_{inhal}).

Consequently, the exposure scenario is considered acceptable for the professional bystander during spraying (relevant for use #2: PT4 – Disinfection of food and feeding areas by manual spraying (low pressure) (professional use)).

PT4 – Food and feed area

PT5 – Drinking water

1.13 PROFESSIONAL USES

1.13.1 Systemic effects

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Any potential systemic toxic effect is considered secondary to local corrosion. Thus, only a local exposure and risk assessment is performed for KMPS which is considered to cover also potential secondary systemic effects.

1.13.2 Local effects

For all intended uses, the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017) is followed for the local assessment of the theoretical product (50 % KMPS) as well as for the relevant diluted in-use solutions.

For the dermal route of exposure a qualitative assessment is performed.

For the inhalation route of exposure, a quantitative assessment (Tier-1 and Tier-2) is performed.

The results of the (semi-)quantitative risk assessment for the intended professional uses of KMPS in PT5 are provided in the table below.

Task/ Scenario	**Tier/PPE**	**inhalation exposure** mg/m³	**AEC_{inhal}** mg/m³	**% AEC_{inhal}**	**acceptable** (yes/no)
Mixing & loading of granules – manual dumping [2.1]	1/none	0.86	0.175	491	no
	2/RPE10	0.086	0.175	49	yes
	3/RPE4	0.063	0.175	36	yes
Application – Water disinfection [2.2]	1/none	n.r. (automated dosing)	0.175	n.r.	yes
Post-application – Handling empty containers [2.3]	1/none	n.r. (negligible)	0.175	n.r.	yes

n.r.: not relevant

Qualitative local risk assessment for dermal and inhalation route – mixing and loading of KMPS granules by manual placing (50 % w/w)

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Conclusion on risk**
High	Skin Corr 1 (H314) Eye Dam 1 (H318) EUH071 STOT RE 1 (H372, eyes)	-	5	Professional users	M&L Manual placing of granules (50 % w/w KMPS) into dosing device or header tank	Skin Eye RT	M&L 10 minutes per day, daily	50 % w/w KMPS (dermal contact, hand to eye transfer, dusting)	**RMM** Labelling • Labelling according to CLP Formulation • Product formulation which reduces dusting (e.g. tablets, granules) Trained personnel • Trained workers • Containment as appropriate • Good standard of general ventilation • Regular cleaning of equipment	**Acceptable** + Engineering controls; + Short duration; + Professionals using PPE; + Professionals following instructions for use; + Good standard of personal hygiene.

									and work area • Avoidance of contact with contaminated tools and objects **PPE** <u>Hand protection:</u> Suitable chemical resistant safety gloves. <u>Eye protection:</u> Tightly fitting safety goggles <u>Body protection:</u> Body protection must be chosen based on level of activity and exposure. <u>Respiratory protection</u>: Suitable RPE.	

According to the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017), risk characterisation for local effects is not required when the active substance and/or co-formulants in a product are classified for local effects but are present at concentrations that do not trigger classification of the product according to the CLP criteria. The concentration of KMPS in the in-use dilution is below the generic concentration limits for local irritant effects (i.e. < 1 % for skin and eye).

1.13.3 Conclusion

Use #1: PT5 - Continuous water sanitation by dosing the header tank or application via a dosing system (professional use)
Quantitative assessment of inhalation exposure using ART (Advanced Reach Tool) with worst case assumptions for the mixing and loading of granules by manual placing results in 4916 % AEC_{inhal} (Tier-1). Application of respiratory protection equipment with a protection factor of 10 (RPE10; Tier-2) results in 49 % AEC_{inhal}. To further refine the assessment, ART with realistic worst-case assumptions (Tier-3) was used to show that realistically, the application of respiratory protection equipment with a protection factor of 4 will suffice to result in safe exposures (36 % AEC_{inhal}).
The dermal exposure towards KMPS granules (50 % KMPS) was assessed qualitatively. For the professional user, application of PPE (gloves, goggles, body protection) is assumed..
During application no exposure occurs.
Inhalation and dermal exposure during handling of empty containers (post-application) is considered negligible.

Consequently, exposure during the use of KMPS for water sanitation by professionals is considered acceptable assuming the application of suitable PPE/RPE.

1.14 NON-PROFESSIONAL USERS

No non-professional uses for KMPS in PT5 are foreseen.

1.15 SECONDARY (INDIRECT) EXPOSURE AS A RESULT OF USE

1.15.1 Systemic effects

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation at the port of entry. Any potential systemic toxic effect is considered secondary to local corrosion. Thus, only a local exposure and risk assessment is performed for KMPS which is considered to cover also potential secondary systemic effects.

1.15.2 Local effects

For all intended uses, the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017) is followed for the local assessment of the theoretical product (50 % KMPS) as well as for the relevant diluted in-use solution.

Secondary exposure of professional or non-professional bystanders/non-users upon dermal contact with treated surfaces is considered to be irrelevant. Due to the high

reactivity of KMPS, residues on surfaces degrade very rapidly. Decomposition to physiological potassium and sulphate ions takes place which are not expected to arise any concerns for human health.

Hence, residue formation and chronic secondary exposure is assumed to be negligible for aqueous solutions of KMPS and only inhalation exposure after application of KMPS is considered to be relevant for the assessment of secondary exposure.

An exception is the exposure of professional bystanders towards KMPS used for treatment of animal drinking water. Here, qualitative dermal risk assessment is performed.

For the inhalation route of exposure, a quantitative assessment (Tier-1 and Tier-2) is performed.

The results of the (semi-)quantitative risk assessment for the relevant secondary exposure scenarios in PT5 are provided in the table below.

Scenario/ work task	**Tier/PPE**	**inhalation exposure** mg/m³	**AEC_{inhal}** mg/m³	**% AEC_{inhal}**				**acceptable** (yes/no)
Secondary exposure: bystander during mixing & loading of granules - manual placing [4.1]	1/none	0.86	0.175	491				inhalation: no dermal: yes
	2/RPE10	0.086	0.175	49				yes
	3/RPE4	0.063	0.175	36				yes
Secondary exposure: Dermal contact to treated water [4.2]	1/none	n.r.	0.175	n.r.				yes

n.r.: not relevant

According to the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation (Parts B+C) (vers. 4.0, Dec. 2017), risk characterisation for local effects is not required when the active substance and/or co-formulants in a product are classified for local effects but are present at concentrations that do not trigger classification of the product according to the CLP criteria. The concentration of KMPS in the in-use dilutions is below the generic concentration limits for local irritant effects (i.e. < 1 % for skin and eye).

Inhalation exposure of bystanders during mixing and loading:
The inhalation exposure to KMPS for professional bystanders during mixing and loading exceeds the $AEC_{inhalation}$. Therefore the use of the same RPE was considered as for the professional performing this task, i.e. RPE 10 (Tier 2) or RPE4 (Tier 3). Since professional bystanders are professionals they are considered to follow the instructions for use and have the required RPE available. Eye protection (goggles) is required when RPE is needed due to the product's classification as STOT RE 1, H372 (eyes).

1.15.3 Conclusion

Scenario 4.1: Secondary exposure: bystander during mixing & loading of granules – manual dumping
Quantitative inhalation exposure assessment for a professional bystander during mixing and loading of KMPS granules by manual placing results in 2966 % AEC_{inhal}. A refined risk assessment was performed in addition: if a bystander is present during mixing and loading of KMPS granules by placing, the bystander has to apply the same set of PPE (goggles) and RPE (Tier 2: RPE10, Tier 3: RPE4) as the professional who handles the biocidal product. The use of required RPE reduces the bystander exposure on an acceptable level (Tier 2: 49 % $AEC_{inhal,}$ Tier 3: 36 % AEC_{inhal}). Taking that into account the refined quantitative risk assessment was performed.

Consequently, the exposure scenario is considered acceptable for the professional bystander during mixing and loading by manual dumping (relevant for use #1: PT5 – Continuous water sanitation by dosing the header tank or application via a dosing system (professional use)).

Scenario 4.2: Secondary exposure: Dermal contact to treated water
A dermal exposure of the general public to treated animal drinking water is below generic concentration limit for skin irritation.
Consequently, the exposure scenario is considered acceptable for the general public dermally exposed to animal drinking water (relevant for use #1: PT5 – Continuous water sanitation by dosing the header tank or application via a dosing system (professional use)).

PT5 – Drinking water

1.16 INDIRECT EXPOSURE VIA FOOD

The mode of action of KMPS is based on its oxidative reactivity. KMPS reacts rapidly with available organic material at the site of first contact leading to local corrosion/irritation. Only the breakdown products K^+ and SO_4^{2-} ions will remain to become systemically available, and are thus the only relevant species for toxicokinetic and metabolic considerations.

The breakdown products of KMPS, i.e. K^+ and SO_4^{2-} ions are chemically and biologically not further degradable because they constitute simple basic structures of inorganic nature. Furthermore, both ions are physiological essential elements of all living organisms. Detailed information on absorption, distribution and excretion of potassium ions (Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on the tolerable upper intake levels of Potassium; FAO/WHO expert consultation on Diet, Nutrition and Prevention of Chronic diseases, see Doc. No. 592-003) as well as sulphate ions (Morris and Levy, J. Toxicol.-Clin.Toxicol. 1983, 20:107-114, see Doc. No. 592-002) are available, which are summarized briefly in chapter 3.1.

As both breakdown products (i.e. potassium ions and sulphate ions) constitute physiologically essential metabolites in the human body which are efficiently excreted via the urine after oral uptake, no systemic livestock and dietary exposure is deemed necessary for intended uses in PT3, PT4 and PT5.

PTs 2, 3, 4, 5

1.17 PRODUCTION / FORMULATION OF ACTIVE SUBSTANCE

Production/formulation of the biocidal product
The production/formulation of the biocidal product is done in accordance with local and national occupational health and safety regulations. Typical formulation practices for biocidal products are similar to those for non-biocidal products, which are fully described in the Chemical Safety Report and exposure scenarios developed in accordance with the requirements of the REACH Regulation.

The production of biocidal products is typically done in a closed system. The raw materials are fed into a vessel equipped with a mixer, with engineering measures taken to prevent emission into the working environment. Workers use adequate PPE during processes in which exposure of workers cannot be excluded, such as sampling for quality control. The workers are trained professionals.

From the vessels the finished product is packaged prior to storage and transport. The exposure of industrial workers is therefore minimal.

Environmental exposure
In case of spillages, the biocidal product is taken up with inert material (sand, earth, chemical absorbent, etc.) and collected in dedicated properly labelled drums. It is disposed of as chemical waste in accordance with local and national laws and regulations.

Disposal of the biocidal product
The disposal of the products and solutions should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Surplus and non-recyclable products should be disposed via a licensed waste disposal contractor. Waste packaging should be disposed or recycled.

1.18 AGGREGATED EXPOSURE

Aggregated exposure is not assessed since the respective guidance is not available yet. Moreover, due to the local mode of action of KMPS and the lack of clear systemic effects, aggregated exposure assessment is not considered necessary at all.

PTs 2, 3, 4, 5

2 RISK CHARACTERISATION FOR THE ENVIRONMENT

2.1 ATMOSPHERE

Conclusion:
Exposure of the atmospheric compartment to KMPS is not considered to be of concern, as KMPS is an inorganic, non-volatile salt with a very low vapour pressure. The Henry's law constant of KMPS, calculated to be 2.04 x 10^{-7} Pa x m^3 x mol^{-1} at 20 °C shows that volatilisation of KMPS from surface waters can be regarded as negligible.

The exposure assessment confirmed that the emission to air is negligible for the inorganic compound KMPS.

2.2 SEWAGE TREATMENT PLANT (STP)

Summary table on calculated PEC/PNEC values	
Scenario	**PEC/PNEC**
PT2a, public swimming pool, chronic release	4.22E-02
PT2a, public swimming pool, acute release	5.57E-01
PT2b, private swimming pools, chronic release, S-EU	3.98E-01
PT2b, private swimming pools, chronic release, N-EU	7.24E-02
PT2b, private swimming pools, acute release, S-EU	1.67E-01
PT2b, private swimming pools, acute release, N-EU	3.34E-02
PT2c, surface disinfection of industrial areas	8.12E-03
PT2d, disinfection of equipment by dipping, other instruments	2.61E-02
PT2d, disinfection of equipment by dipping, pre-disinfection dipping	2.43E-02
PT3a, disinfection of animal housing, STP	6.26E-02
PT3b, disinfection of footwear, STP	1.30E-03
PT4a, disinfection of slaughterhouses and butcheries	8.12E-02
PT4b, disinfection of large catering kitchen	1.62E-02

Conclusion: As shown in the table above, the PEC/PNEC values calculated from the proposed uses of KMPS as disinfectant in product types 2, 3 and 4 are below 1, indicating acceptable risks to organisms involved in the biological processes of the sewage treatment works.

The risk for the use of KMPS in PT5 (Disinfection of animal drinking water) is considered covered by the risk assessments performed for the uses in PT3.

2.3 AQUATIC COMPARTMENT

Summary table on calculated PEC/PNEC values*	
Scenario	**PEC/PNEC**
PT2a, public swimming pool, chronic release	1.90E-01
PT2a, public swimming pool, acute release	6.40E-01
PT2b, private swimming pools, chronic release, S-EU	**1.79**
PT2b, private swimming pools, chronic release, N-EU	3.26E-01
PT2b, private swimming pools, acute release, S-EU	1.92E-01
PT2b, private swimming pools, acute release, N-EU	3.84E-02
PT2c, surface disinfection of industrial areas	3.66E-02
PT2d, disinfection of equipment by dipping, other instruments	1.18E-01
PT2d, disinfection of equipment by dipping, pre-disinfection dipping	1.10E-01
PT3a, disinfection of animal housing, STP	2.82E-01
PT3b, disinfection of footwear, STP	5.85E-03
PT4a, disinfection of slaughterhouses and butcheries	3.66E-01
PT4b, disinfection of large catering kitchen	7.31E-02

* for acute releases PNECintermittent release = 0.087 mg/L has been used

Conclusion: As shown in the table above, the PEC/PNEC values calculated from the proposed uses of KMPS as disinfectant in product types 2, 3 and 4 are below 1, indicating acceptable risks to organisms in the water column (freshwater), with the exception of chronic emission due to cleaning of filtration systems following use in private swimming pools in the Southern EU scenario (PT2b).

The physico-chemical properties of KMPS (calculated log K_{OW} = -3.90) and its rapid degradation in surface waters suggest that the active substance is not likely to partition into sediment to a significant extent. Given the negligible exposure, the risk to sediment organism can also be considered acceptable.

The risk for the use of KMPS in PT5 (“Disinfection of animal drinking water”) is considered covered by the risk assessments performed for the uses in PT3.

2.4 TERRESTRIAL COMPARTMENT

Summary table on calculated PEC/PNEC values	
Scenario	**PEC/PNEC**
PT2a, public swimming pool, chronic release	1.51E-05
PT2a, public swimming pool, acute release	2.00E-04
PT2b, private swimming pools, chronic release, S-EU	1.43E-04
PT2b, private swimming pools, chronic release, N-EU	2.59E-05
PT2b, private swimming pools, acute release, S-EU	5.99E-05
PT2b, private swimming pools, acute release, N-EU	1.20E-05
PT2c, surface disinfection of industrial areas	2.91E-06
PT2d, disinfection of equipment by dipping, other instruments	9.36E-06
PT2d, disinfection of equipment by dipping, pre-disinfection dipping	8.72E-06
PT3a, disinfection of animal housing, STP	2.24E-05
PT3a, disinfection of animal housing, slurry/manure // arable land	7.56E-03
PT3a, disinfection of animal housing, slurry/manure // grassland	7.56E-03
PT3b, disinfection of footwear, STP	4.65E-07
PT3b, disinfection of footwear, slurry/manure // arable land	4.16E-02
PT3b, disinfection of footwear, slurry/manure // grassland	4.16E-02
PT4a, disinfection of slaughterhouses and butcheries	2.91E-05
PT4b, disinfection of large catering kitchen	5.81E-06

Conclusion: As shown in the table above, the PEC/PNEC values calculated from the proposed uses of KMPS as disinfectant in product types 2, 3, and 4 are below 1, indicating acceptable risks to the terrestrial compartment and hence, soil organisms.

The risk for the use of KMPS in PT5 (“Disinfection of animal drinking water”) is considered covered by the risk assessments performed for the uses in PT3.

2.5 GROUNDWATER

For inorganic rapidly reacting substances (e.g. substances reacting with organic matter such as e.g. hydrogen peroxide) no groundwater exposure assessment is needed in line with the TAB ENV 208 (November 2021) since it is very unlikely that substance will reach groundwater. Since KMPS is also a peroxide and likewise rapidly reacting as other peroxides, a quantitative groundwater assessment is not required.

2.6 PRIMARY AND SECONDARY POISONING

Primary poisoning
Not relevant for the product types concerned.

Secondary poisoning

Conclusion: KMPS does not bioaccumulate. It is an inorganic salt with ionic structure, which is readily soluble in water and dissociates completely. The estimated log Pow value is below 0.30 at 20 °C (calculated value -3.90). Furthermore, KMPS is not a surface active substance (surface tension measured: 72.9 mN/m at 23 °C) and it breaks down to inorganic salts (potassium and sulphate ions) of ubiquitous nature. It can therefore be excluded that KMPS should concentrate in the food chain.

2.7 AGGREGATED EXPOSURE (COMBINED FOR RELEVANT EMMISSION SOURCES)

Biocidal active substances are used in various applications and are often contained in many different products. The exposure assessment of single uses may therefore underestimate the actual concentrations of the active substance to be found in the environment. Article 19(2) of the Biocidal Products Regulation (BPR, 528/2012 EU) states that "the evaluation […] shall take into account the following factors: […] (d) cumulative effects, (e) synergistic effects." This is further elaborated in Annex VI (common principles for the evaluation of biocidal products) which states that the risks associated with the relevant individual components of the biocidal product shall be assessed, taking into account any cumulative and synergistic effects. This refers to the environmental risk assessment of an active substance contained in different products of the same Product Type (PT) or of different PTs.

KMPS was notified in PTs 2-5. The main entry pathways into the environment are via STP and for PT3 uses via application of slurry/manure to soil, thus a combination of exposures to KMPS for all affected environmental compartments may be possible. Nonetheless summing all the relevant emissions would lead to unrealistic worst case situation since it is not realistic to assume that all uses are performed at the same time and location. In addition, high reactivity of KMPS with oxidizable substances (organic and inorganic) and decomposition by hydrolysis and disproportionation prevent a persistence of the active substance in the environment.

Conclusion: Aggregated exposure assessment is not regarded relevant due to the high reactivity of the active substance

3 RISK CHARACTERISATION FOR THE PHYSICO-CHEMICAL PROPERTIES

Based on submitted data, the active substance KMPS is not classified relating to physical hazard. As theoretical Product is a model product which is not manufactured and not placed on the market therefore risk characterization for the physico-chemical properties of the product, containing the active substance KMPS, is not possible.

The active substance KMPS is white granular solid that is non-explosive, non-flammable, non-pyrophoric, non-self-heating and non- oxidizing. It should be properly stored in multi-wall plastic lined bag, away from metals, excessive heat, and moisture which lead to decomposition.

4 MEASURES TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

As the theoretical Product is a model products which is not manufactured and not placed on the market, in the following measures to protect man, animals and the environment are described for KMPS.

4.2 RECOMMENDED METHODS AND PRECAUTIONS CONCERNING HANDLING, USE, STORAGE, TRANSPORT OR FIRE

4.2.1 Handling and use

Safe handling advice:
Use only in well-ventilated areas.
Do not breathe dust.
Avoid dust formation in confined areas.
Avoid contact with skin and eyes.
Keep away from heat and flame.

4.2.2 Storage

Requirements for storage areas and containers:
Keep containers tightly closed in a dry, cool and well-ventilated place.
Protect from contamination.
Store in original container.

Further information:
Stable under recommended storage conditions.

Storage conditions:
Keep away from combustible material.
Never allow product to get in contact with water during storage.

4.2.3 Exposure controls/Personal protection

KMPS is corrosive to skin and eyes and irritating to the respiratory tract. This risk of skin irritation and/or respiratory irritation from KMPS active substance however, is readily controllable through the use of proper risk mitigation measures when handling concentrated formulations.
Therefore, packaging, equipment and procedures, should be designed to prevent exposure to biocidal product as far as possible. Moreover, effective skin protection such as gloves, goggles and protective overalls are required under all the identified scenarios for mixing and loading – manual placing of KMPS based biocidal products. Respiratory protective equipment is as well required for the task of manual dosing and for wiping and spraying application of KMPS based biocidal product. For professional bystanders the same PPE and RPE is required as for the professional performing the respective task for which the use of PPE are RPE is required to insure the safe use of biocidal product.
Regarding non-professional use of KMPS based product for disinfection of swimming pools product integrated risk mitigation measures must be taken into account (labelling according to CLP; clear instructions for use and storage, product formulation that reduces dusting (granules, tablets, water soluble packaging, films covering surface and preventing contact with the active substance), child proof closure, small package size, dose scoop or tool delivered with the product.

Respiratory protection
When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

Hand protection
Material: butyl-rubber

Break through time: >= 8 h

Glove thickness: 0.5 mm

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).

Eye protection
Wear safety glasses or coverall chemical splash goggles.

Eye protection complying with EN 166.

Skin and body protection
Where there is potential for skin contact, have available and wear as appropriate, impervious gloves, apron, trousers, jacket, hood and boots. Remove and wash contaminated clothing before re-use.

Hygiene measures
Wash hands before breaks and immediately after handling the product. Regular cleaning of equipment, work area and clothing. Handle in accordance with good industrial hygiene and safety practice.

Protective measures
When using do not eat or drink. Do not breathe dust.

Engineering measures
Ensure adequate ventilation, especially in confined areas.

Components with workplace control parameters

Dust

Form of exposure	Control parameter	Update	Basis
Respirable dust, TWA 8 hrs	3 mg/m³ 4 mg/m³	2006 2005	TRGS 900 (Germany) EH40 WEL
Total inhalable dust, TWA 8 hrs	10 mg/m³ 10 mg/m³	2006 2005	TRGS 900 (Germany) EH40 WEL

4.2.4 Transport information

Land transport ADR/RID

Class	8
ADR/RID-Labels	8
UN-No	3260
Packaging group	II
Classification Code	C2
HI No.	80

Proper shipping name:
Corrosive solid, acidic, inorganic, n.o.s. (contains: Potassium peroxomonosulfate)

Sea transport IMDG-Code

Class	8
Labelling No.	8
UN-No	3260
Packaging group	II
EmS	F-A, S-B

Proper shipping name:
Corrosive solid, acidic, inorganic, n.o.s. (contains: Potassium peroxomonosulfate)

Air transport ICOA-TI/IATA-DGR

Class	8
Labelling No.	8
UN-No	3260
Packaging group	II

Proper shipping name:
Corrosive solid, acidic, inorganic, n.o.s. (contains: Potassium peroxomonosulfate)

4.2.5 Fire-fighting measures

Suitable extinguishing media
Water

Extinguishing media which shall not be used for safety reasons
Carbon dioxide
High volume water jet

Specific hazards during fire-fighting
Cool closed containers exposed to fire with water spray. Fight any surrounding fire with suitable fire-extinguishing agents. Flood small amounts of decomposition products with water (add foam agent to water for better penetration). Remove any unaffected product. Control smoke with water spray.

