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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS

Product family identifier in R4BP	Evonik PAA BPF PT 11 PT 12
Product type(s):	PT 11 (Preservatives for liquid-cooling and processing systems) PT 12 (Slimicides)
Active ingredient(s):	peracetic acid
Case No. in R4BP	BC-TB040177-48
Asset No. in R4BP	DE-0032054-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/11.00001 710-05-11-00001-00-00-00-0000
Date	05.04.2024

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1 Overall conclusion

The biocidal product family (BPF) “Evonik PAA BPF PT 11 PT 12“ consists of products containing the active substance peracetic acid. The products are soluble concentrates. The products of the BPF are used as preservatives for liquid-cooling and processing systems (product-type (PT) 11) and as slimicides in the pulp and paper industry (PT 12) by professional users. The BPF consists of 3 meta-SPCs.

The overall conclusion of the evaluation is that the BPF meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised for the preservation of cooling water in once-through, small and large open recirculating systems (PT11) and as slimicide in the pulp and paper industry (PT12) as specified in chapter 2.3 of the PAR. Please find detailed information on the uses appropriate for authorisation, risk mitigation measures and instructions for use in chapter 2.3 of the PAR.

General

Detailed information on the intended uses of the BPF as applied for by the applicant and proposed for authorisation is provided in section 3.1 of the PAR.

The BPF contains the equilibrium component hydrogen peroxide which is evaluated as a substance of concern for the environment. Please refer to the confidential annex for further information.

Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore no corresponding regulatory measures are required.

The BPF contains peracetic acid which does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered as a candidate for substitution. Therefore, a comparative assessment of the BPF is not required.

Composition

The qualitative and quantitative information on the non-confidential composition of the BPF is detailed in sections 2.2 and 2.3 of the PAR. Information on the full composition is provided in the confidential annex.

The chemical identity, quantity, and technical equivalence requirements for the active substance in the BPF are met. More information is available in sections 2.2 of the PAR.

Conclusions of the assessments for each area

The intended uses as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal products. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards were identified. Meta SPCs 1 and 2 have the following classification: Metal Corr 1, Org Perox G., Oxid. Liquid 2. Meta SPC 3 has the following classification: Metal Corr 1, Org Perox F. More information is available in section 3.3 of the PAR.

Methods for detection and identification

Validated analytical methods for the determination of the concentration of the active substance and the equilibrium partner of the active substance are available. More information on the analytical methods is available in section 3.4 of the PAR.

Validated analytical methods are provided for monitoring of relevant components of the biocidal product family in air, water and body fluids. More information is available in section 3.4 of the PAR.

Efficacy against target organisms

The BPF has been shown to be preventively efficacious against bacteria and curatively efficacious against bacteria, *Legionella spp*., and green algae in PT11 with the application rates defined in section 2.3 of the PAR. A general curative / preventive algaecidal claim cannot be made, as no valid data for cyanobacteria are available.

The BPF has been shown to be preventively efficacious against bacteria and yeast in PT12 with the application rates defined in section 2.3 of the PAR.

More information is available in section 3.5 of the PAR.

Risk assessment for human health

A human health risk assessment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.7 of the PAR.

Since hydrogen peroxide is an equilibrium partner of the active substance, the human health risk assessment is based on peracetic acid and on hydrogen peroxide.

Based on the risk assessment, it is unlikely that the intended uses cause any unacceptable acute or chronic risk to professional users, professional bystanders and general public, if the directions for use, as specified in section 2.3 of the PAR, are followed.

Dietary risk assessment

Considering the use(s), food, or feed contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substance is considered as negligible, and no dietary risk assessment has been performed.

Risk assessment for animal health

Risk of exposure of domestic animals and pets is covered by human health effect assessment for the general public. As a consequence, no risk assessment for animal health has been performed.

Risk assessment for the environment

A risk assessment for the environment has been carried out for all the intended uses as applied by the applicant. More information is available in section 3.8 of the PAR.

Since hydrogen peroxide is an equilibrium partner of the active substance, the risk assessment for the environment is based on peracetic acid and on hydrogen peroxide.

The risk assessment of the intended use “Preservation of cooling water in once-through systems” has shown unacceptable risk for freshwater in all meta-SPCs and therefore these uses are not proposed for authorisation. By using marine water as cooling water no unacceptable risks are to be expected.

Based on the risk assessment, it is unlikely that the other intended uses cause any unacceptable risk for the environment, if the directions for use, as specified section 2.3 of the PAR, are followed.