Specific protective equipment for fire-fighters
Wear self-contained breathing apparatus and protective suit.

Further information
The product itself does not burn. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Do not allow run-off from fire-fighting to enter drains or water courses. Never add other substances or waste material to product residue. Move product residue to a safe place and dispose of properly.

4.3 EMERGENCY MEASURES IN CASE OF AN ACCIDENT

4.3.1 Personal precautions in case of accidental release

Evacuate personnel to safe areas.
Avoid contact with skin, eyes and clothing.
Avoid breathing dust.
Wear personal protective equipment.
Ensure adequate ventilation, especially in confined areas.

4.3.2 First aid measures

General advice
Remove from exposure, lie down. Never give anything by mouth to an unconscious person.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.

If symptoms: Call 112/ambulance for medical assistance.

If no symptoms: Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.
IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

4.3.3 Environmental-protection measures:

Environmental precautions
Should not be released into the environment. Do not contaminate water. Do not allow material to contaminate ground water system. If the product contaminates rivers and

lakes or drains inform respective authorities.

Methods for cleaning up
Sweep up and shovel into suitable containers for disposal. Avoid dust formation. Wash small residues with plenty of water.

Additional advice
Never add other substances or other waste material to product residue. Move product residue to a safe place and dispose of in accordance with local regulations.

4.4 PROCEDURES FOR WASTE MANAGEMENT OF THE ACTIVE SUBSTANCE FOR INDUSTRY OR PROFESSIONAL USERS

Product
Disposal according to local authority regulations.
It is recommended to offer surplus and non-recyclable substance to a licensed disposal company.
If necessary contact the relevant authorities.

Uncleaned packaging
Before disposal rinse empty containers with water.
Offer rinsed packaging material to local recycling facilities.

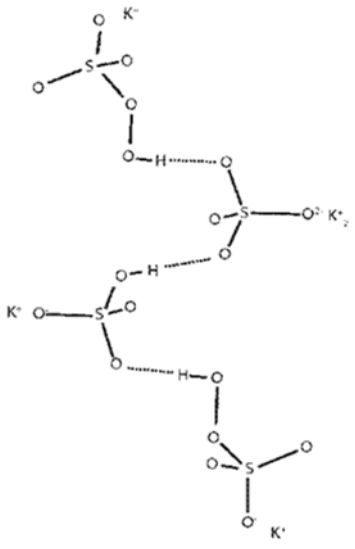
Part D: Appendices

Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Name)	Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate). Potassium monopersulfate - KMPS
Product-type	PT 2: Disinfectants and algaecides not intended for direct application to humans or animals PT 3: Veterinary hygiene PT 4: Food and feed area PT 5: Drinking water

Identity

Chemical name (IUPAC)	Pentapotassium bis((hydroperoxysulfonyl)oxidanide) hydrogen sulfate sulfate		
CAS No	70693-62-8		
EC No	274-778-7		
Other substance No.	Not applicable		
Minimum purity of the active substance as manufactured (g/kg or g/l)	890		
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	Relevant impurity		
	7727-21-1	Dipotassium peroxodisulphate ($K_2S_2O_8$)	20 g/kg
Molecular formula	$K_5H_3S_4O_{18}$ $K_5(HSO_5)_2(HSO_4)(SO_4)$		
Molecular mass	614.76 g/mol		
Structural formula			

Physical and chemical properties

Melting point (state purity)	KMPS decomposes before melting. (purity: 99.1 %)
Boiling point (state purity)	KMPS does not possess a boiling temperature due to the decomposition. (purity: 99.1 %
Appearance (state purity)	White solid powder (purity: 99.1 %)
Relative density (state purity)	2.35 at 20 °C (purity: 99.1 %)
Surface tension	72.9 mN/m at 23 °C
Vapour pressure (in Pa, state temperature)	< 1.2 x 10^{-4} Pa at 20 °C (extrapolated) < 1.7 x 10^{-4} Pa at 25 °C (extrapolated)
Henry's law constant (Pa m^3 mol^{-1})	2.04 x 10^{-7} Pa x m^3 x mol^{-1} (calculated)
Solubility in water (g/l or mg/l, state temperature)	364 g/L at 20 °C, pH not recorded
	pH 4, 7, 9: 250 -300 g/L at 22 °C
Solubility in organic solvents (in g/l or mg/l, state temperature)	Due to its oxidising properties, KMPS would react with organic solvents and therefore testing is technically not feasible.
Stability in organic solvents used in biocidal products including relevant breakdown products	Due to the reactivity of KMPS with organic solvents, KMPS is not stable in solution with organic solvents.
Partition coefficient (log P_{OW}) (state temperature)	log Pow < 0.30 at 20°C (measured). Calculated: log Kow = -3.90 pH dependence is not expected.
Dissociation constant	pK_{a1} = 2.47 pK_{a2} = 7.06

Physical hazards and respective characteristics

Explosives	No
Flammable gases	No
Flammable aerosols	Not applicable
Oxidising gases	Not applicable
Gases under pressure	Not applicable
Flammable liquids	Not applicable
Flammable solids	No
Self-reactive substances and mixtures	No
Pyrophoric liquids	Not applicable
Pyrophoric solids	No
Self-heating substances and mixtures	No
Substances and mixtures which in contact with water emit flammable gases	No
Oxidising liquids	Not applicable
Oxidising solids	No
Organic peroxides	Not applicable
Corrosive to metals	Not applicable
Auto-ignition temperature(liquids and gases)	Not applicable
Relative self-ignition temperature for solids	No
Dust explosion hazard	Not applicable

Classification and proposed labelling

with regard to physical hazards	-	
with regard to human health hazards	**Hazard Class and Category**	**Hazard Statement**

	Acute Tox. 4 Skin Corr. 1 STOT RE 1	H302: Harmful if swallowed H314: Causes severe skin burns and eye damage. H372: Causes damage to eyes through prolonged or repeated exposure.
	Supplementary Hazard Statement	
	EUH071: Corrosive to the respiratory tract. EUH208: Contains dipotassium peroxodisulphate (CAS 7727-21-1). May produce an allergic reaction.	
with regard to environmental hazards	**Hazard Class and Category**	**Hazard Statement**
	Aquatic Acute 1 (M=1) Aquatic Chronic 3	H410: Very toxic to aquatic life with long-lasting effects

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	A validated method for the determination of the active substance is available.
Impurities in technical active substance (principle of method)	A validated method for the determination of the relevant impurity $K_2S_2O_8$ is available.

Analytical methods for residues

Soil (principle of method and LOQ)	Limited exposure; no method required.
Air (principle of method and LOQ)	For dusts: NIOSH 0500 (https://www.cdc.gov/niosh/docs/2003-154/pdfs/0500.pdf) Method in air (aerosols) is missing and is post approval requirement.
Water (principle of method and LOQ)	No method developed as KMPS is instable in water and the decomposition products (potassium ions, hydrogensulfate ions, oxygen and water) are innocuous.
Body fluids and tissues (principle of method and LOQ)	No method required as KMPS is an instable inorganic salt and not classified as highly toxic or toxic.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	KMPS is an instable inorganic salt which does not bioccumulate; no method required.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	KMPS is an instable inorganic salt which does not bioccumulate; no method required.

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	No value for the oral absorption of KMPS was determined. Due to the high reactivity of KMPS and its immediate dissociation into potassium and sulphate ions when in contact with wet tissues, oral absorption of KMPS itself is not considered relevant. Regarding the breakdown products, i.e. potassium and sulphate ions, oral absorption data is available (K^+: 85-90%, SO_4^{2-}: more than 80%). Both ions constitute physiologically essential metabolites in the human body, which can efficiently be excreted, and are not toxic *per se* even when becoming systemically available. KMPS exerts only local effects (i.e. corrosion) at the site of first contact due to direct chemical reactivity. Any potential systemic effects are considered secondary to this local mode of action. Thus, oral absorption values are not deemed necessary.
Rate and extent of dermal absorption*:	No value for the dermal absorption of KMPS was determined. Due to the high reactivity of KMPS and its immediate dissociation into potassium and sulphate ions when in contact with wet tissues, dermal absorption of KMPS itself is not considered relevant. Regarding the breakdown products, i.e. potassium and sulphate ions, dermal absorption is not considered relevant as ions are unlikely to penetrate the dermal barrier. Moreover, both breakdown products are physiologically relevant metabolites and not toxic *per se* (as detailed above) even when becoming systemically available. KMPS exerts only local effects (i.e. corrosion) at the site of first contact due to direct chemical reactivity. Any potential systemic effects are considered secondary to this local mode of action. Thus, dermal absorption values are not deemed necessary.
Distribution:	Due to the high reactivity of KMPS and its immediate dissociation into potassium and sulphate ions when in contact with wet tissues, no ADME study has been performed nor is it considered feasible or relevant. KMPS dissociates into potassium and sulphate ions in aqueous environment. Data is available for the distribution of these breakdown products. Both ions are widely distributed throughout the body, as they constitute physiological relevant metabolites.
Potential for accumulation:	Due to the high reactivity of KMPS and its immediate dissociation into potassium and sulphate ions when in contact with wet tissues, accumulation of KMPS is not considered relevant. KMPS dissociates into potassium and sulphate ions in aqueous environment, which are both rapidly excreted and do not accumulate.

Rate and extent of excretion:	Due to the high reactivity of KMPS and its immediate dissociation into potassium and sulphate ions when in contact with wet tissues, no ADME study has been performed nor is it considered feasible or relevant. KMPS dissociates into potassium and sulphate ions in aqueous environment. Data is available for the elimination of these breakdown products, which constitute physiological relevant metabolites. K^+ is eliminated mostly via urine, minor excretion is via sweat or faeces. SO_4^{2-} is eliminated mostly via urine.
Toxicologically significant metabolite(s)	none

* the dermal absorption value is applicable for the active substance and might not be usable in product authorization

Acute toxicity

Rat LD_{50} oral	LD_{50}=500 mg/kg bw Acute Tox. 4 (H302: Harmful if swallowed)
Rat LD_{50} dermal	LD_{50}>2000 mg/kg bw no classification warranted
Rat LC_{50} inhalation	LC_{50}>5.0 mg/L (4 h inhalation) no classification warranted

Skin corrosion/irritation	Corrosive to skin Skin Corr. 1 (H314: Causes severe skin burns and eye damage)
Eye irritation	Causes serious eye damage. Eye Dam. 1 (H318: Causes serious eye damage)
Respiratory tract irritation	Expected to be corrosive to the respiratory tract based on classification as Skin Corr. 1 EUH071 Corrosive to the respiratory tract
Skin sensitisation (test method used and result)	No skin sensitiser in Magnusson-Kligman Guinea Pig maximisation Test (GPMT) As KMPS contains impurity dipotassium peroxodisulphate ($K_2S_20_8$) which has a harmonised classification as Skin Sensitiser 1, H317 and Respiratory Sensitiser 1, H334 and is present in a concentration greater than that specified in Table 3.4.6 of Annex I of Regulation (EC) 1272/2008 the active substance KMPS shall be labelled with EUH208 "Contains dipotassium peroxodisulphate (CAS 7727-21-1). May produce

	an allergic reaction.”
Respiratory sensitisation (test method used and result)	No indications for skin sensitisation by KMPS were identified; hence, KMPS is not expected to have respiratory sensitisation potential.

Repeated dose toxicity

Short term

Species / target / critical effect	rat (oral, inhalation)/local irritation at port of entry, no systemic effects
Relevant oral NOAEL / LOAEL	Rat, 14-days NOAEL: >1000 mg/kg bw/day (NOAEC >100 mg/mL) LOAEL/LOAEC: not determined
Relevant dermal NOAEL / LOAEL	No dermal short-term repeated dose study is available for KMPS. A dermal short-term repeated dose study is not considered relevant due to the corrosive properties of KMPS and the absence of clear systemic effects.
Relevant inhalation NOAEL / LOAEL	Rat, 14-days NOAEC: 1.4 mg/m³ LOAEC: 10.1 mg/m³ STOT RE 1, H372 (“Causes damage to eyes through prolonged or repeated exposure”)

Sub-chronic

Species/ target / critical effect	rat (oral)/local irritation at port of entry, no systemic effects
Relevant oral NOAEL / LOAEL	Rat, 90-days NOAEL: 200 mg/kg bw/day (NOAEC 20 mg/mL) NOAEL: 600 mg/kg bw/day (LOAEC: 60 mg/mL)
Relevant dermal NOAEL / LOAEL	No dermal subchronic repeated dose study is available for KMPS. A dermal subchronic repeated dose study is not considered relevant due to the corrosive properties of KMPS and the absence of clear systemic effects.
Relevant inhalation NOAEL / LOAEL	No inhalation subchronic repeated dose study is available for KMPS. An inhalation subchronic repeated dose study is not considered necessary as KMPS does not exert primary systemic effects.

Long term

Species/ target / critical effect	none
Relevant oral NOAEL / LOAEL	No oral long-term repeated dose study is available for KMPS.
Relevant dermal NOAEL / LOAEL	No dermal long-term repeated dose study is available for KMPS.

Relevant inhalation NOAEL/LOAEL	No inhalation long-term repeated dose study is available for KMPS.

Genotoxicity

Bacterial reverse mutation assay: negative Chromosomal aberrations in human peripheral blood lymphocytes: positive± S9 1st gene mutation assay (tk±/L5178Y): positive ±S9 2nd gene mutation assay (tk±/L5178Y): negative ±S9 Genotoxic *in vitro*. Micronucleous assay in mouse: negative. *In vivo* Comet Assay in rat: negative Not genotoxic *in vivo*.

Carcinogenicity

Species/type of tumour	no study available
Relevant NOAEL/LOAEL	no study available Based on weight of evidence from 14- and 90-day oral repeated dose toxicity studies in rats and the *in vivo* genotoxicity study in mice and due to the lack of systemic effects KMPS is not considered to have carcinogenic potential.

Reproductive toxicity

Developmental toxicity

Species/ Developmental target / critical effect	rat/no indication for prenatal developmental toxicity
Relevant maternal NOAEL	NOAEL: 250 mg/kg bw/day (NOAEC: 25 mg/mL) LOAEL: 750 mg/kg bw/day (LOAEC: 75 mg/mL)
Relevant developmental NOAEL	NOAEL:≥ 750 mg/kg bw/day (NOAEC: ≥75 mg/mL) LOAEL/LOAEC: not determined in the study KMPS did not affect development of rat fetuses.

Fertility

Species/critical effect	no study available
Relevant parental NOAEL	no study available KMPS is not considered to affect fertility of exposed animals based on weight of evidence from 14- and 90-day oral repeated dose toxicity studies in rats and due to the lack of systemic effects.
Relevant offspring NOAEL	no study available
Relevant fertility NOAEL	no study available

Neurotoxicity

Species/ target/critical effect	no neurotoxicity study available KMPS is not considered to have neurotoxic potential as it is structurally not related to compounds known to induce neurotoxicity. Functional and observational battery and motor activity assessments performed in the course of the 90-day oral repeated dose toxicity study gave no indications for neurotoxicity of KMPS.

Developmental Neurotoxicity

Species/ target/critical effect	no developmental neurotoxicity study available KMPS is not considered to have neurotoxic potential as it is structurally not related to compounds known to induce neurotoxicity.

Immunotoxicity

Species/ target/critical effect	no immunotoxicity study available KMPS is not considered to exert immunotoxic effects as it does not become systemically available.

Developmental Immunotoxicity

Species/ target/critical effect	no developmental immunotoxicity study available KMPS is not considered to exert immunotoxic effects as it does not become systemically available.

Other toxicological studies

Two human studies are available examining potential skin sensitising and skin irritation effects of KMPS.

In the first study 109 participants received 7100 ppm KMPS for 24 hrs under occlusion for 4 days/week for 3 week, following the exposure during challenge phase.

In the second study 25 volunteers were included per concentration tested and received 0, 12, 150 and 7000 ppm KMPS for 24 hrs under occlusion for 4 days/week for 3 week, following the exposure during challenge phase.

In both studies aqueous solutions containing 7000 or 7100 ppm of KMPS have been demonstrated to be not irritating to human skin when applied for more than 24 h under occlusive conditions, except for 1 participant who exhibited signs of mild skin irritation. However, with repeated exposure to KMPS at 0.71 or 0.70 % incidence and severity of skin reactions was increasing. At 150 ppm transient signs of skin irritation were seen in three individuals and were observed only on one day during study. At 12 ppm no signs of skin irritation were seen in any exposed volunteer.
The major deviation of these two studies is that three test substances were concurrently tested in the same individuals; therefore, no conclusion can be drawn for the sensitising properties of the individual substances, especially when considering that one tested substance is classified as respiratory and skin sensitizer. Additionally, as the concentrations used for the induction and challenge phase were identical and have been shown to be irritating in some individuals after

repeated 24 h-exposures under occlusive conditions, it is not possible to distinguish between an irritant and a sensitisation skin response in the study.

Based on the results of these two studies, no firm conclusion can be drawn on the skin sensitising properties of KMPS.

The derivation of a dermal NOAEC value was considered unnecessary due to the risk management measures that will be applied due to the classification of KMPS for corrosive properties.

Medical data

Medical surveillance data of workers (150 persons, females and males) exposed during production, analysis and application of KMPS were examined for health effects periodically within 6 years. Exposure levels and exposure duration was not stated. Examination included hearing tests, sight tests, lung function tests, ECG, blood and urine examinations. No specific adverse effects of KMPS on health were observed.

A more recent respiratory health surveillance was submitted. 33 employees working in Oxone manufacturing facility filled out questionnaires regarding respiratory health problem and were tested in the pulmonary function test. No pulmonary symptoms were reported among the employees for the 2013-2016 calendar year.

Summary

	Value	Study	Safety factor
Inhalation AEC[12]	0.175 mg/m³	14-day inhalation study in rat	8
ADI[13]	not relevant		
ARfD	not relevant		

MRLs

Relevant commodities	Not considered relevant for KMPS as this substance acts by a local mode of action only.

Dermal absorption

Study (*in vitro/vivo*), species tested	Dermal absorption is not considered relevant as KMPS exerts local effects only. Any potential systemic effects are considered secondary to the local effects.
Formulation (formulation type and including concentration(s) tested, vehicle)	/
Dermal absorption values used in risk assessment	/

Chapter 4: Fate and Behaviour in the Environment

[12] Value concerns the active substance as manufactured.
[13] If residues in food or feed.

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	DT_{50} 145 h (pH 7, 20 °C) DT_{50} > 800 h (pH 4, 20 °C) DT_{50} 2.8 h (pH 9, 20 °C)
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Phototransformation of KMPS can be excluded as degradation pathway because the substance does not absorb light in the relevant wavelengths (290 – 800 nm).
Readily biodegradable (yes/no)	Not applicable; KMPS is an inorganic salt.
Inherent biodegradable (yes/no)	Not applicable; KMPS is an inorganic salt.
Abiotic degradation in activated sludge	DT_{50} at 12 °C: Geometric mean: 0.844 hr
Biodegradation in freshwater	Not applicable; KMPS is an inorganic salt.
Biodegradation in seawater	Not applicable; KMPS is an inorganic salt.
Non-extractable residues	Not relevant
Distribution in water / sediment systems (active substance)	KMPS is an inorganic salt expected to partition exclusively into the water phase.
Distribution in water / sediment systems (metabolites)	Not relevant, see above.

Route and rate of degradation in soil

Mineralization (aerobic)	Not relevant, KMPS decomposes either by hydrolysis, disproportionation to potassium ions, hydrogen sulphate and oxygen or upon contact with oxidizable substances (organic and inorganic).
Laboratory studies (range or median, with number of measurements, with regression coefficient)	No studies available, see above.
DT_{50lab} (20 °C, aerobic):	No data available
DT_{90lab} (20 °C, aerobic):	No data available
DT_{50lab} (10 °C, aerobic):	No data available
DT_{50lab} (20 °C, anaerobic):	No data available
degradation in the saturated zone:	No data available
Field studies(state location, range or median with number of measurements)	No data available
DT_{50f}:	No data available
DT_{90f}:	No data available
Anaerobic degradation	KMPS decomposes either by hydrolysis, disproportionation to potassium ions, hydrogen sulphate and oxygen or upon contact with oxidizable substances (organic and inorganic).
Soil photolysis	Not relevant, KMPS does not absorb light in the visible wavelengths.
Non-extractable residues	Not relevant, see above.

Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	Not relevant, see above.
Soil accumulation and plateau concentration	Not relevant, KMPS decomposes to ubiquitously available substances.

Adsorption/desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	Not relevant KMPS decomposes either by hydrolysis, disproportionation to potassium ions, hydrogen sulphate and oxygen or upon contact with oxidizable substances (organic and inorganic).

Fate and behaviour in air

Direct photolysis in air	KMPS: 4.011 days (24 h day, corresponding to 96.264 h) Caro's acid: 3.875 days (24 h day, corresponding to 93.009 h)
Quantum yield of direct photolysis	Not determined.
Photo-oxidative degradation in air	Latitude: ..... Season: ..... DT_{50} .....
Volatilization	Negligible, the Henry's law constant of KMPS, calculated to be 2.04 x 10^{-7} Pa x m^3 mol^{-1}.

Reference value for groundwater

According to BPR Annex VI, point 68	

Monitoring data, if available

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	No data available
Ground water (indicate location and type of study)	No data available
Air (indicate location and type of study)	No data available

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale / design	Endpoint	Toxicity (mg KMPS/L)
Fish			
Oncorhynchus mykiss (Rainbow trout)	96 h / semi-static	Mortality, LC_{50}	53
Cyprinodon variegates (Sheephead minnow) (Saltwater species*)	96 h / static	Mortality, LC_{50}	0.467
	37 d / flow-through	Egg hatchability, NOEC	0.889
		Fry survival and length, NOEC	0.444
		Blotted wet weight, NOEC	0.222

Invertebrates			
Americamysis bahia (Mysid shrimp) (Saltwater species*)	96 h / static	Immobilisation, LC_{50}	0.513
	28 d / flow-through	Adult survival, NOEC 96 h juvenile survival, NOEC Length, NOEC Young per female, NOEC	0.267
Algae			
Pseudokierchneriella subcapitata	96 h / static	72 h NOE_bC / E_bC_{50} 72 h NOE_rC / E_rC_{50}	- / 0.84 0.43 / >0.87
Skeletonema costatum (Saltwater species*)	96 h / static	NOE_bC / E_bC_{50} NOE_rC / E_rC_{50}	0.074 /0.325 0.295 / 0.370
Microorganisms			
Activated sludge	3 h	Respiration rate, EC_{50}	>100

*The toxicity observed for saltwater species likely overestimates the toxicity of KMPS to freshwater species, because in saltwater chlorine is generated from sodium chloride by oxidation with KMPS, increasing the biocidal activity of the application solution.

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms	LC_{50} >1000 mg KMPS/kg dw soil
Reproductive toxicity to earthworms	No data available

Effects on soil micro-organisms

Nitrogen mineralization	No data available
Carbon mineralization	No data available

Effects on terrestrial vertebrates

Acute toxicity to mammals	No data available
Acute toxicity to birds	No data available
Dietary toxicity to birds	No data available
Reproductive toxicity to birds	No data available

Effects on honeybees

Acute oral toxicity	No data available
Acute contact toxicity	No data available

Effects on other beneficial arthropods

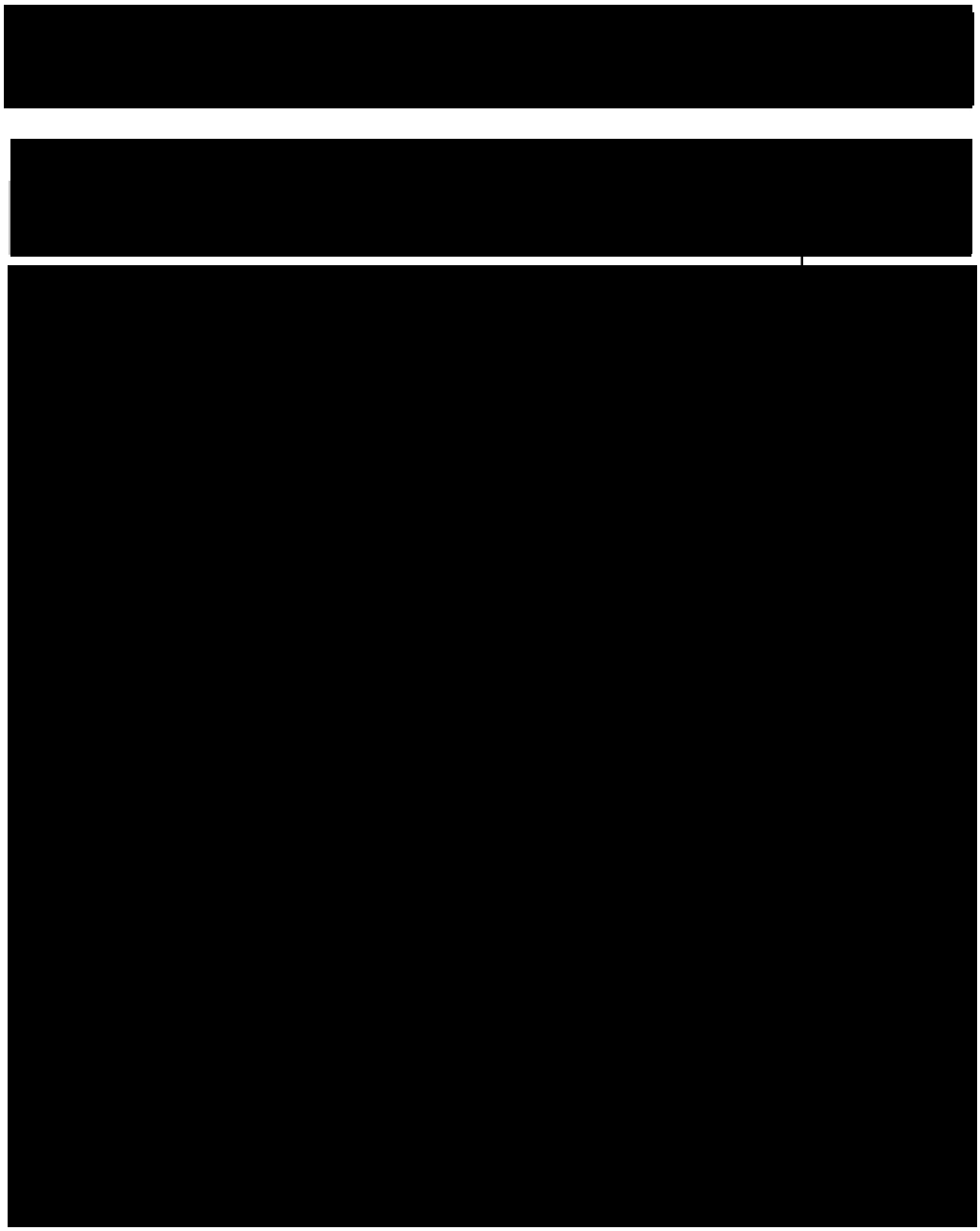
Acute oral toxicity	No data available
Acute contact toxicity	No data available

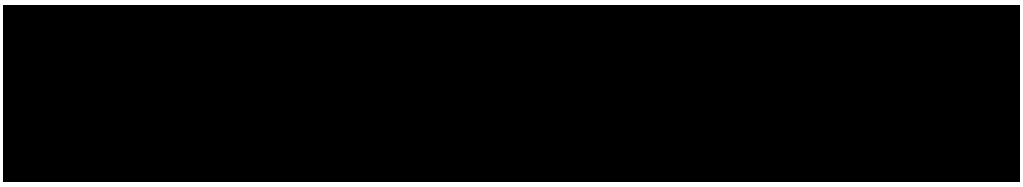
Bioconcentration

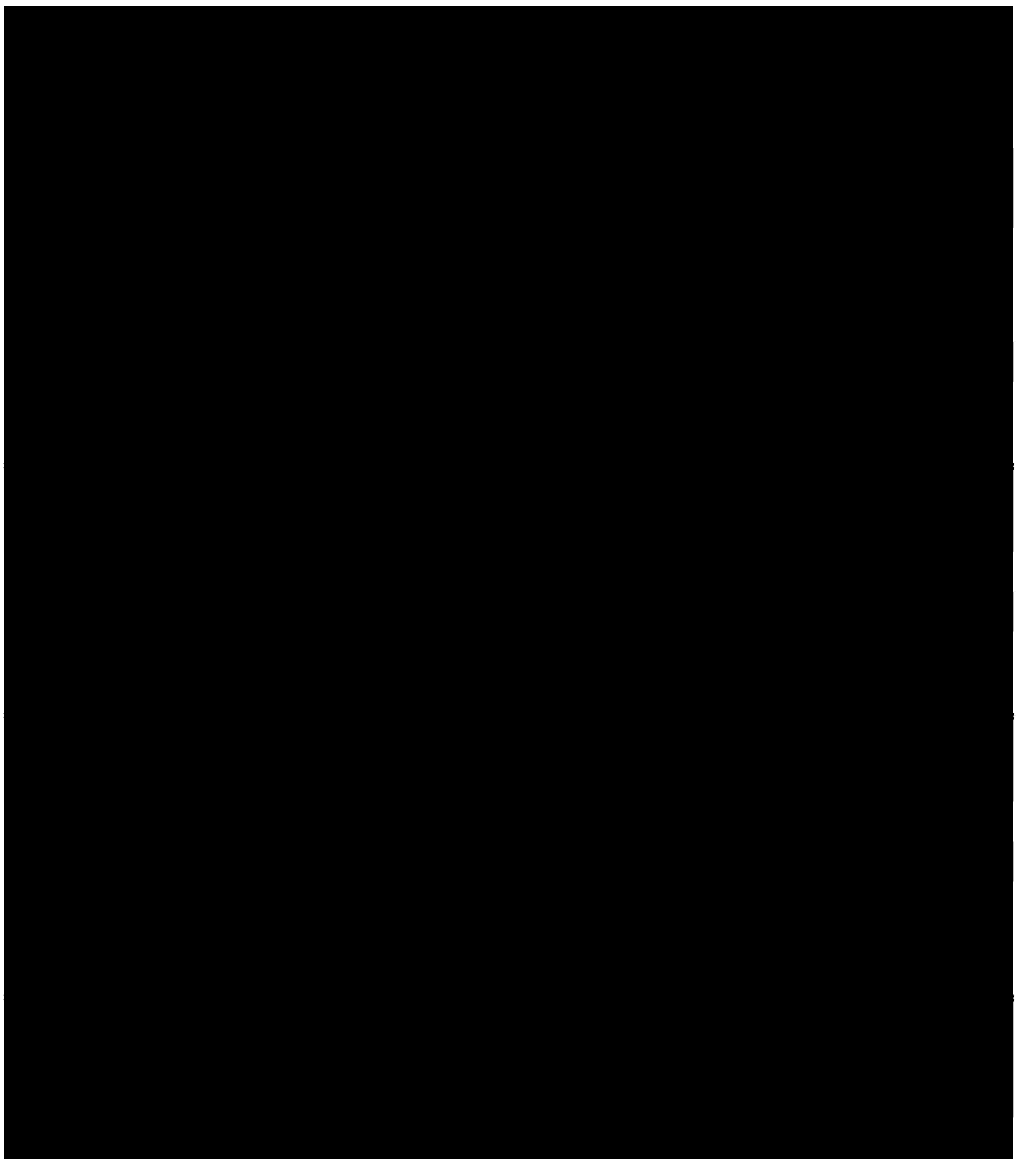
Bioconcentration factor (BCF)	KMPS has a low potential for bioconcentration and bioaccumulation (log Pow < 0.30 measured at 20 °C and -3.90 calculated) and dissipates rapidly in the environment.
Depuration time (DT_{50})	Not relevant, see above.
Depuration time (DT_{90})	Not relevant, see above.
Level of metabolites (%) in organisms accounting for > 10 % of residues	Not relevant, see above.

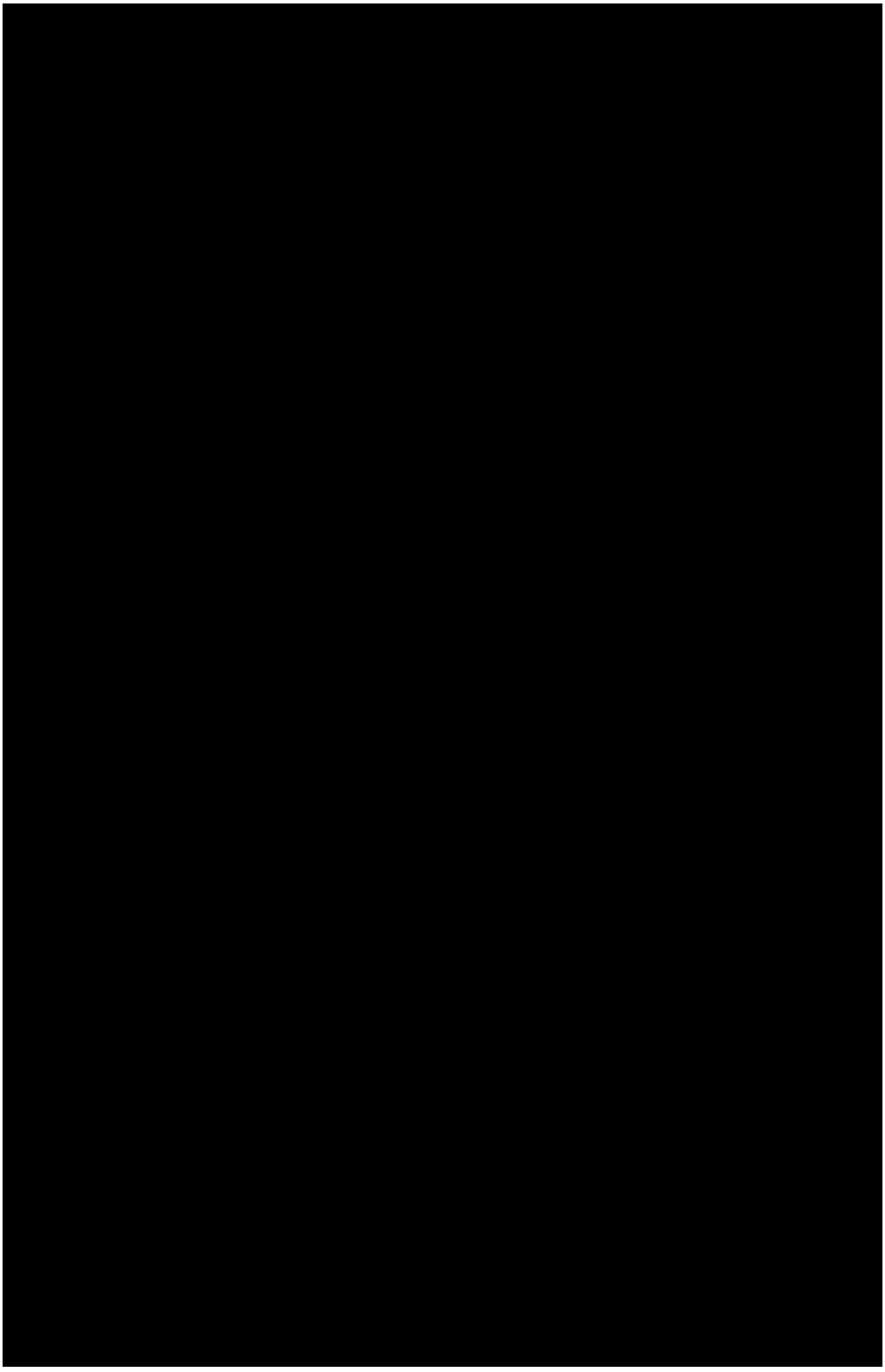
Chapter 6: Other End Points

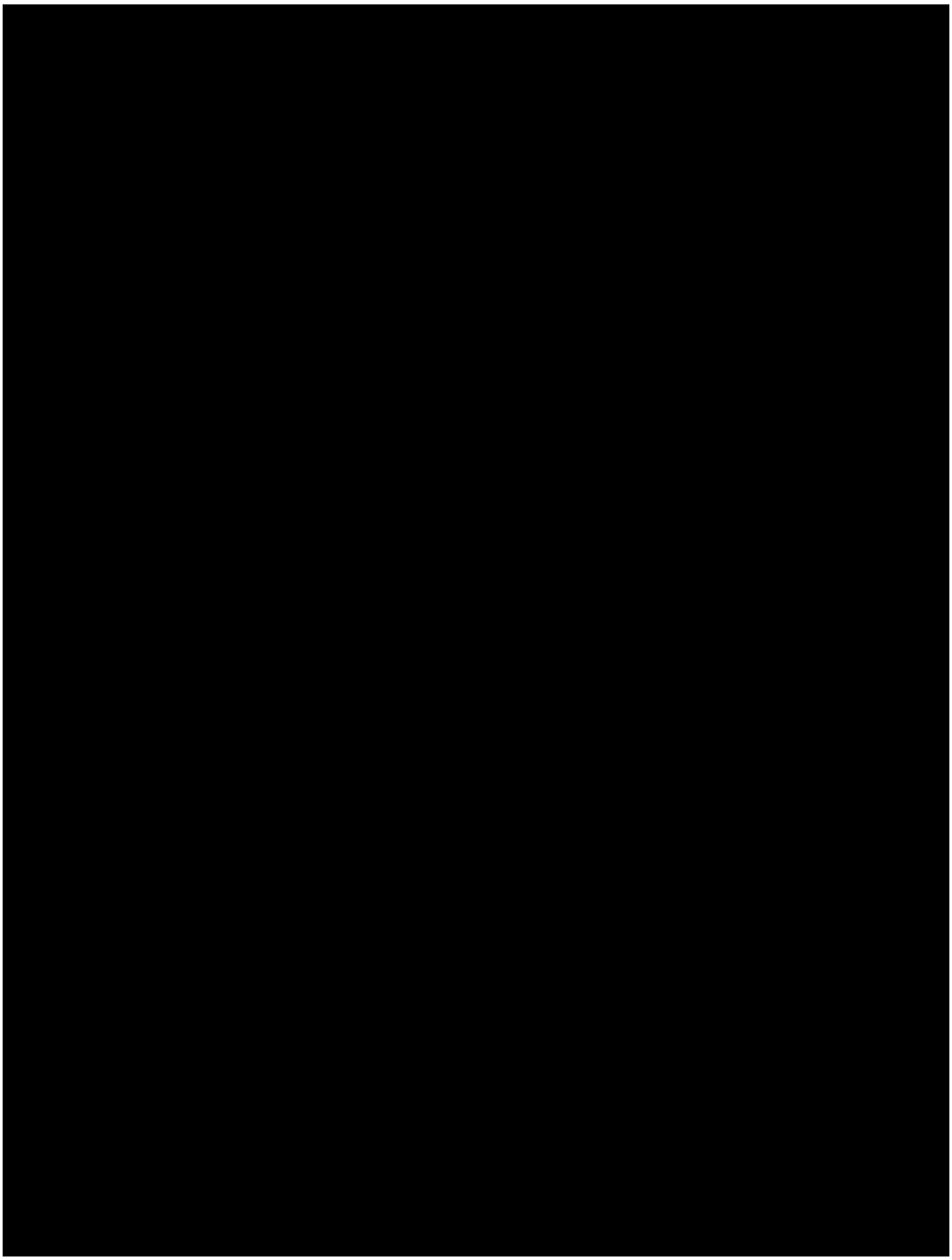
Appendix II: Human exposure calculations