2 Summary of the product family assessment

2.1 Administrative information (first information level)

2.1.1 Identifier in R4BP

Evonik PAA BPF PT 11 PT 12

2.1.2 Product type(s)

PT 11 (Preservatives for liquid-cooling and processing systems) PT 12 (Slimicides)

2.1.3 Manufacturer(s) of the product(s)

Name of manufacturer	Evonik Peroxid GmbH
Address of manufacturer	Industriestraße 1, 9721 Weißenstein, Austria
Location of manufacturing sites	Industriestraße 1, 9721 Weißenstein, Austria

Name of manufacturer	Mepavex Logistics BV
Address of manufacturer	Blankenweg 11, 4612 RC Bergen-op-Zoom, The Netherlands
Location of manufacturing sites	Van Konijnenburgweg 107, 4612 RC Bergen-op-Zoom, The Netherlands

2.1.4 Manufacturer(s) of the active substance(s)

Active substance	peracetic acid
Name of manufacturer	Evonik Peroxid GmbH
Address of manufacturer	Industriestraße 1, 9721 Weißenstein, Austria
Location of manufacturing sites	Industriestraße 1, 9721 Weißenstein, Austria

2.2 Composition and formulation (first information level)

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Peracetic acid		Active substance	79-21-0	201-186-8	1.7	15.0
Hydrogen peroxide	Hydrogen peroxide	Equilibrium partner of the active substance	7722-84-1	231-765-0	14.3	48.4
Acetic Acid	Acetic acid	Equilibrium partner of the active substance	64-19-7	200-580-7	0.1	16.3

Information on the full composition is provided in the confidential annex (Access level: “Restricted” to applicant and authority).

According to the information provided the products in family contain no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

2.2.2 Information on technical equivalence

Is the source of the active substance(s) the same as the one evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012? Yes ☒
No ☐

2.2.3 Information on endocrine disrupting properties

Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore no corresponding regulatory measures are required. Further information on the procedure of ED-assessment is provided in the confidential annex.

2.2.4 Information on the substance(s) of concern

No substance of concern was identified:

> Hydrogen peroxide (CAS No. 7722-84-1) as equilibrium partner of the active substance for all meta SPC (1-3) is evaluated like a substance of concern for the environment.

Further information is provided in the confidential annex.

2.2.5 Candidate(s) for substitution

No candidate for substitution was identified.

2.2.6 Type(s) of formulation

SL - soluble concentrate

2.3 Meta SPC(s) (second information level)

2.3.1 Meta SPC 1

2.3.1.1 Administrative information

2.3.1.1.1 Meta SPC identifier

META SPC 1 - PERACLEAN GROUP 1

2.3.1.1.2 Suffix to the authorisation number

01

2.3.1.1.3 Product type(s) of the products in the meta SPC

PT 11 (Preservatives for liquid-cooling and processing systems)

2.3.1.2 Composition and formulation of the products within the meta SPC

2.3.1.2.1 Qualitative and quantitative information on the composition of the products in the meta SPC

Table 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Peracetic acid		Active substance	79-21-0	201-186-8	1.7	2.4
Hydrogen peroxide	Hydrogen peroxide	Equilibrium partner of the active substance	7722-84-1	231-765-0	46.0	48.4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Acetic acid	Acetic acid	Equilibrium partner of the active substance	64-19-7	200-580-7	0.1	0.6

2.3.1.2.2 Type(s) of formulation of the products in the meta SPC

SL - soluble concentrate

2.3.1.3 Classification and Labelling according to the Regulation (EC) 1272/2008[1]

Besides the active substance peracetic acid and the equilibrium partner of the active substancehydrogen peroxide, the other components do not affect the classification of the products in the meta SPC.

The current harmonised classification of the active substance peracetic acid is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). For the environment the currently available harmonised classification is aquatic acute 1. However, in the active substance Assessment Report (PT 11,12, 2016) it was stated that based on the data presented there, the classification would be required as aquatic acute 1, M=1 and aquatic chronic 1, M=10 for peracetic acid. This is taken into account for the classification of the biocidal products in the meta SPC.

The current harmonised classification of the equilibrium partner of the active substancehydrogen peroxide is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). The currently available harmonised classification states no classification for the environment. However, in the active substance Assessment Report for hydrogen peroxide (PT 11,12, 2017) it is stated, that according to the data presented there, a classification would be required with aquatic chronic 3 (H412) for hydrogen peroxide. This is taken into account for the classification of the biocidal products in the meta SPC.

Classification of the products in the meta SPC pursuant to the Regulation (EC) 1272/2008 is required.

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[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Table 3

Classification Hazard classes, Hazard categories	Hazard statements
Organic peroxide G	-
Oxidizing liquid 2	H272
Metal corr. 1	H290
Acute Tox. 4 (oral)	H302
Acute Tox. 4 (inhalation)	H332
Skin Corr. 1A	H314
Eye Dam. 1	-
Aquatic chronic 2	H411

Table 4

Labelling	Code	Pictogram / Wording
Pictograms	GHS03	
	GHS05	
	GHS07	
	GHS09	
Signal word	-	Danger
Hazard statements	H272	May intensify fire; oxidiser
	H290	May be corrosive to metals.
	H302	Harmful if swallowed.
	H332	Harmful if inhaled.
	H314	Causes severe skin burns and eye damage.
	H411	Toxic to aquatic life with long-lasting effects
Supplemental hazard information	EUH071	Corrosive to the respiratory tract.
	-	-
Supplemental label elements	-	-
Precautionary statements	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