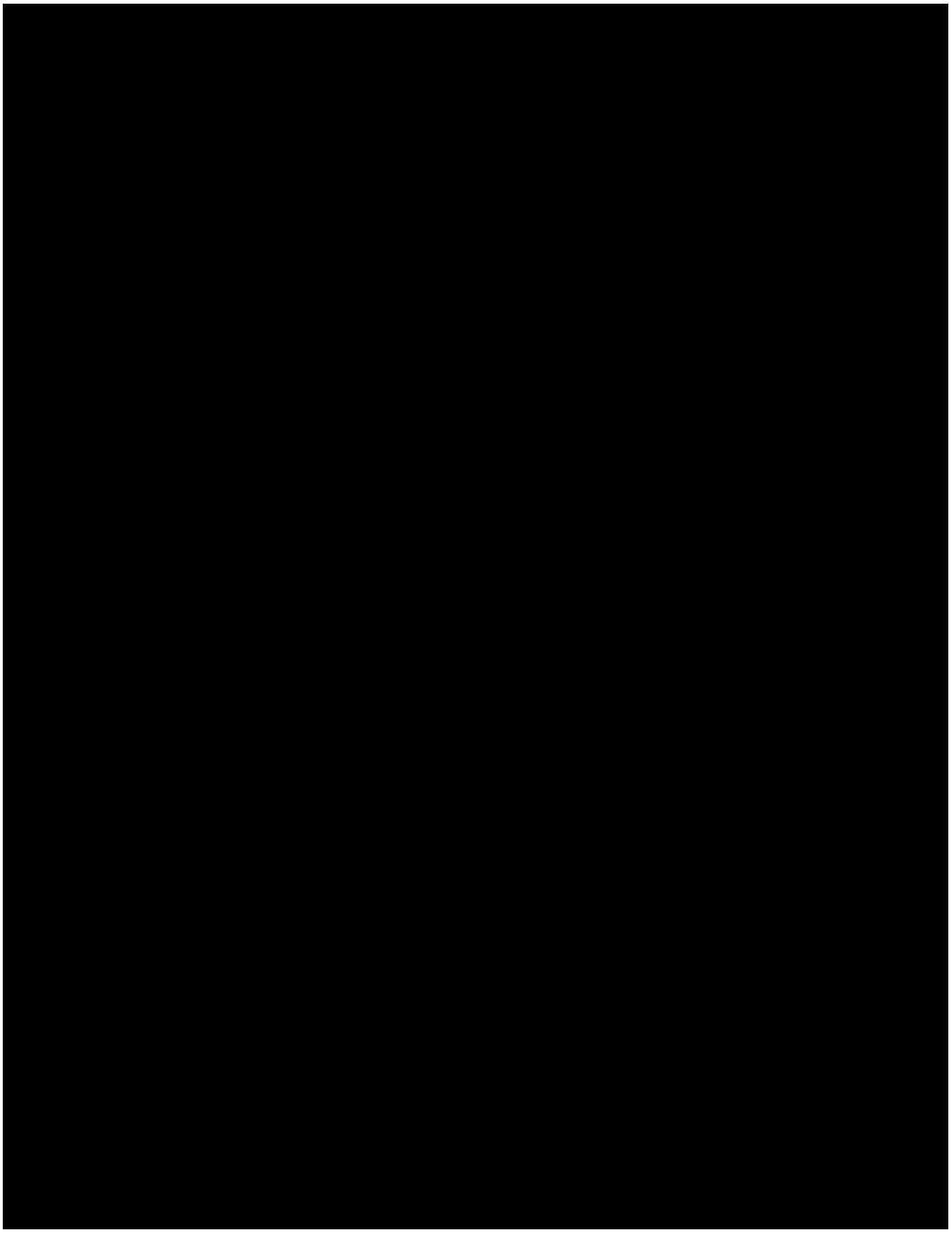


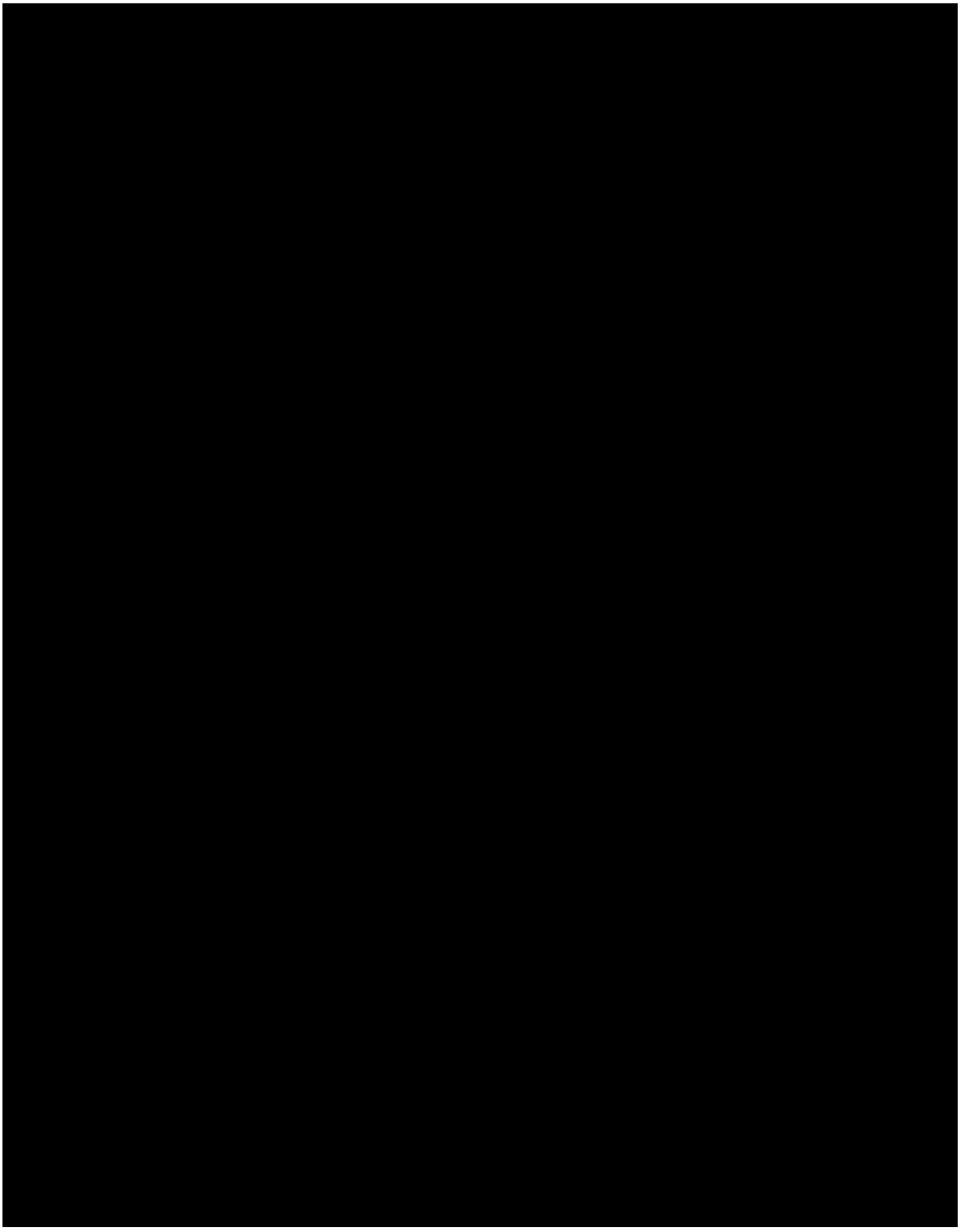


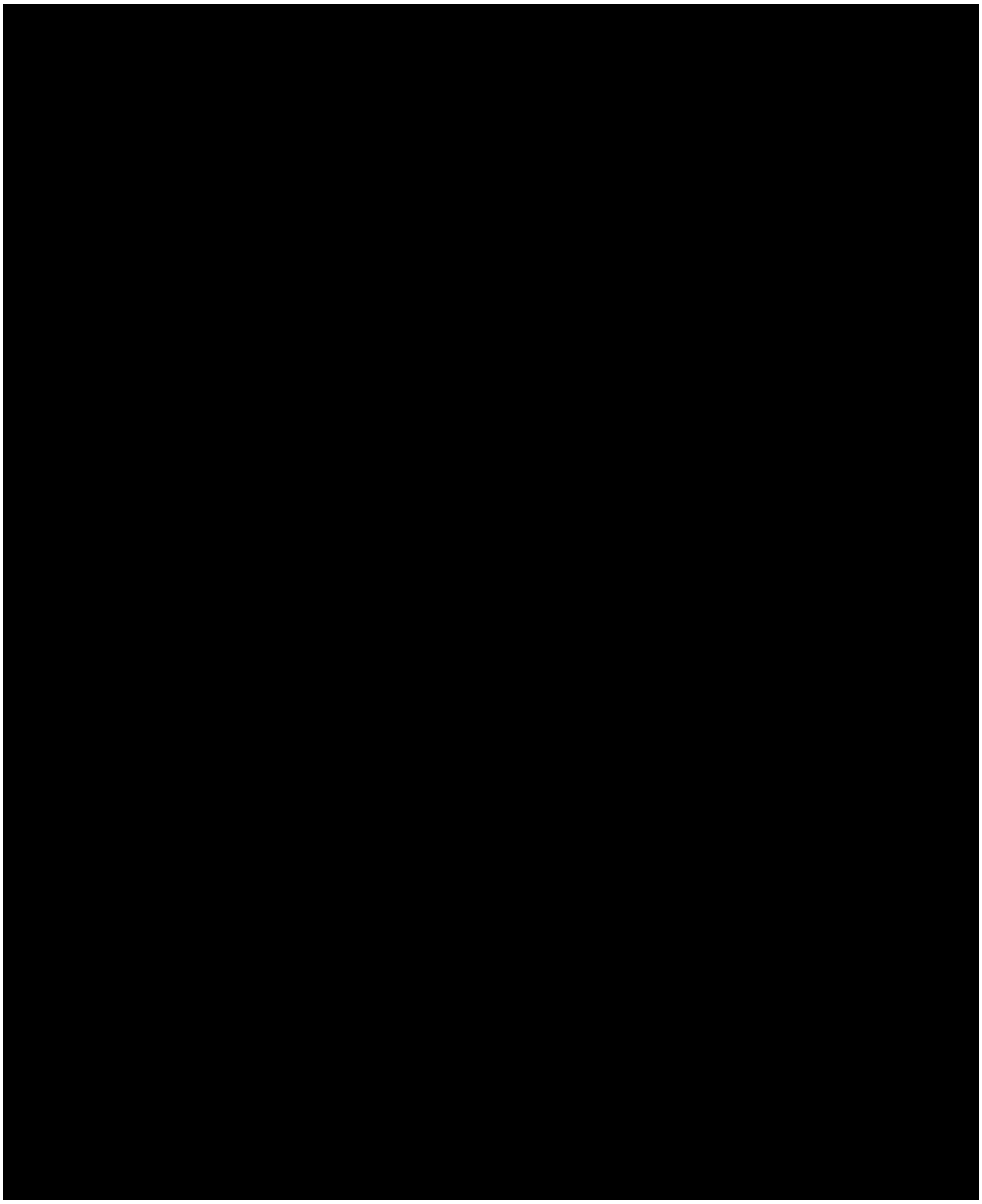


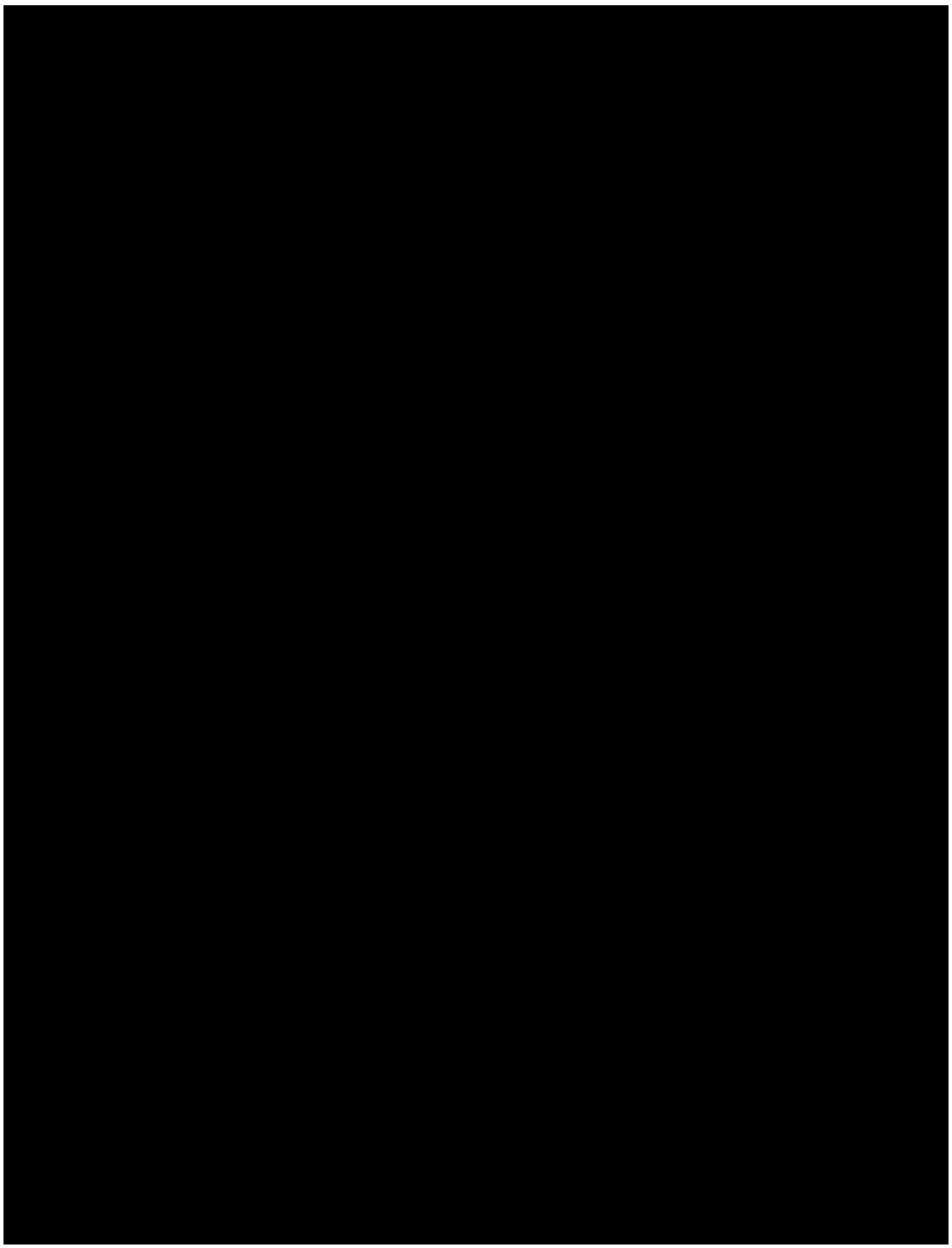


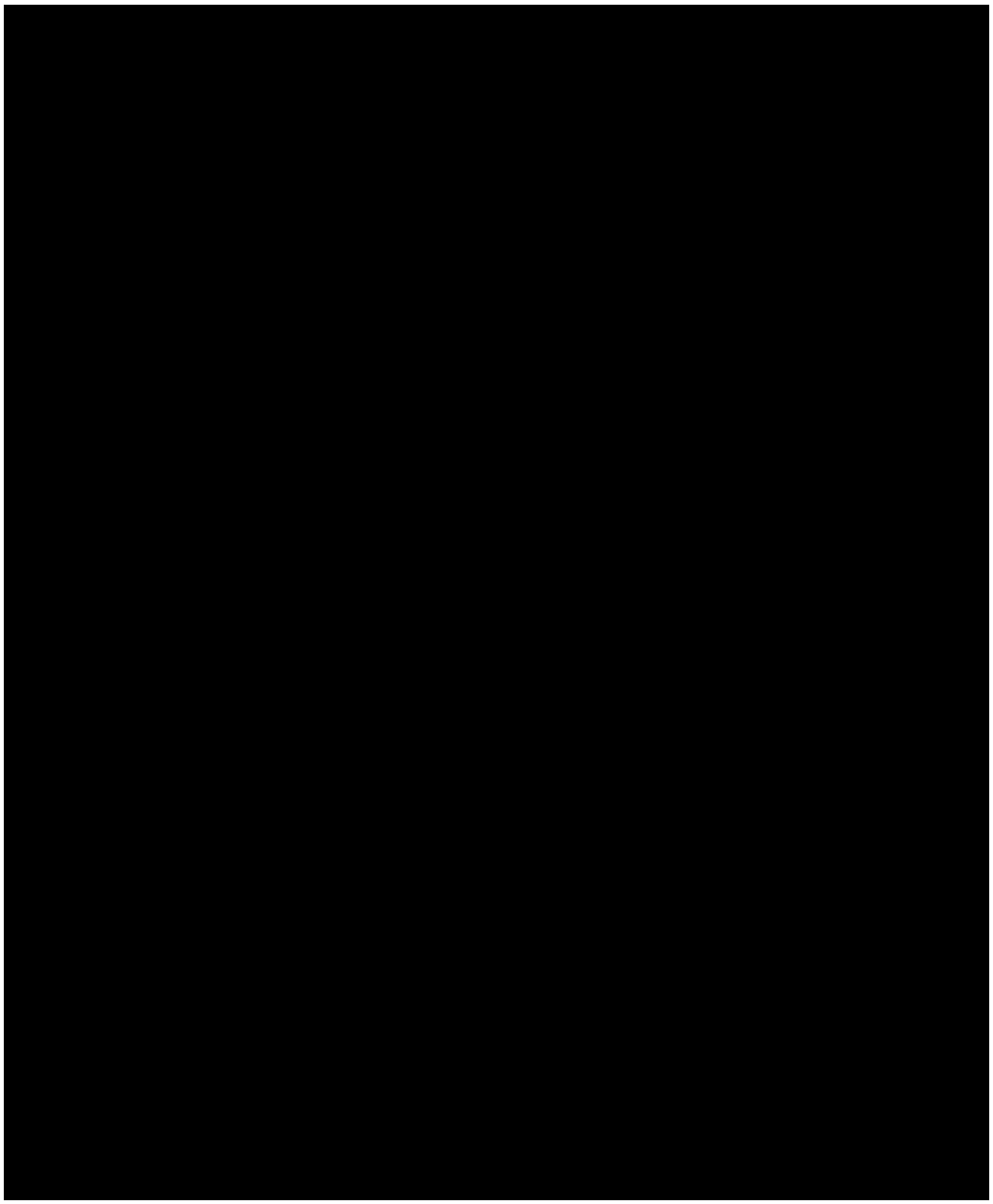


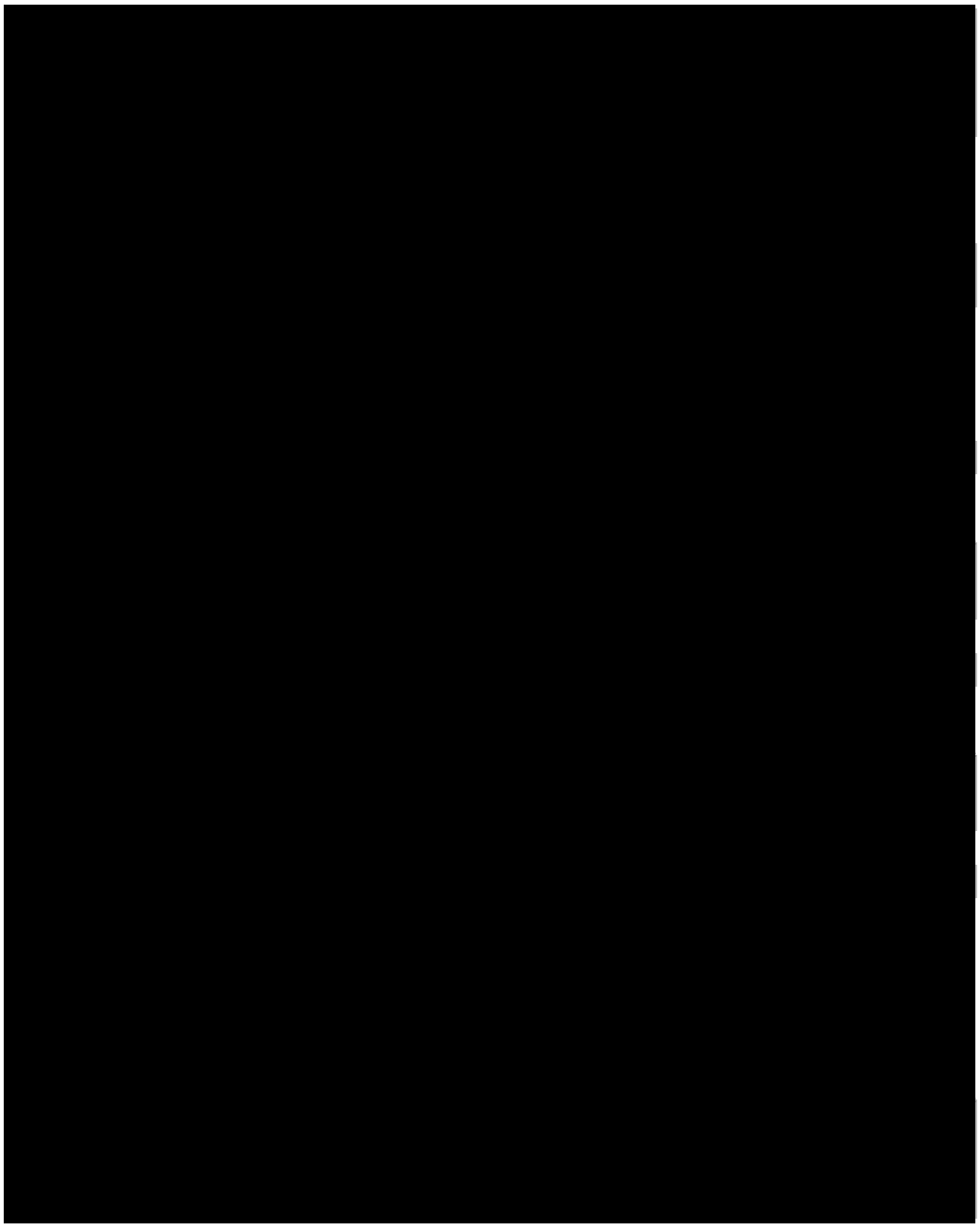


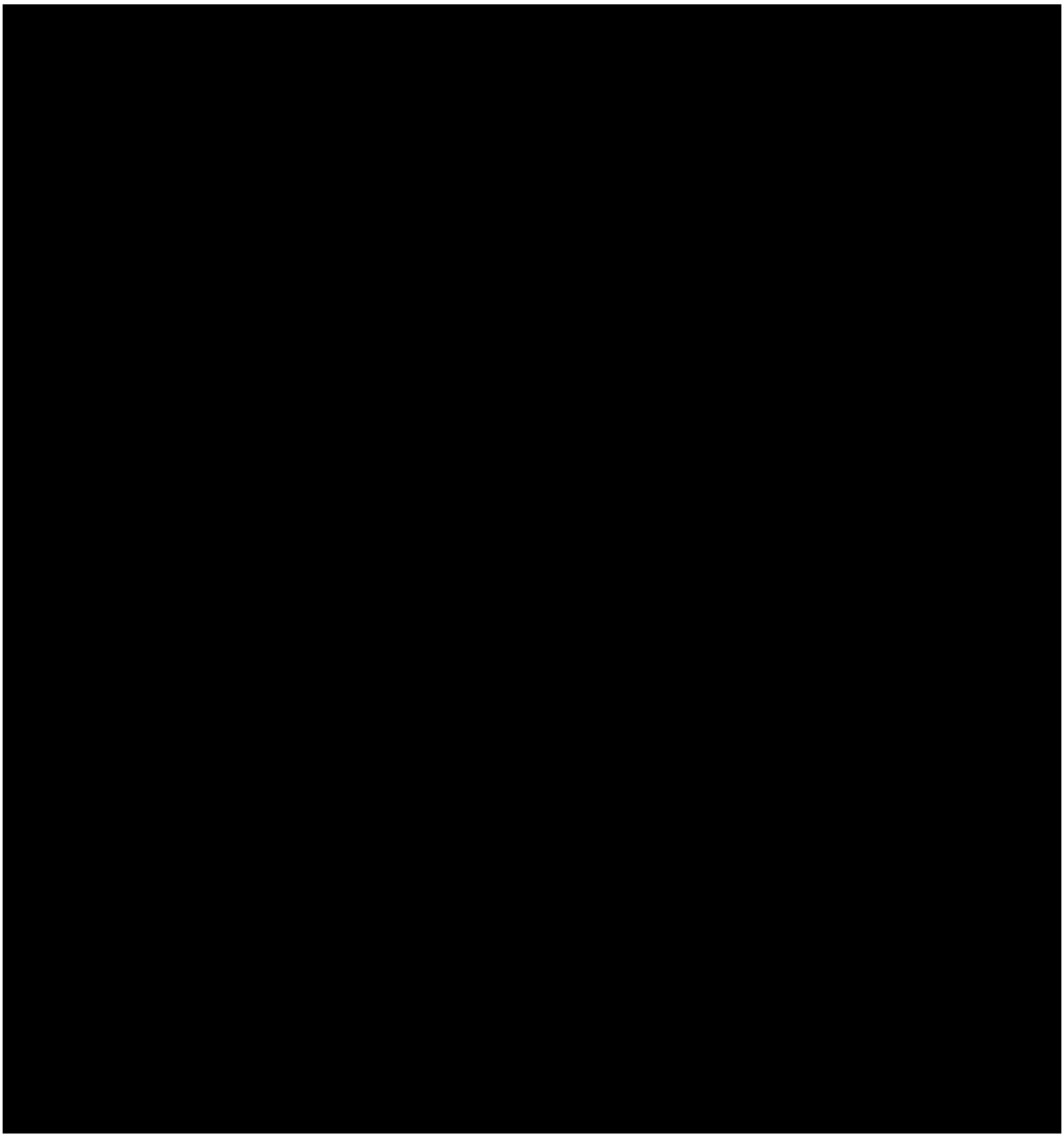


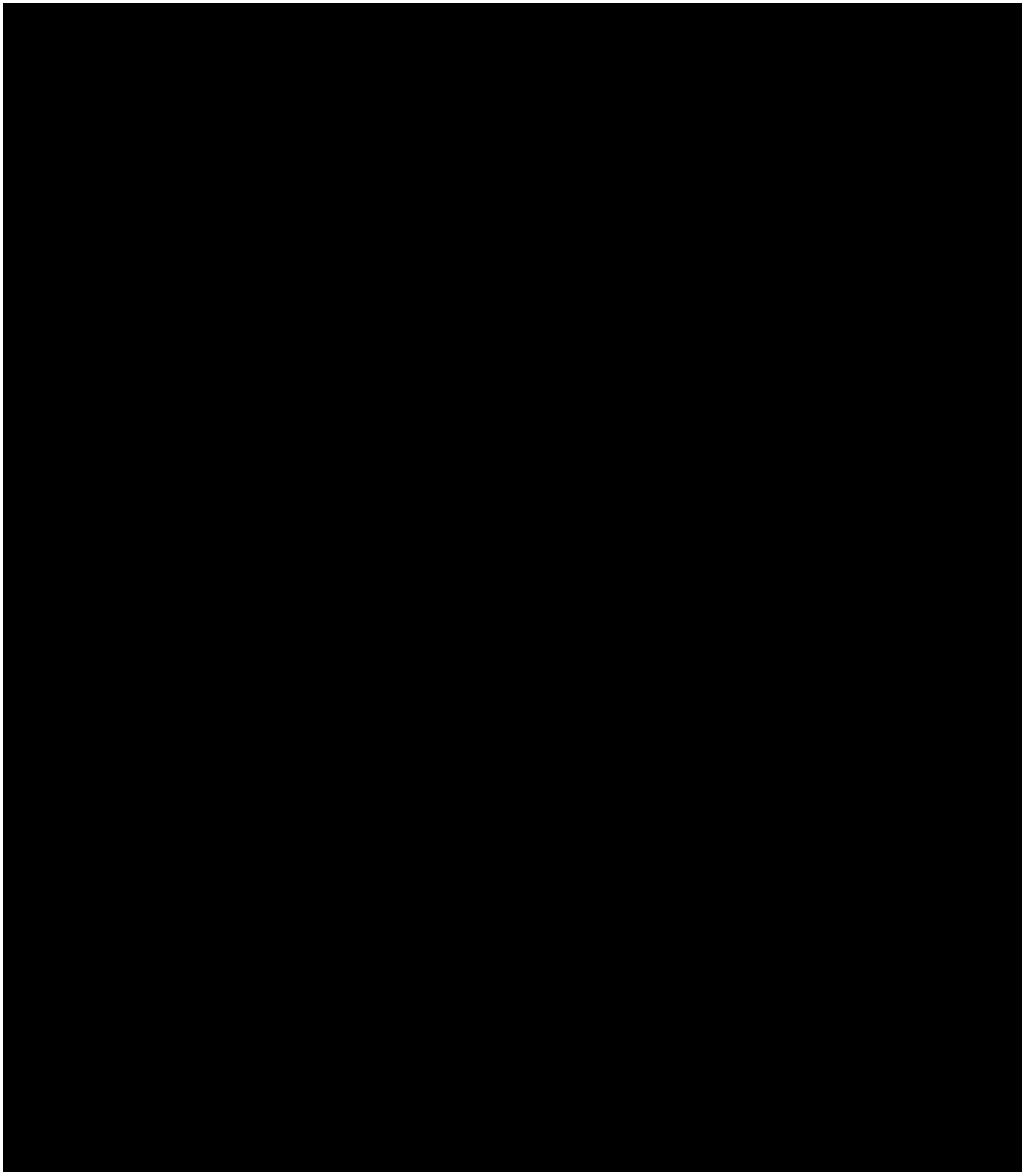


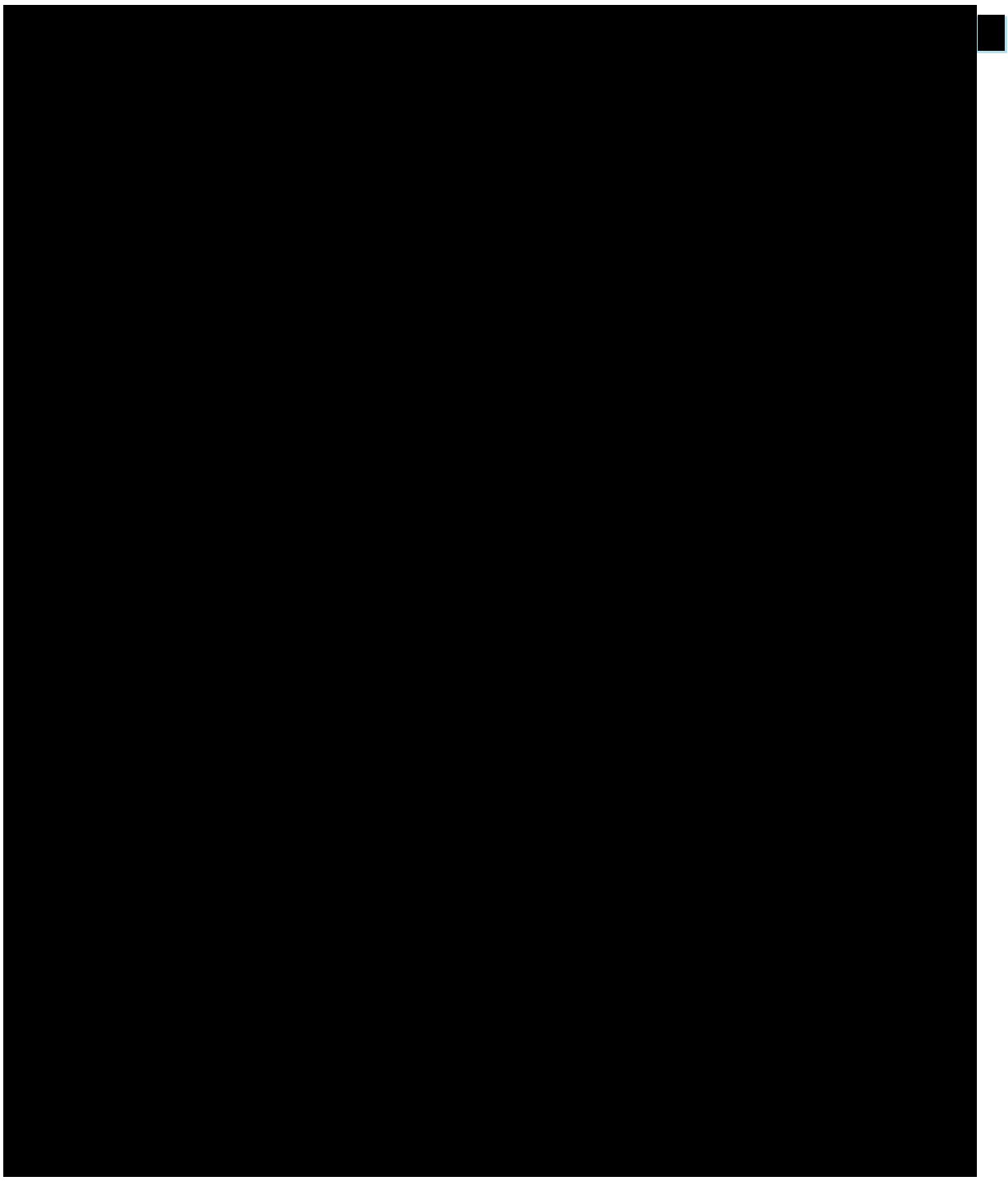


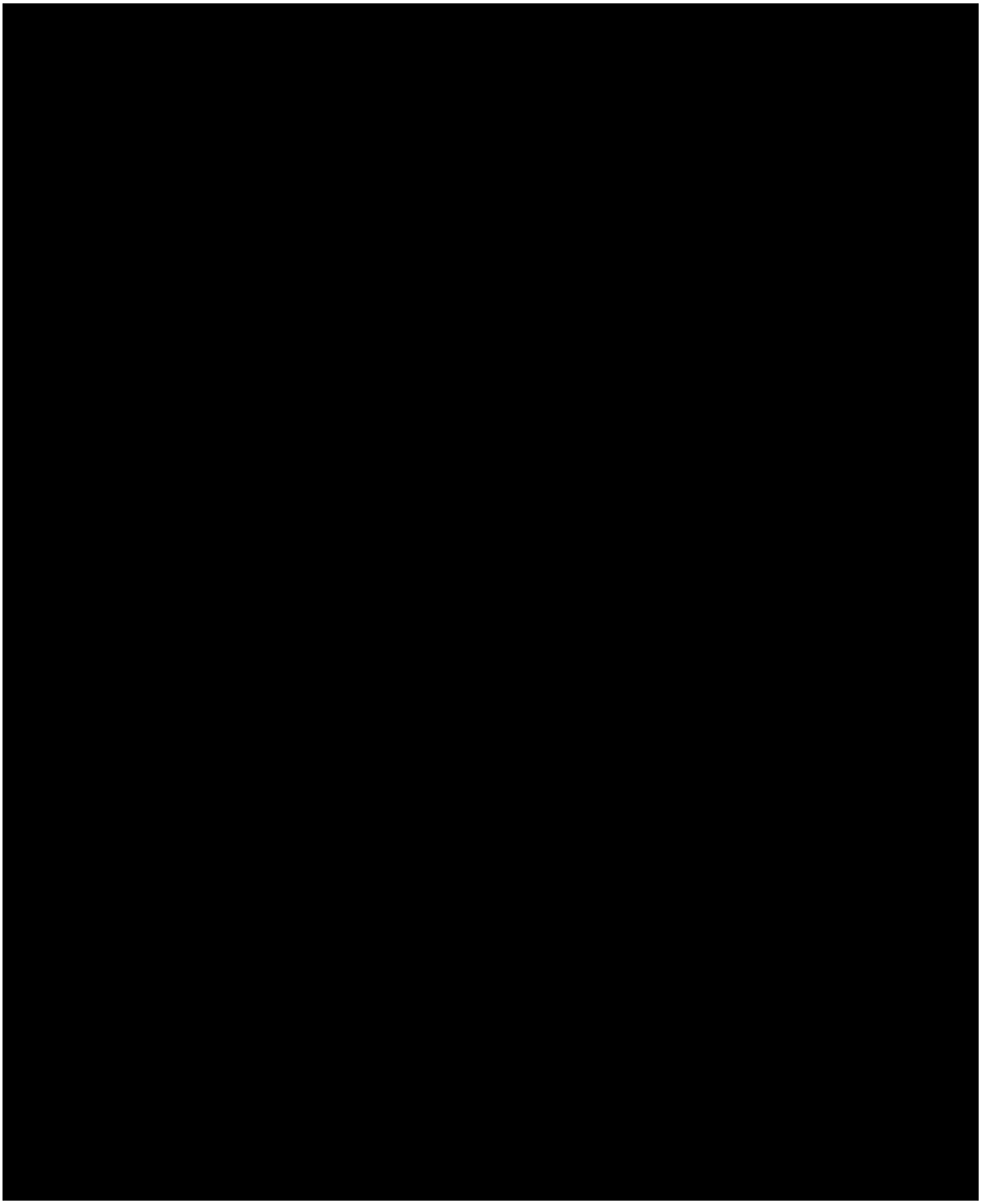


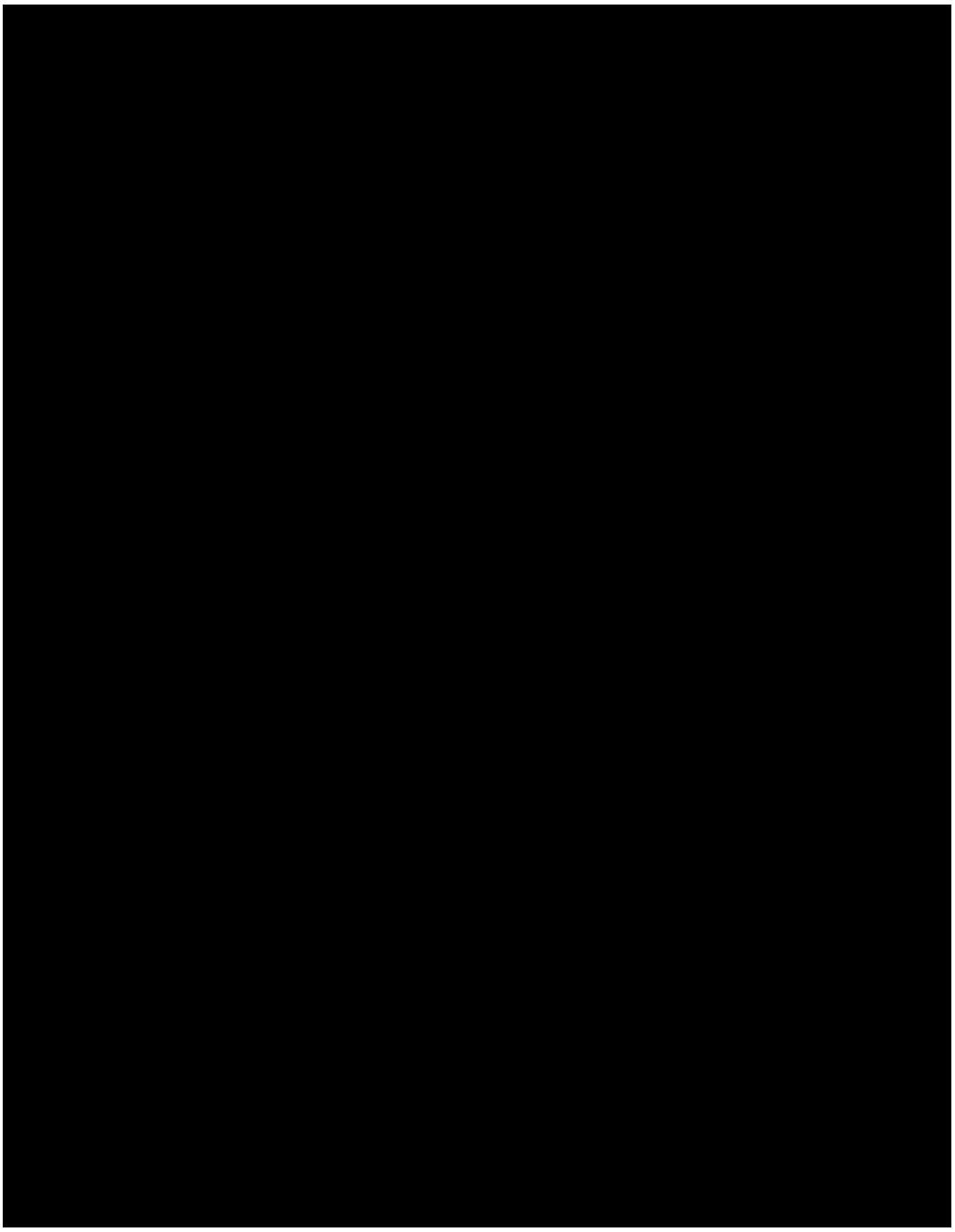


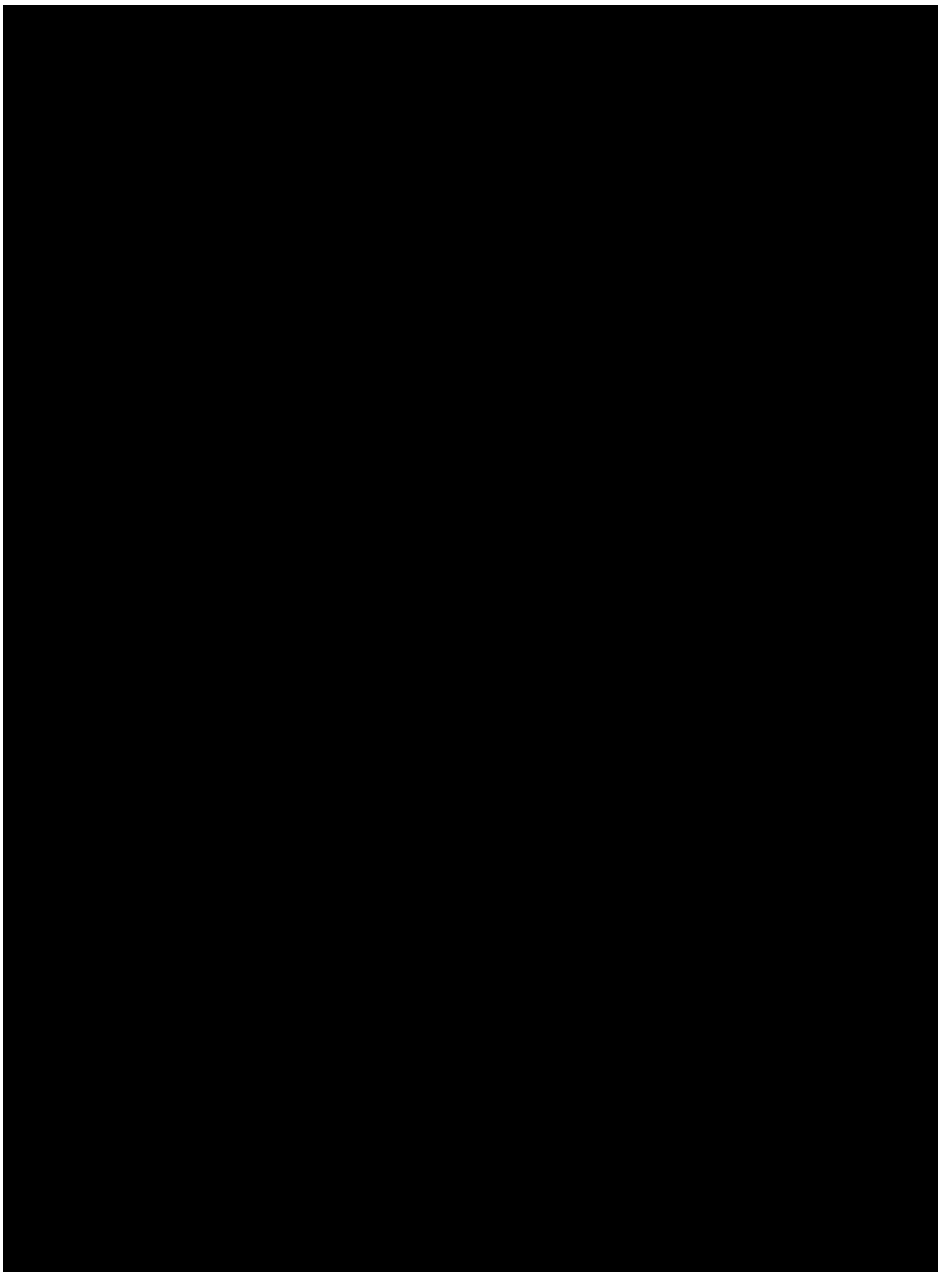


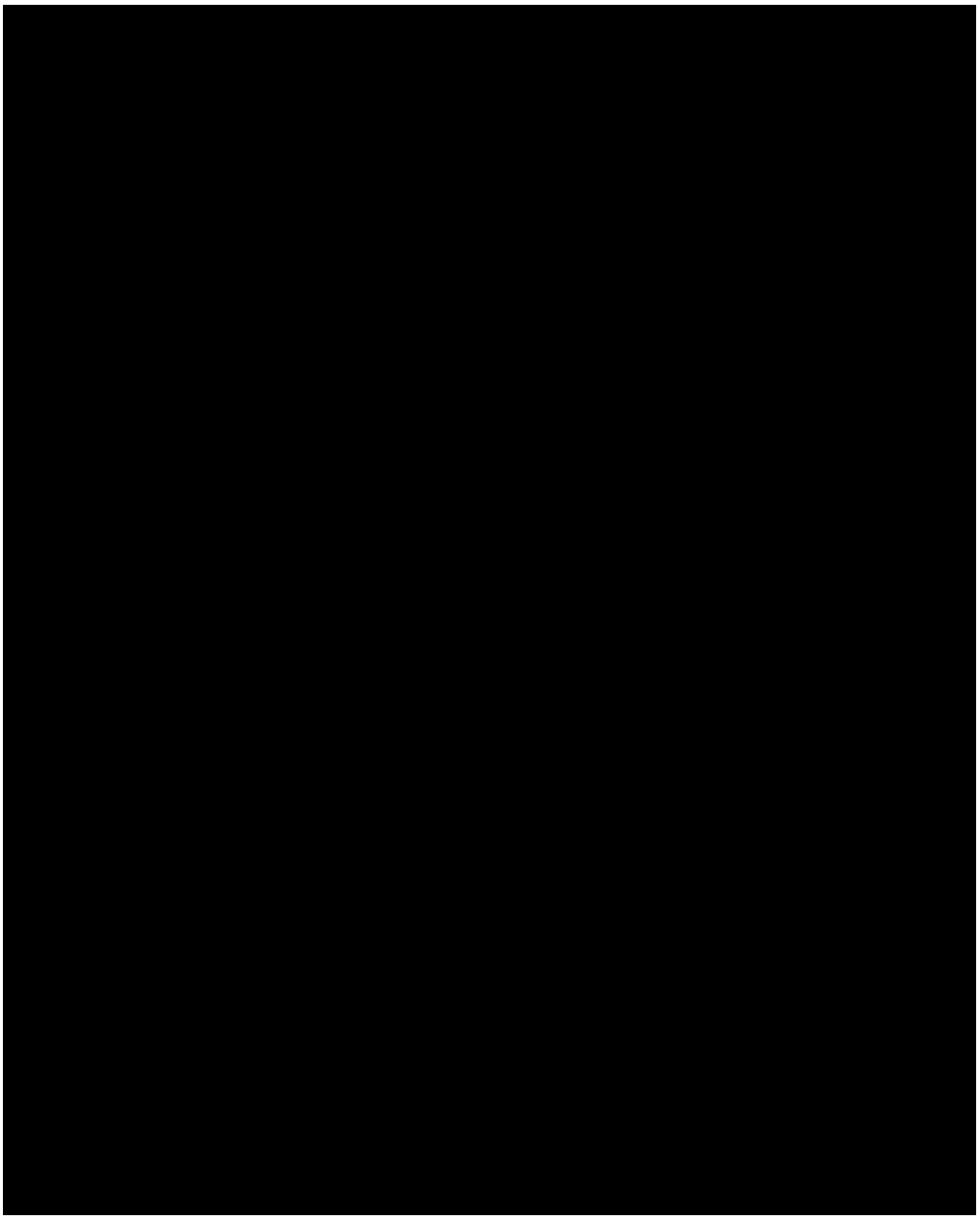


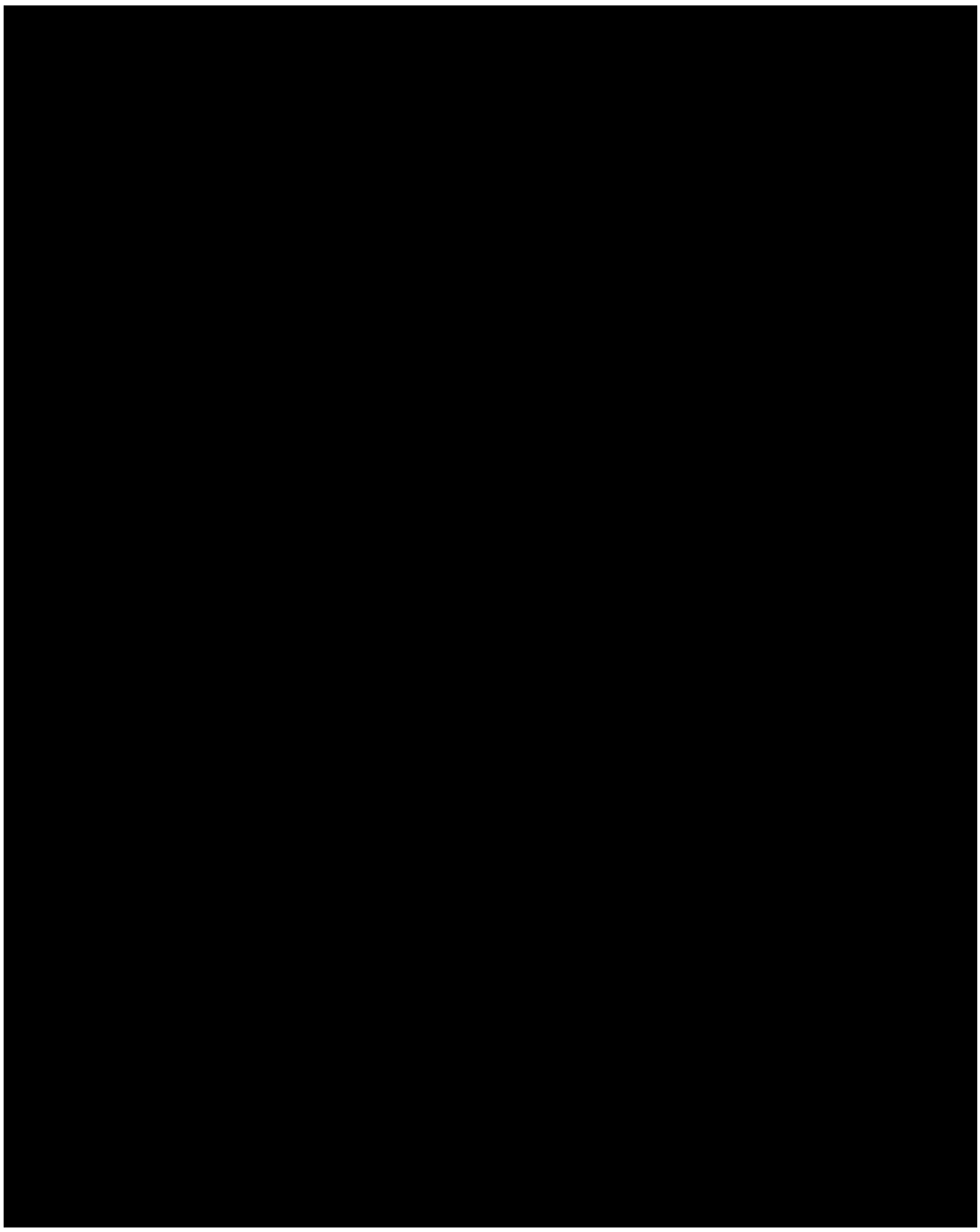


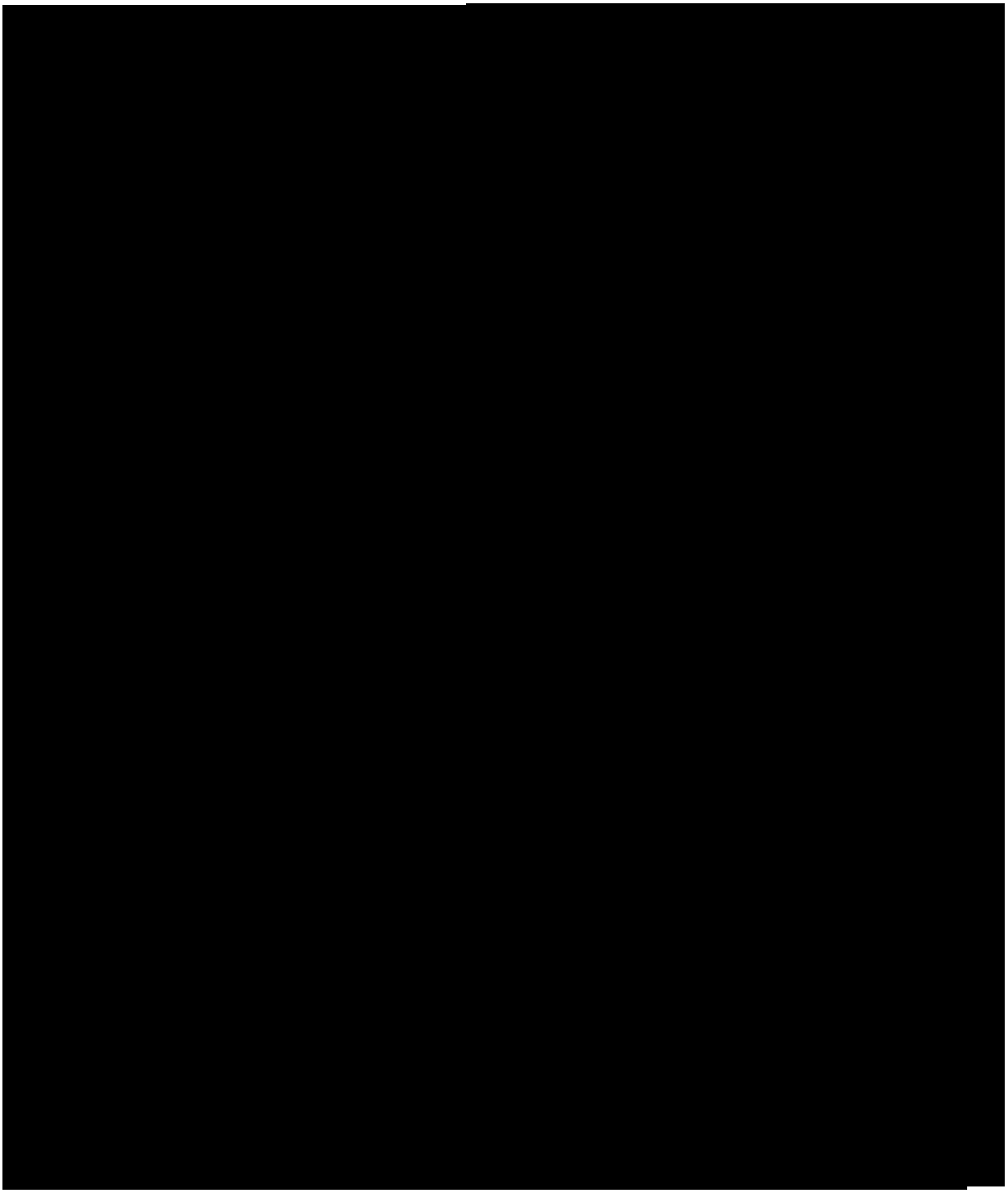


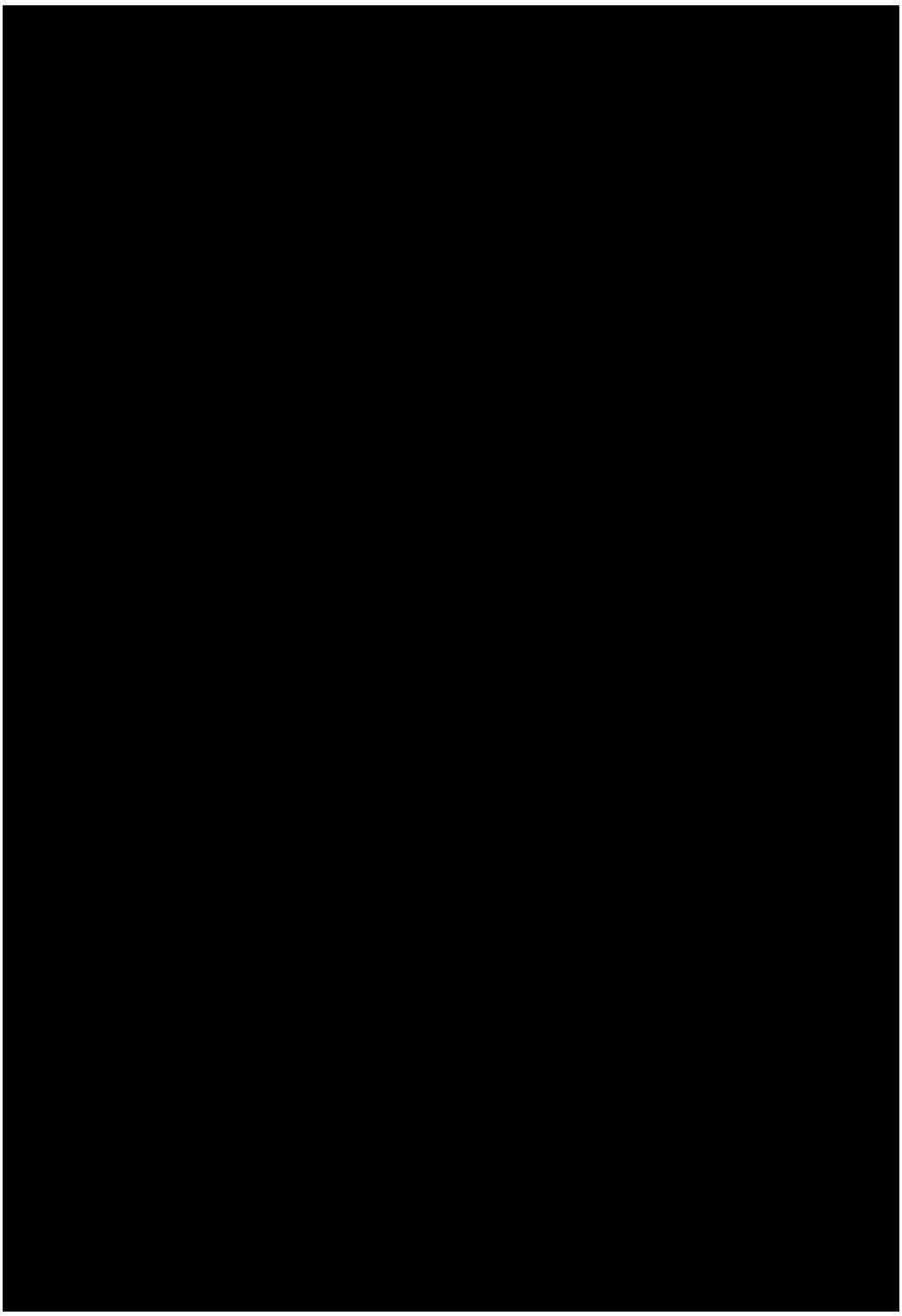


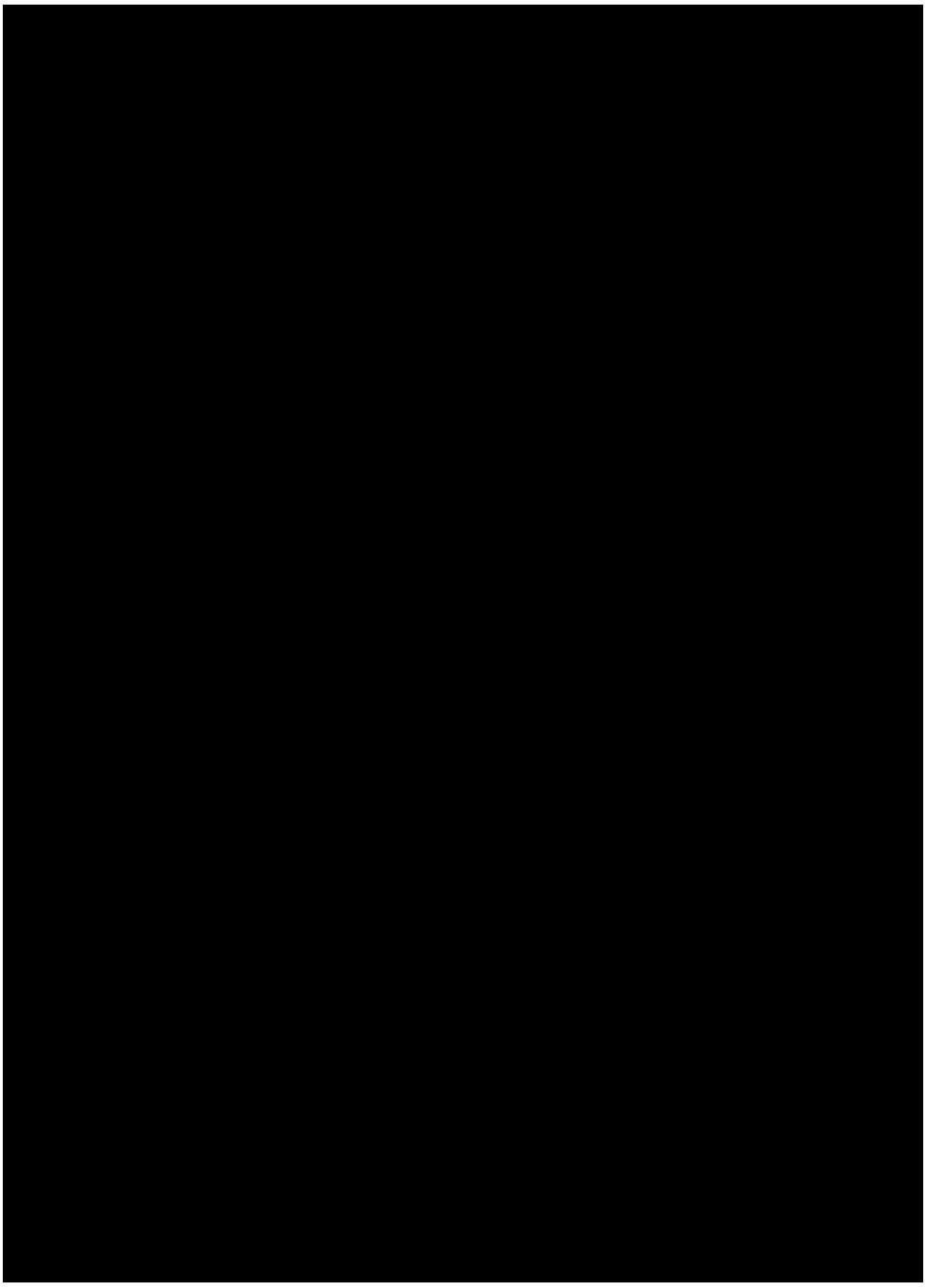


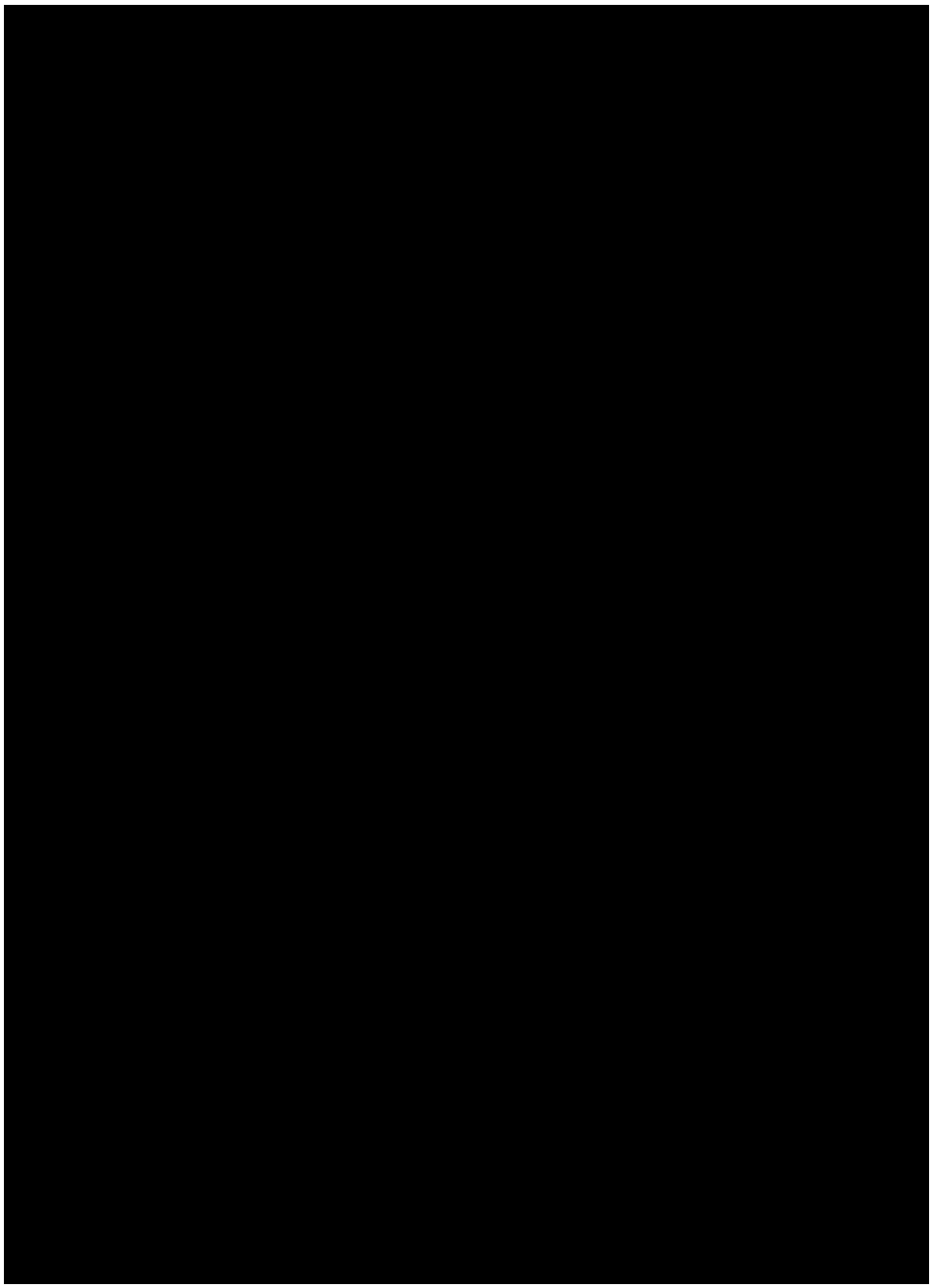


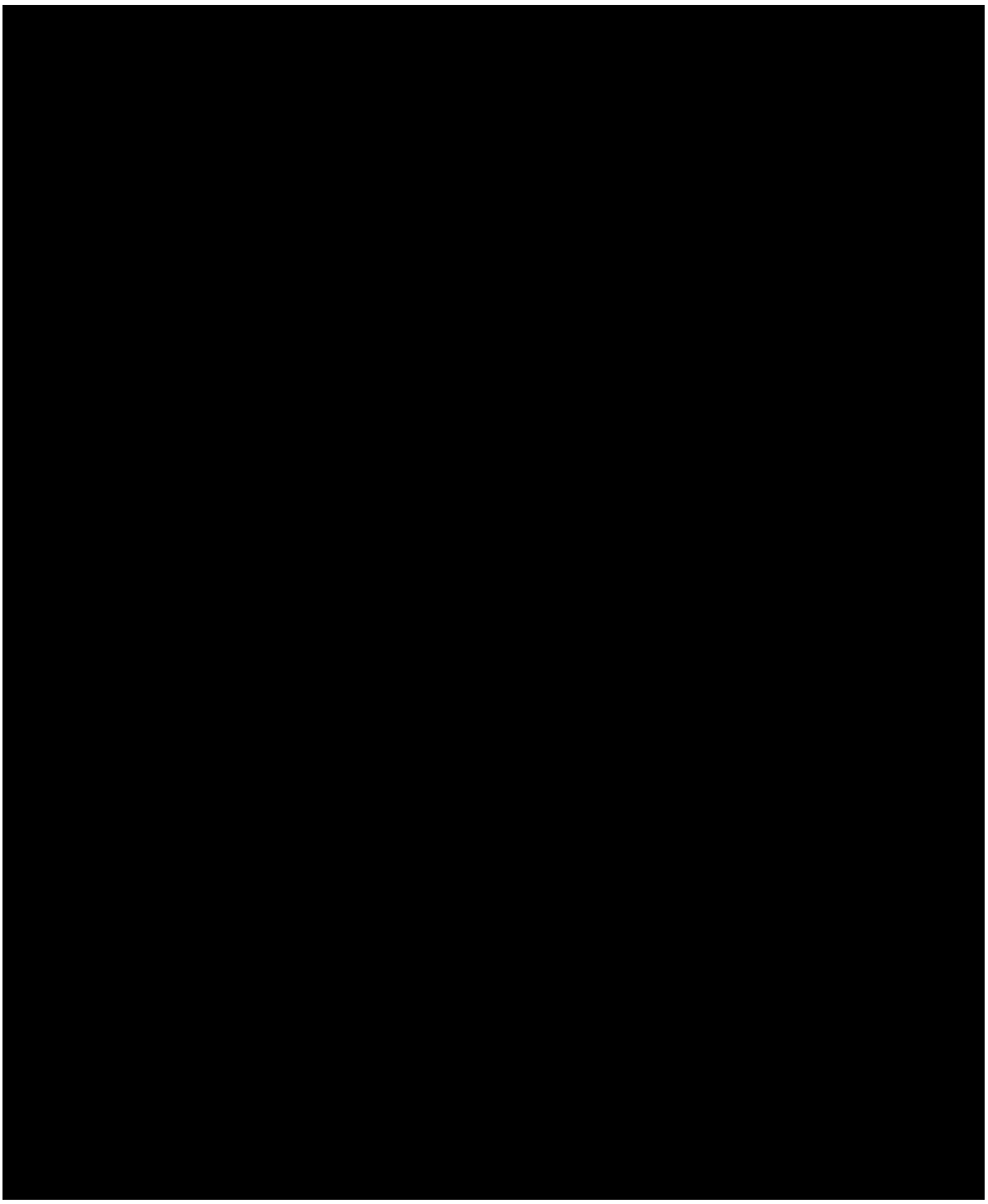


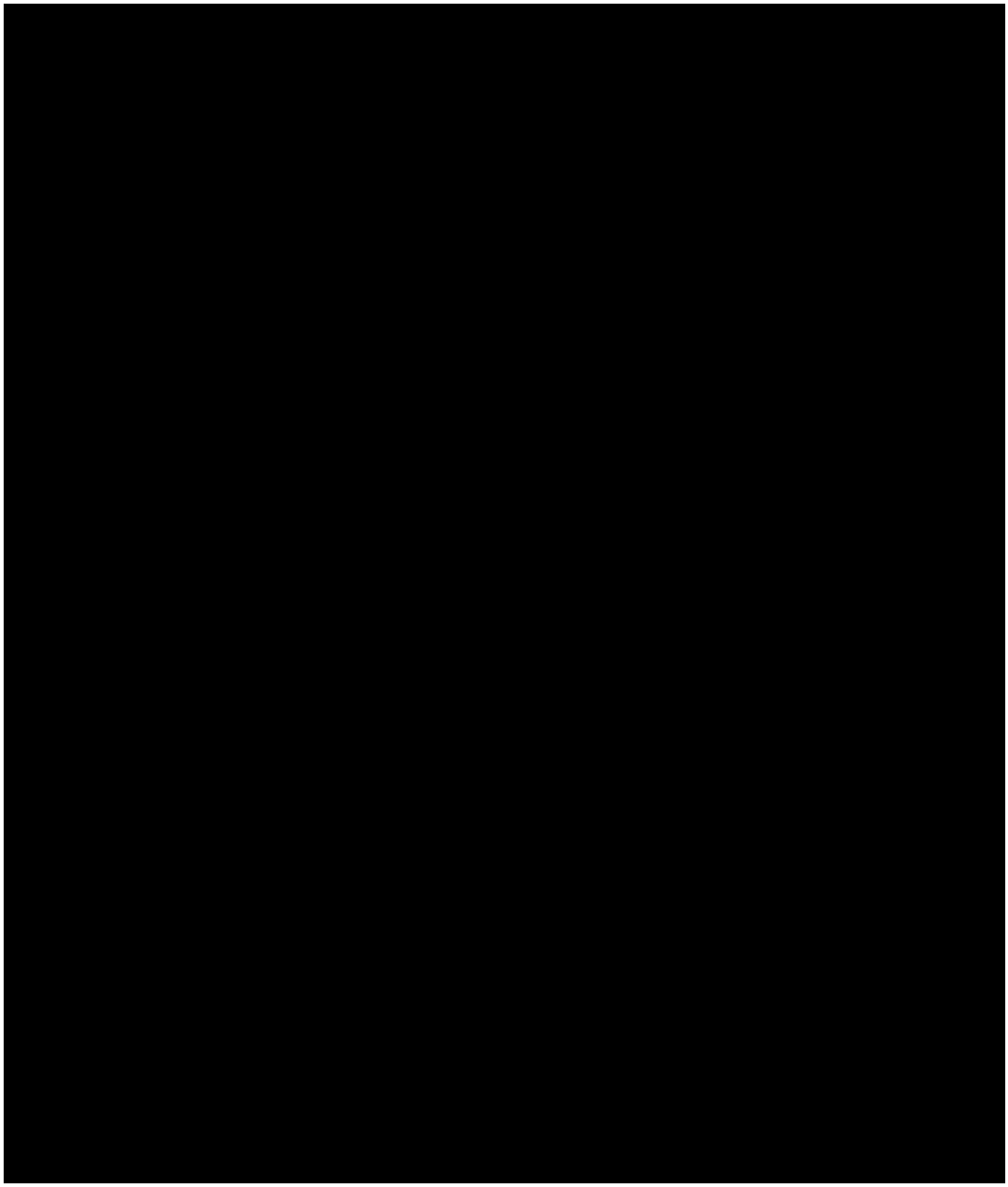


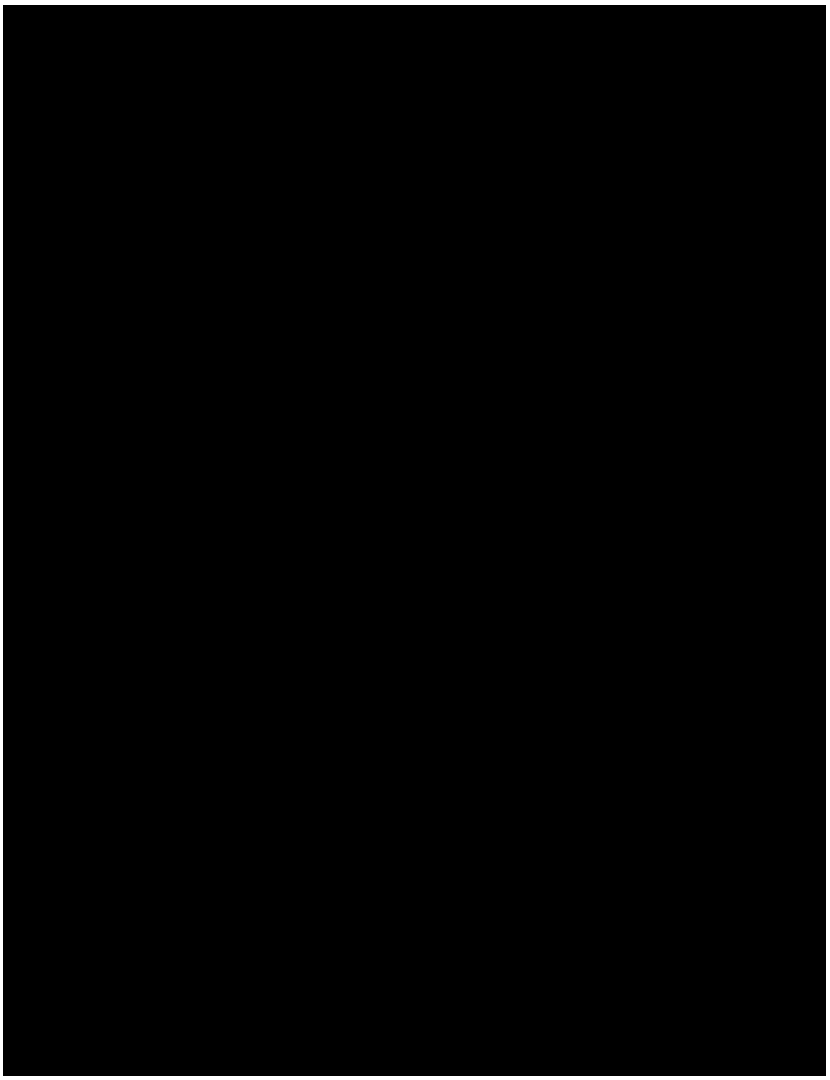


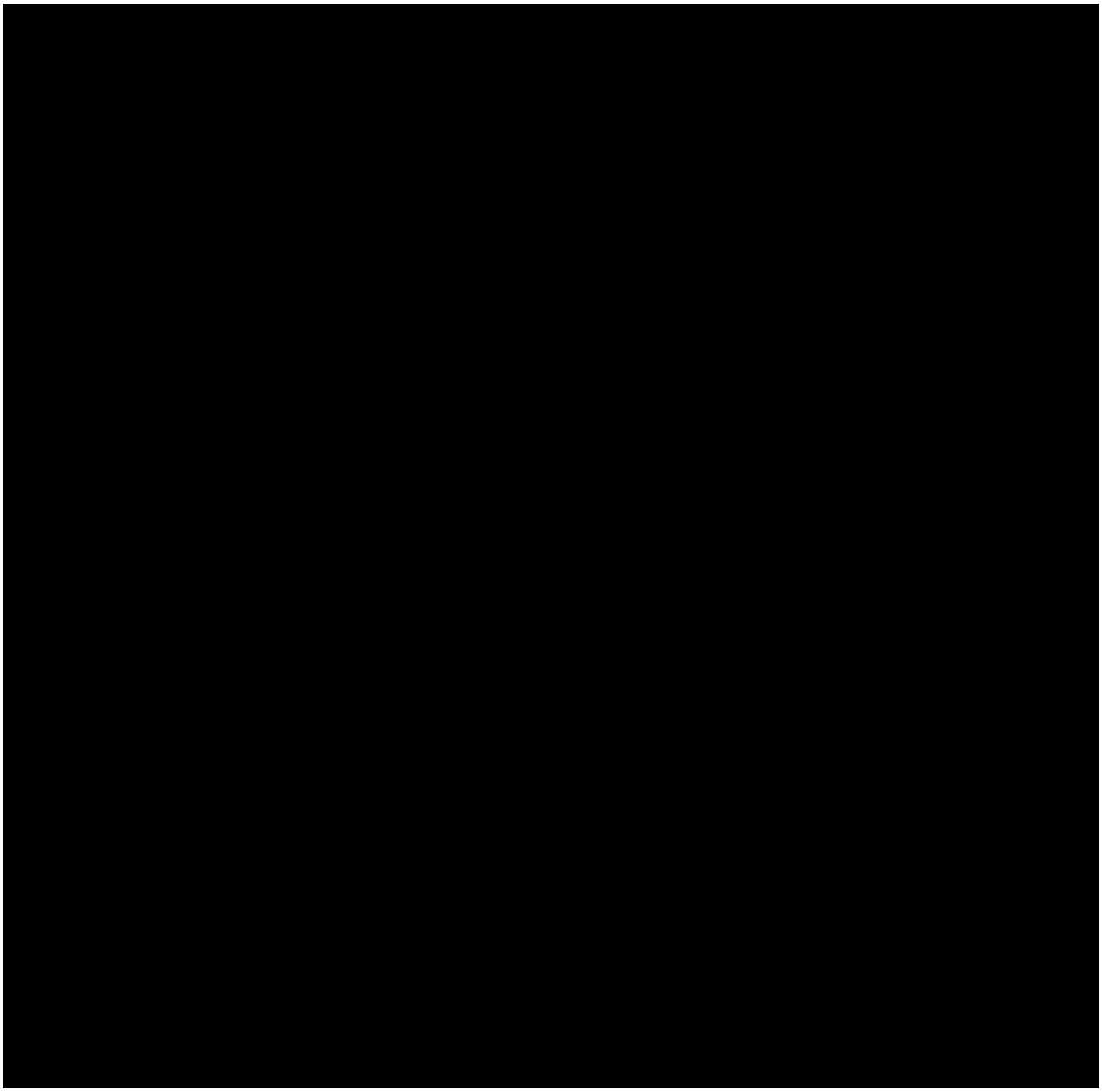


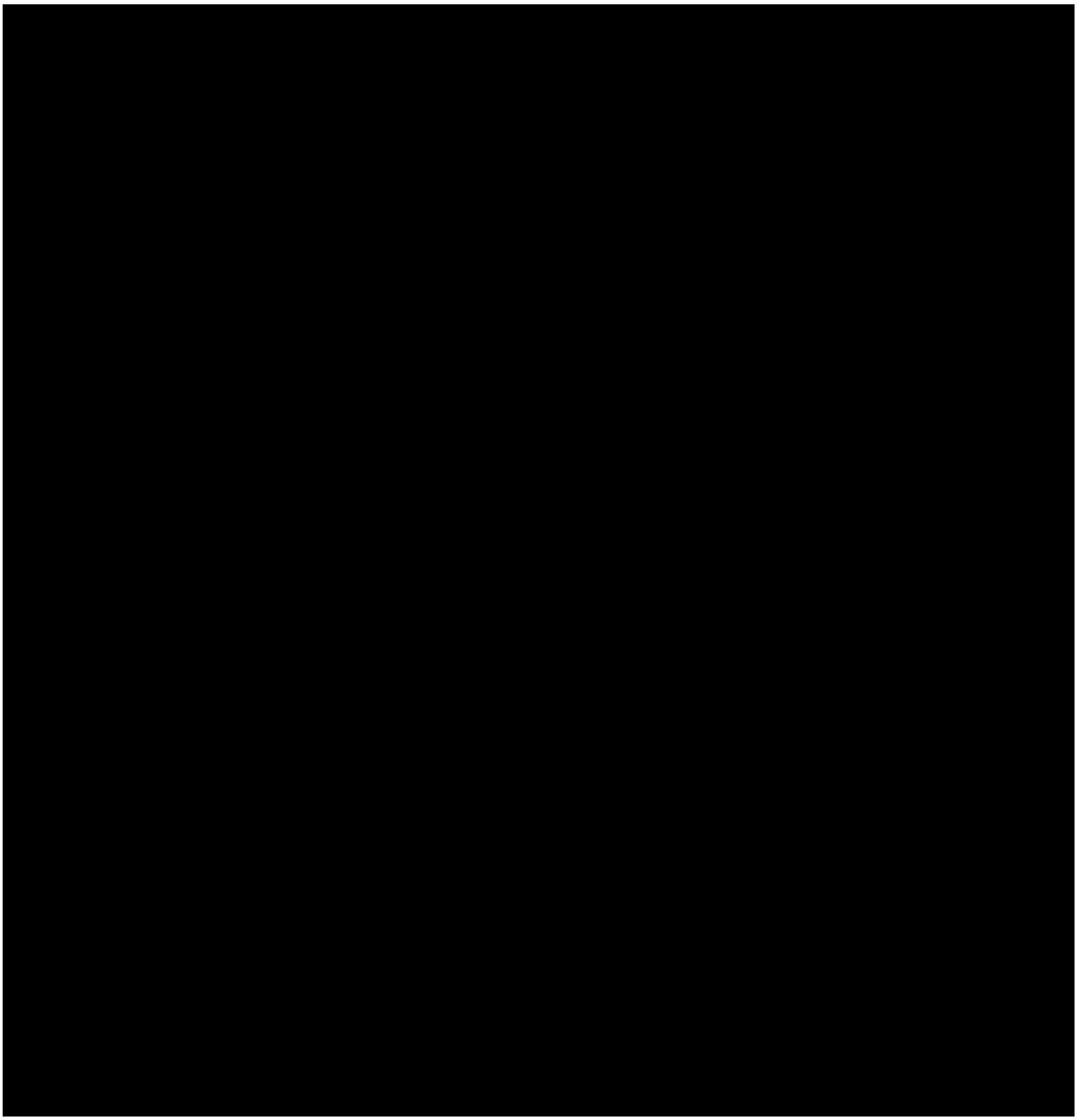


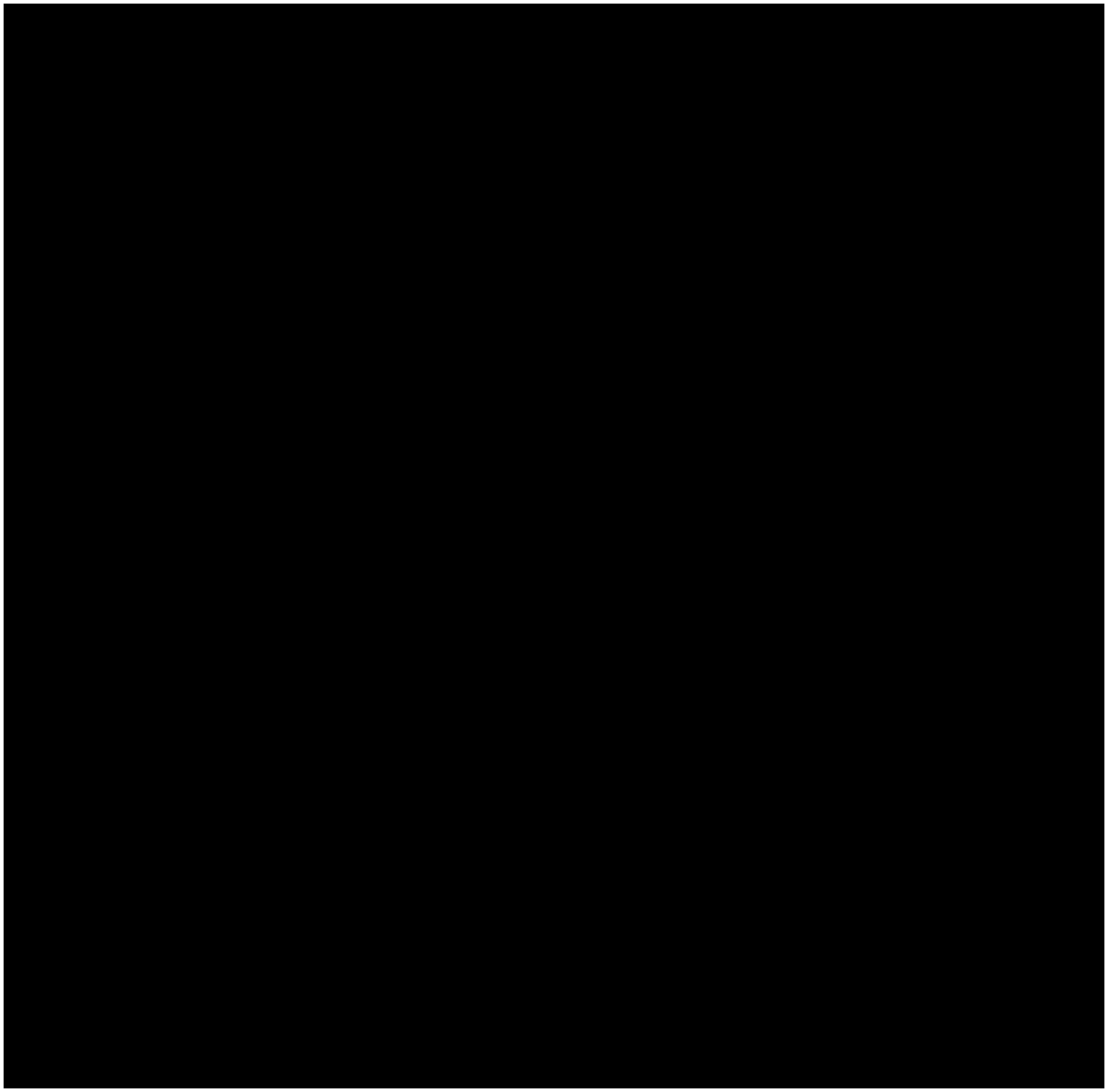


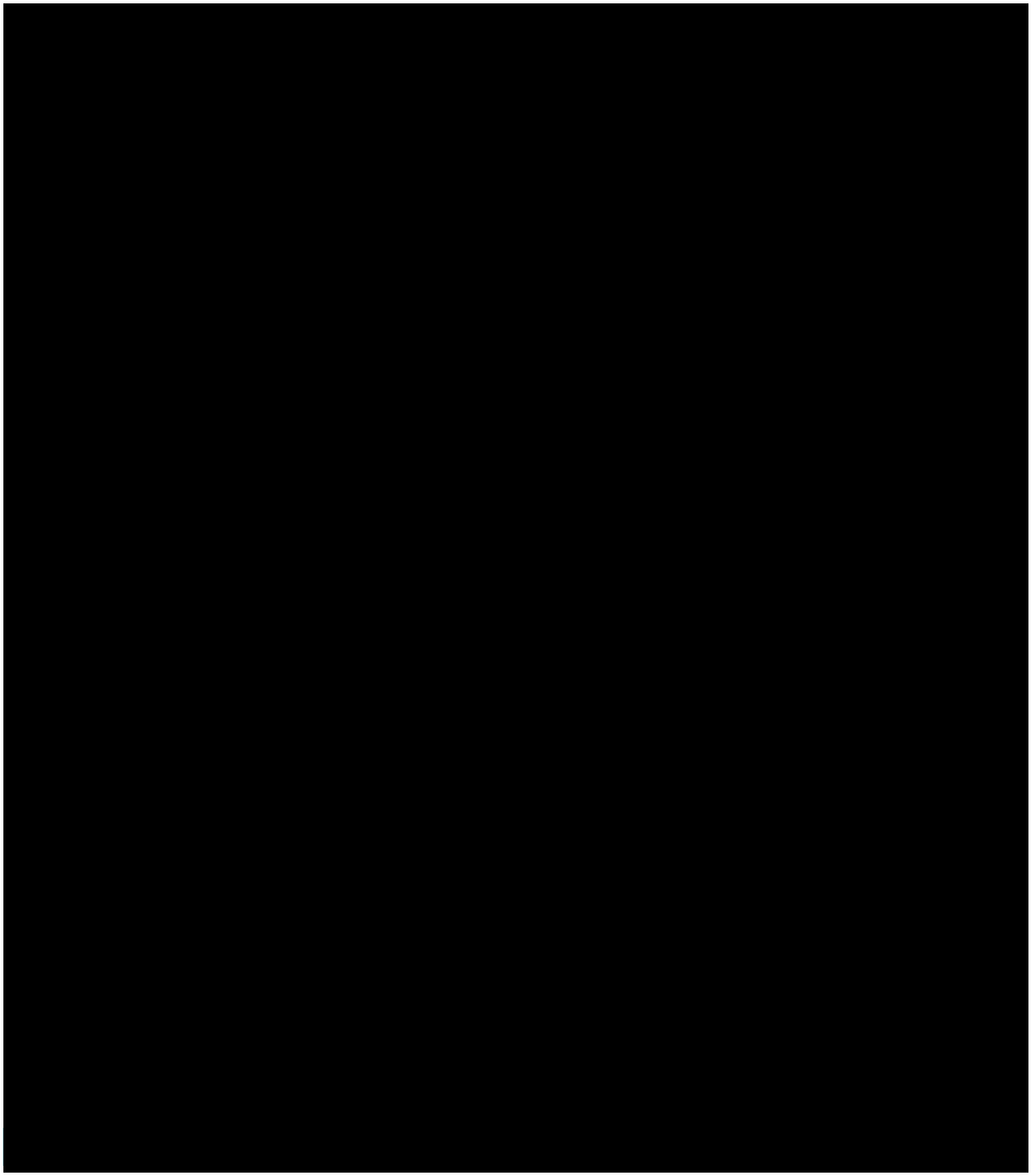


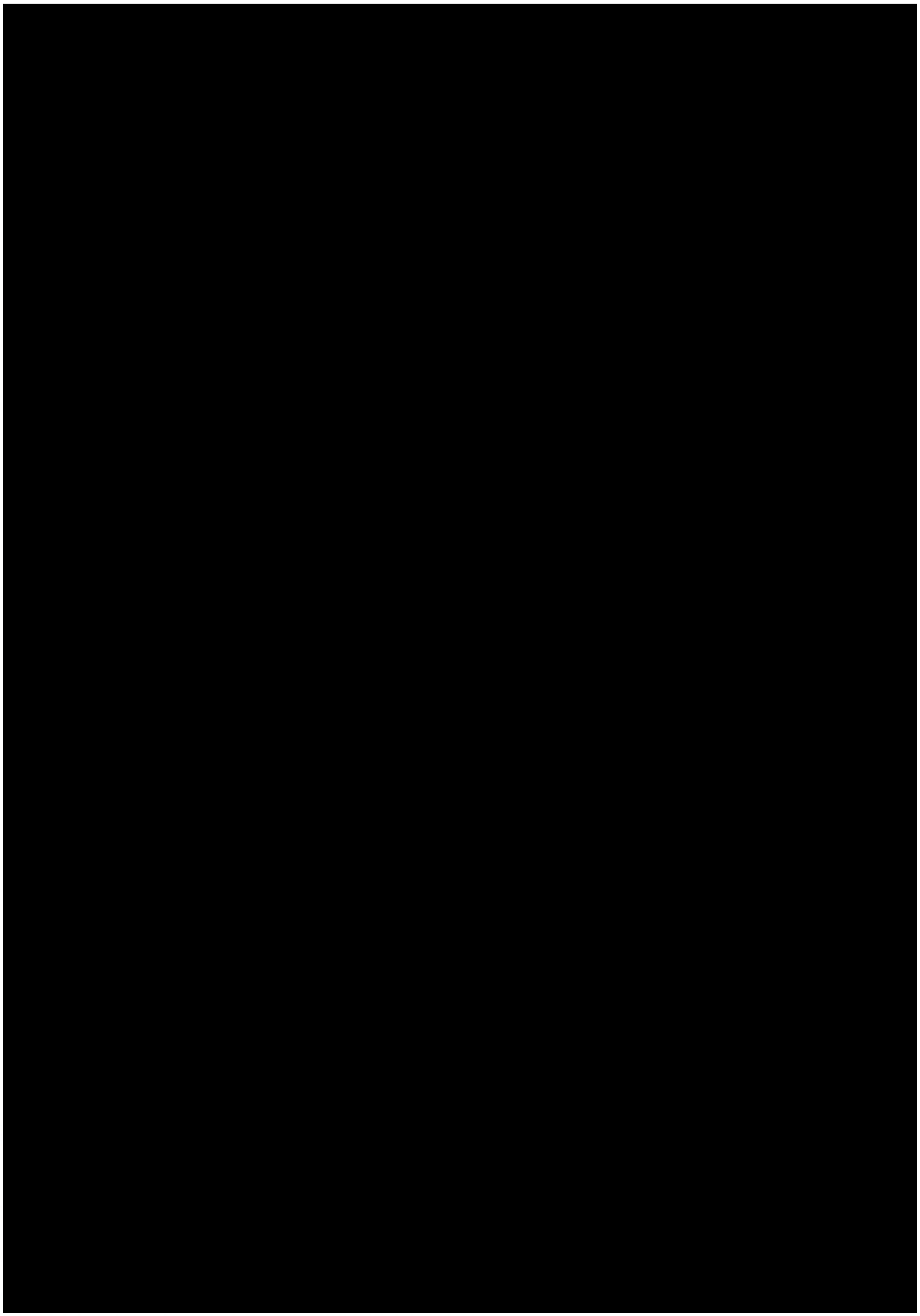


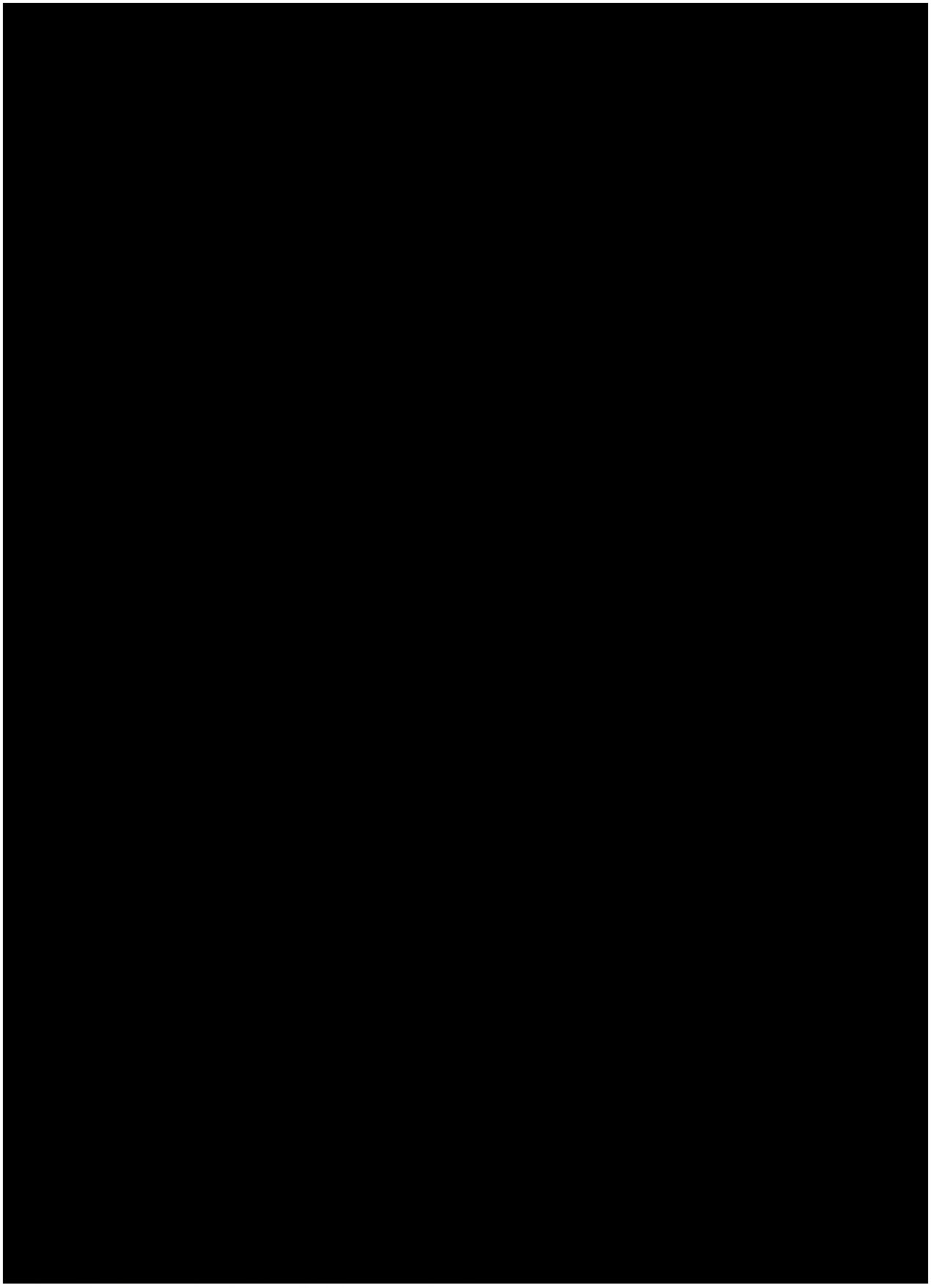












Appendix III: Environmental emission (and exposure) calculations

All details are provided in Chapter 9.

Appendix IV: List of terms and abbreviations

No

Appendix V: Overall reference list *(including data owner and confidentiality claim)*

Section No./ Reference No.	**Author(s)**	**Year**	**Title Source (laboratory) Report No. GLP; (un)published Doc. No.**	**Data protection**	**Owner**
A3.1/01	[redacted]	2002	OXONE MONOPERSULFATE COMPOUND - PHYSICOCHEMICAL PROPERTIES Source: Huntingdon Life Science Report No.: DPT 557/012940 GLP; (unpublished) Doc. No.: 119-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A3.1/02	[redacted]	2007	PHYSICAL AND CHEMICAL CHARACTERISTICS OF OXONE:UV/VISIBLE ABSORPTION, CHARACTERIZATION SPECTRUM (IR), DISSOCIATION CONSTANT, MELTING POINT, FLAMMABILITY (SOLIDS), FLAMMABILITY (CONTACT WITH WATER) AND PYROPHORIC PROPERTIES Source: Case Consulting Laboratories, Inc., Whippany, N.J., United States Report No.: 3280-38 Antec International Ltd-24458 GLP; (unpublished) Doc. No.: 119-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A3.2/01	[redacted]	2007	CALCULATION OF THE HENRY´S LAW CONSTANT - PENTAPOTASSIUM BIS (PEROXYMONOSULPHATE) BIS (SULPHATE) Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 115-001 Not GLP; (unpublished) Doc. No.: 115-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	KMPS Registration Group
A3.3/01	[redacted]	2007	PHYSICAL AND CHEMICAL CHARACTERISTICS OF KMPS	Yes (Data on existing	KMPS Registration

			P-16 - APPEARANCE, EFFECT OF PH ON SOLUBILITY, HYDROLYSIS AS A FUNCTION OF PH, SURFACE TENSION AND ACCELERATED STORAGE STABILITY Source: Case Consulting Laboratories, Inc., Whippany, N.J., United States Report No.: 3280-27 Antec International Ltd-21226 Not GLP; (unpublished) Doc. No.: 119-003	a.s. submitted for the first time for entry into Annex I.)	Group
A3.3/02	Anonymous	2001	FRENCH/EUROPEAN STANDARD NF EN 12678 - AFNOR 2001 - CHEMICALS USED FOR TREATMENT OF WATER INTENDED FOR HUMAN CONSUMPTION - POTASSIUM PEROXOMONSULFATE Source: Associoation Francaise de Normalisation Report No.: NF EN 12678 N-20040401-063271-T Not GLP; (unpublished) Doc. No.: 989-001	No	n.a.
A3.4/01	Anonymous	2005	SPECTRUM-PEAK REPORT - OXONE Source: Not indicated Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 117-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A3.4/02	Turner, P. Kouris, N.	2005	FTIR DEMONSTRATION - INSTRUMENT: TENSOR 27 WITH SINGLE REFLECTION DIAMOND ATR (GOLDEN GATE) Source: Not indicated Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 117-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A3.9/01	[redacted]	2007	CALCULATION OF THE LOG OCTANOL-WATER PARTITION COEFFICIENT OF POTASSIUM PEROXOMONOSULFATE Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 848-006 Not GLP; (unpublished) Doc. No.: 114-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	KMPS Registration Group
A3.11.5/01	[redacted]	2008	KMPS - LABORATORY STUDY OF RELATIVE SELF-IGNITION TEMPERATURE Source: E.I. DuPont de Nemours and Company DuPont Haskell laboratory Report No.: DuPont 24463 GLP; (unpublished) Doc. No.: 142-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A3.15/01	[redacted]	2007	KMPS - LABORATORY STUDY OF EXPLOSIVE PROPERTIES	Yes (Data on existing	KMPS Registration

			Source: E.I. DuPont de Nemours and Company Agricultural Products Report No.: DuPont 22465 GLP; (unpublished) Doc. No.: 141-001	a.s. submitted for the first time for entry into Annex I.)	Group
A3.16/01	Turner, B.	2003	OXONE MONOPERSULFAE COMPOUND - OXIDISING PROPERTIES (SOLIDS) Source: Huntingdon Life Science Report No.: DPT636/024171 GLP; (unpublished) Doc. No.: 143-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A3.16/02	Comb, A.L.	2002	OXONE - UN TEST 0.1: TEST FOR OXIDISING SOLIDS Source: Huntingdon Life Science Report No.: DPT630/023228 GLP; (unpublished) Doc. No.: 143-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A3.17/01	[redacted]	2008	Physical and Chemical Properties of Oxone PS-16; Storage Stability OPPTS TEST GUIDELINES, SERIES 830, PRODUCT PROPERTIES: 830.6317 Source: Case Consulting Laboratories, Inc., Whippany, N.J., United States Report No.: 3280-28 Not GLP; (unpublished) Doc. No.: 145-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	KMPS Registration Group
A6.1.1/01	[redacted]	2001	OXONE MONOPERSULFATE COMPOUND - ACUTE ORAL TOXICITY TO THE RAT (ACUTE TOXIC CLASS METHOD) Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 521-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.1.2/01	[redacted]	2001	OXONE MONOPERSULFATE COMPOUND - ACUTE DERMAL TOXICITY TO THE RAT Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 522-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.1.3/02	[redacted]	1995	INHALATION MEDIAN LETHAL CONCENTRATION (LC50) STUDY WITH H-20981 IN RATS Source: [redacted] Report No.: [redacted]	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH

			[redacted] GLP; (unpublished) Doc. No.: 528-002		
A6.1.3/01	[redacted]	1980	INHALATION LETHAL CONCENTRATION (LC50) Source: [redacted], Report No. [redacted] Not GLP; (unpublished) Doc. No. 523-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.1.4/01	[redacted]	1983	BERICHT ÜBER DIE PRÜFUNG DER LOKALEN REIZWIRKUNG VON CAROAT NACH EINMALIGER APPLIKATION AN DER HAUT DES KANINCHENS (PATCH TEST) - INCLUDING ENGLISH TRANSLATION Source: [redacted] Report No.: [redacted] Not GLP; (unpublished) Doc. No.: 565-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	United Initiators
A6.1.4/02	[redacted]	1985	RD/1/85: ACUTE EYE IRRITATION/CORROSION TEST IN THE RABBIT Source: [redacted] Report No.: [redacted] Not GLP; (unpublished) Doc. No.: 566-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	United Initiators
A6.1.5/01	[redacted]	2001	OXONE MONOPERSULFATE COMPOUND - SKIN SENSITIZATION TO THE GUINA-PIG (MAGNUSSON & KLIGMAN METHOD) Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 567-007	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.2.1	Morris, M.E., Levy, G.	1983	ABSORPTION OF SULFATE FROM ORALLY ADMINISTERED MAGENSIUM SULFATE IN MAN Source: J. Toxicol-Clin. Toxicol., 1983, 20, (2), 107-114 Not GLP; (published) Doc. No. 592-002	No	N.R.
A6.2.1	Anonymous	2005	OPINION OF THE SCIENTIFIC PANEL ON DIETETIC PRODUCTS; NUTRITION AND ALLERGIES ON A REQUEST FROM THE COMMISSION RELATED TO THE TOLERABLE UPPER INTAKE LEVEL OF POTASSIUM Source. The EFSA Journal, 2005, 193, 1-19 Not GLP; (published) Doc. No. 592-003	No	N.R
A6.3.1/01	[redacted]	2001	OXONE MONOPERSULFATE COMPOUND - PRELIMINARY	Yes (Data on existing	LANXESS Deutschland

			TOXICITY STUDY BY ORAL ADMINISTRATION TO CD RATS FOR 14 DAYS Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 531-002	a.s. submitted for the first time for entry into Annex I.)	GmbH
A6.3.3/01	[redacted]	1981	SUBACUTE INHALATION TOXICITY OF OXONE Source: [redacted] Report No.: [redacted] Not GLP; (unpublished) Doc. No.: 531-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.4.1/01	[redacted].	2002	OXONE MONOPERSULFATE COMPOUND - TOXICITY STUDY BY ORAL ADMINISTRATION TO CD RATS FOR 13 WEEKS (VOLUME 1 AND 2) Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 533-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.6.1/01	[redacted]	2001	OXONE MONOPERSULFATE COMPOUND - BACTERIAL REVERSE MUTATION ASSAY WITH AN INDEPENDENT REPEAT ASSAY Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 557-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.6.2/01	[redacted]	2001	OXONE MONOPERSULFATE COMPOUND - IN VITRO MAMMALIAN CHROMOSOME ABERRATION TEST IN HUMAN LYMPHOCYTES (AMENDED FINAL REPORT) Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 557-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.6.3/01	[redacted]	2002	OXONE MONOPERSULFATE COMPOUND - MAMMALIAN CELL MUTATION ASSAY Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 557-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.6.3/02	[redacted]	2019	In vitro Mammalian Cell Gene Mutation Assay (Thymidine Kinase Locus/TK+/-) in Mouse	Yes (Data on existing active substance	LANXESS Deutschland GmbH, United

			Lymphoma L5178Y Cells with KMPS (technical) Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 557-005	(a.s.) submitted for the first time for approval of the a.s.)	Initiators GmbH
A6.6.4/01	[redacted]	2001	OXONE MONOPERSULFATE COMPOUND - MAMMALIAN ERYTHROCYTE MOUSE MICRONUCLEUS TEST Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 557-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.6.5/01	[redacted]	2021	*In vivo* Mammalian Alkaline A Assay of (Liver, Forestomach, Glandular Stomach and Duodenum) Cells in Rats with KMPS Triple Salt [CAS No. 70693-62-8] Administered on 2 consecutive Days. Source: Report No.: [redacted] GLP; (unpublished) Doc. No. 557-006	Yes (Data on existing active substance (a.s.) submitted for the first time for approval of the a.s.)	LANXESS Deutschland GmbH, United Initiators GmbH
A6.6.5	Anonymous	2005	IUCLID - DATA SET - DISODIUM PEROXODISULFATE (PEROXYDISULFURIC ACID, DISODIUM SALT) - CAS No. 7775-27-1 Source: OECD HPV Chemicals Programme Not GLP, (published in the Internet) Doc. No.: 987-006	No	N.R.
A6.8.1/01	[redacted]	2004	OXONE MONOPERSULFATE COMPOUND - DEVELOPMENT TOXICITY STUDY IN RATS Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 551-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.12.1/01	[redacted]	2005	POTASSIUMPEROXOMONOSULFATE - OCCUPATIONAL MEDICAL STATEMENT Source: Not relevant Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 574-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	United Initiators
A6.12.2/01	[redacted]	1992	100-PERSON HUMAN PATCH TEST WITH AMMONIUM PERSULFATE, SODIUM PERSULFATE, AND IMPACT Source: [redacted] Report No.: [redacted] Not GLP; (unpublished) Doc. No.: 572-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH

A6.12.2/02	[redacted]	1992	EVALUATION OF DERMAL SENSITIZATION POTENTIAL OF IMPACT IN HUMANS Source: [redacted] Report No.: [redacted] Not GLP; (unpublished) Doc. No.: 572-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
	EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) et al.	2016	Scientific opinion on dietary reference values for potassium. EFSA Journal 2016; 14(10):4592, 56 pp. (Published)	No	EFSA
	Rodan, A.R.	2018	Potassium - friend or foe? Pediatr Nephrol. 2017 Jul; 32(7): 1109–1121 (Published)	No	N.R.
	Larivée, N.L. et al.	2023	Hyperkalemia: Prevalence, Predictors and Emerging Treatments. Cardiol Ther 2023; 12,35-63. https://doi.org/10.1007/s40119-022-00289-z(Published)	No	N.R.
	Yamada, S. and Inaba, M.	2021	Potassium Metabolism and Management in Patients with CKD. Nutrients. 2021 May 21;13(6):1751 (Published)	No	N.R.
	EFSA Panel on Food Additives and Flavourings (FAF) et al.	2019	Scientific Opinion on the re-evaluation of sulphuric acid and its sodium, potassium, calcium and ammonium salts (E 513, 514 (i), 514 (ii), 515 (i), 515 (ii), 516 and 517) as food additive. *EFSA Journal* 2019;17(10):5868, 38 pp. (Published)	No	EFSA
	WHO	2011	Guidelines for Drinking-water Quality, Fourth Edition, World Health Organization, Geneva, ISBN 978 92 4 154815 1 (Published)	No	WHO
	WHO	2012	Guideline: Potassium intake for adults and children, World Health Organization, Geneva, ISBN 978 92 4 150482 9 (Published)	No	WHO
	Basil, M.C. et al.	2020	The Cellular and Physiological Basis for Lung Repair and Regeneration: Past, Present, and Future. Cell Stem Cell 26, April 2, 2020 (Published)	No	N.R.
	Clegg, D.J. et al.	2020	Impact of Dietary Potassium Restrictions in CKD on Clinical Outcomes: Benefits of Plant-Based diet. Kidney Med. 2020 Jun 15;2(4):476-487. (Published)	No	N.R.

	[redacted]	1992	A Physiologically Based Pharmacokinetic and Pharmacodynamic Model to Describe the Oral Dosing of Rats with Ethyl Acrylate and Its Implications for Risk Assessment. Toxicol Appl Pharmacol. 1992 Jun;114(2):246-60. (Published)	No	N.R.
	[redacted]	2018	An Adverse Outcome Pathway (AOP) for forestomach tumors induced by non-genotoxic initiating events. Regulatory Toxicology and Pharmacology 96 (2018) 30–40 (Published)	No	N.R.
	[redacted]	2020	A comprehensive view on mechanistic approaches for cancer risk assessment of non-genotoxic agrochemicals. Regulatory Toxicology and Pharmacology 118 (2020) 104789 (Published)	No	N.R.
	[redacted]	2018	Thresholds of Genotoxic and Non-Genotoxic Carcinogens. Toxicol. Res. Vol. 34, No. 4, pp. 281-290 (2018) (Published)	No	N.R.
	[redacted]	2021	Assessing chemical carcinogenicity: hazard identification, classification, and risk assessment. Insight from a Toxicology Forum state-of-the science Workshop. Critical Reviews in Toxicology, 51:8, 653-694 (Published)	No	N.R.
	[redacted]	2018	The role of ethyl acrylate induced GSH depletion in the rodent forestomach and its impact on MTD and in vivo genotoxicity in developing an adverse outcome pathway (AOP). Regulatory Toxicology and Pharmacology 92 (173-181) (Published)	No	N.R.
	Liou, G.-Y. and Storz, P.	2010	Reactive oxygen species in cancer. Free Radic Res. 2010 May; 44(5) (Published)	No	N.R.
	[redacted]	2020	Towards a mechanism-based approach for the prediction of nongenotoxic carcinogenic potential of agrochemicals. CRITICAL REVIEWS IN TOXICOLOGY 2020, VOL. 50, NO. 9, 725–739 (Published)	No	N.R.
	Horiba, K.	1994	Synchronous appearance of	No	N.R.

	and Fokuda, Y.		fibronectin, integrin alpha 5 beta 1, vinculin and actin in epithelial cells and fibroblasts during rat tracheal wound healing. Virchows Arch 1994;425(4):425-34		
	[redacted]	2021	Review: Glutathione: Role in Oxidative/Nitrosative Stress, Antioxidant Defense, and Treatments. Volume6, Issue18, 2021, pp 4566-4590. Graphical Abstract, https://doi.org/10.1002/slct.202100773 (Published)	No	N.R.
	Anonymous	2022	Potassium. Fact Sheet for Health Professionals. National Institute of Health: 2022. https://ods.od.nih.gov/factsheets/Potassium-HealthProfessional/#change, updated June 2, 2022 (Publiched)	No	N.R.
	National Academies of Sciences, Engineering, and Medicine	2019	Dietary Reference Intakes for Sodium and Potassium. Washington, DC: The National Academies Press. https://doi.org/10.17226/25353. (Published)	No	N.R.
A7.1.1.1.1/01	[redacted]	2007	PHYSICAL AND CHEMICAL CHARACTERISTICS OF KMPS P-16 - APPEARANCE, EFFECT OF PH ON SOLUBILITY, HYDROLYSIS AS A FUNCTION OF PH, SURFACE TENSION AND ACCELERATED STORAGE STABILITY Source: Case Consulting Laboratories, Inc., Whippany, N.J., United States Report No.: 3280-27 Dupont-21226 Not GLP; (unpublished) Doc. No.: 119-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	KMPS Registration Group
A7.1.1.1.1/02	[redacted]	2007	DEPLETION OF POTASSIUM MONOPERSULFATE IN SYNTHETIC POOL WATER Source: DuPont Chemical Solutions Enterprise Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 711-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A.7.1.1.1.1/03	[redacted]	2016	LONG-TERM DATA ON DEGRADATION OF KMPS IN AQEOUS SOLUTION Source: DuPont Chemical Solutions Enterprise, Sudbury, UK Report No.: Not applicable GLP; (unpublished) Doc. No.: 711-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH

A.7.1.1.1.1/04	[redacted]	2016	STUDY ON OXONE™ IN SOLUTION: IS HYDROGEN PEROXIDE RELEASED? Source: Chemours Chemical Solutions, Sudbury UK Report No: Not applicable Not GLP; (unpublished) Doc. No. 711-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A.7.1.1.1/01	[redacted]	2012	DECOMPOSITION OF OXONE® IN ACTIVATED SLUDGE FROM STP Source: E.I. du Pont de Nemours and Company DuPont Chemicals & Fluoroproducts, experimental Station E402/5220 Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 713-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	KMPS Registration Group
A.7.1.1.1/02	[redacted]	2011	ANALYSIS OF KMPS DEGRADATION IN ACTIVATED SLUDGE AT 12°C. Source: DuPont Chemical Solutions Enterprise Laboratory Notebook. Report No.: Not applicable Not GLP; (unpublished) Doc. No. 713-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A.7.1.1.1/03	[redacted]	2018	Degradation of Oxone™ in Activated Sludge Source: Antec International Ltd Report No.: 2018KB0007 Not GLP; (unpuplished) Doc. No. 713-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Lanxess Deutschland GmbH
A7.3.1/01	[redacted]	2007	ESTIMATION OF THE ATMOSPHERIC RESIDENCE TIME OF POTASSIUM PEROXOMONOSULFATE USING THE ATKINSON METHOD Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 743-001 Not GLP; (unpublished) Doc. No.: 743-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	KMPS Registration Group
A7.4.1.1/01	[redacted]	2001	OXONE MONOPERSULFATE COMPOUND - ACUTE TOXICITY TO FISH Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 821-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A7.4.1.1/02	[redacted]	2007	KMPS: ACUTE TOXICITY WITH THE SHEEPHEAD MINNOW, *CYPRINODON VARIEGATUS*, DETERMINED UNDER STATIC TEST CONDITIONS Source: [redacted] Report No.: [redacted]	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH

			[redacted] GLP; (unpublished) Doc. No.: 821-004		
A7.4.1.2/01	[redacted]	2001	OXONE MONOPERSULFATE COMPOUND - ACUTE TOXICITY TO *DAPHNIA MAGNA* Source: Huntingdon Life Science Report No.: DPT 580/013091 DuPont-5756 GLP; (unpublished) Doc. No.: 822-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A7.4.1.2/02	[redacted]	2007	KMPS - ACUTE TOXICITY WITH MYSID SHRIMP, *AMERICAMYSIS BAHIA*, DETERMINED UNDER STATIC-RENEWAL TEST CONDITIONS Source: ABC Laboratories, USA Report No.: 61456 16918 260 GLP; (unpublished) Doc. No.: 825-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	KMPS Registration Group
A7.4.1.3/01	[redacted]	2001	OXONE MONOPERSULFATE COMPOUND - ALGAL GROWTH INHIBITION ASSAY Source: Huntingdon Life Science Report No.: DPT 581/013092 DuPont-5757 GLP; (unpublished) Doc. No.: 823-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A7.4.1.3/02	[redacted]	2007	KMPS: STATIC GROWTH INHIBITION TEST WITH THE MARINE DIATOM, *SKELETONEMA COSTATUM* Source: ABC Laboratories, USA Report No.: 61457 16918 323 GLP; (unpublished) Doc. No.: 823-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	KMPS Registration Group
A7.4.1.4/01	[redacted]	2001	OXONE MONOPERSULFATE COMPOUND - ACTIVATED SLUDGE - RESPIRATION TEST Source: Huntingdon Life Science Report No.: DPT 558/012378 GLP; (unpublished) Doc. No.: 842-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A7.4.3.2/01	[redacted]	2007	KMPS: EARLY LIFE-STAGE TOXICITY TEST WITH THE SHEEPSHEAD MINNOW, *CYPRINODON VARIEGATUS*, UNDER FLOW-THROUGH CONDITIONS Source: [redacted] Report No.: [redacted]	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	KMPS Registration Group

			[redacted] GLP; (unpublished) Doc. No.: 826-002		
A7.4.3.4/01	[redacted]	2007	KMPS -- LIFE-CYCLE TOXICITY TEST OF THE SALTWATER MYSID SHRIMP, *AMERICAMYSIS BAHIA*, CONDUCTED UNDER FLOW-THROUGH TEST CONDITIONS Source: ABC Laboratories, USA Report No.: 61458 16918 290 GLP; (unpublished) Doc. No.: 829-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	KMPS Registration Group
A7.5.1.2/01	Warbritton, R.	2007	KMPS - ACUTE TOXICITY WITH THE EARTHWORM, *EISENIA FETIDA* Source: ABC Laboratories, USA Report No.: 61453 GLP; (unpublished) Doc. No.: 833-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	KMPS Registration Group
A7.5.3.1.1/ 01	[redacted]	2007	KMPS: AN ORAL TOXICITY STUDY WITH THE NORTHERN BOBWHITE QUAIL USING MULTIPLE DAILY DOSAGES Source: [redacted] Report No.: [redacted] GLP; (unpublished) Doc. No.: 812-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	KMPS Registration Group

Appendix VI: Confidential information

Confidential information (Appendix VI) is given in a separate file.

Appendix VII: Applicants' assessment of potential endocrine disrupting (ED) properties of KMPS

(Eco)-Toxicological assessment of trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) (CAS No. 70693-62-8; KMPS) in accordance with the Guidance for the identification of endocrine disruptors in the context of Regulation (EU) No 528/2012 and (EC) No 1107/2009 (ECHA and EFSA, 2018)

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Appendix I: EXCEL table for reporting the available information on KMPS relevant for ED assessment

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Appendix II: Literature review report for endocrine disruption for KMPS and potassium hydrogenperoxomonosulphate

Appendix_II_Literatu
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Appendix III: Database search and *in silico* analyses report on potential endocrine disruptive properties for KMPS and potassium hydrogenperoxomonosulphate

Appendix_III_Datab
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