	P220	Keep away from clothing and other combustible materials.
	P234	Keep only in original packaging.
	P260	Do not breathe dust/fume/gas/mist/vapours/spray.
	P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
	P264	Wash … thoroughly after handling.
	P270	Do no eat, drink or smoke when using this product.
	P271	Use only outdoors or in a well-ventilated area.
	P273	Avoid release to the environment.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P301 + P312	IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell.
	P301 + P330 + P331 + P310	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/doctor.
	P303 + P361 + P353 + P310	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. Immediately call a POISON CENTER/doctor.
	P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
	P310	Immediately call a POISON CENTER/doctor.
	P312	Call a POISON CENTRE/doctor if you feel unwell.
	P321	Specific treatment (see … on this label).
	P330	Rinse mouth.
	P363	Wash contaminated clothing before reuse.
	P370 + P378	In case of fire: Use ... to extinguish.
	P390	Absorb spillage to prevent material damage.
	P391	Collect spillage.
	P405	Store locked up.
	P501	Dispose of contents/container to a hazardous waste disposal service in accordance with the statutory regulations.
Note	-	-

2.3.1.4 Use(s) of the products in the meta SPC appropriate for authorisation[2]

2.3.1.4.1 Use 1 appropriate for authorisation – Preservation of cooling water in once-through systems

Product Type(s)	PT 11
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	Bacteria *Legionella spp.*
Field(s) of use	Indoor Curative action Preservation of cooling water in once-through systems.
Application method(s)	Automated dosing into cooling water stream
Application rate(s) and frequency	In-use concentration: Curative treatment against bacteria (incl. *Legionella spp*.): 10 ppm (w/w) PAA Dilution: The biocidal product is diluted down accordingly in order to achieve an in-use concentration of 10 ppm (w/w) PAA. Example for dilution: __ mL concentrate added up with water to 10L result in a solution of 10 ppm (w/w) PAA. [*The authorisation holder must indicate the relevant quantities on the label for the specific biocidal product*] Number and timing of application: Frequency: Max. 1 Operation/day, Max. 15 min/day; 220 days/year. Contact time: 15 min
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Intermediate bulk container (IBC) // Plastic, HDPE // 1000 L Drum // Plastic, HDPE // 200 L Jerry can // Plastic, HDPE // 10 L; 20 L, 30 L and 60 L Bottles Plastic, HDPE // 1 L, 5 L

2.3.1.4.2 Use-specific instructions for use

See general directions for use of the products in the meta SPC.

2.3.1.4.3 Use-specific risk mitigation measures

1) Application of the product is limited to cooling systems which use marine water as cooling water.

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2 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

2) Blowdown water must be treated with sodium sulphite or a comparable reducing agent before release into marine water. The residential time before release should be sufficient to achieve the desired reduction. The efficacy of treatment must be verified with control measurements to determine residual hydrogen peroxide and peracetic acid.

2.3.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of the products in the meta SPC.

2.3.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the products in the meta SPC.

2.3.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the products in the meta SPC.

2.3.1.4.7 Use 2 appropriate for authorisation – Preservation of cooling water in open recirculating systems

Product Type(s)	PT 11
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	Bacteria *Legionella spp.* Green algae
Field(s) of use	Indoor Preventive / curative action Preservation of cooling water in small open recirculating cooling systems. Small systems are characterized by a blowdown flow rate of ≤ 2 m^3/h.
Application method(s)	Automated dosing into cooling water stream
Application rate(s) and frequency	In-use concentration: Preventive treatment against bacteria (incl. *Legionella spp.*): 1.14 - 10 ppm (w/w) PAA Curative treatment of microbial contamination: • 15 min contact time: ➢ bacteria: 6 – 10 ppm (w/w) PAA ➢ *Legionella spp.*: 8.5 – 10 ppm (w/w) PAA • 3 h contact time: ➢ bacteria (incl. *Legionella* spp.): 5 – 10 ppm (w/w) PAA

	• 24 h contact time: ➢ bacteria 1.14 - 10 ppm (w/w) PAA ➢ *Legionella* spp.: 3.5 - 10 ppm (w/w) PAA ➢ green algae 8.5 - 10 ppm (w/w) PAA Dilution: The biocidal product is diluted down accordingly in order to achieve an in-use concentration of 1.14 – 10 ppm (w/w) PAA. Example for dilution: __ mL or __ mL concentrate added up with water to 10L result in a solution of 1.14 ppm (w/w) PAA or 10 ppm (w/w) PAA respectively. [*The authorisation holder must indicate the relevant quantities on the label for the specific biocidal product*] Number and timing of application: Frequency: Max. 1 Operation/day, Max. 15 min/day; 220 days/year. Contact time: 15 min- 24 h
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Intermediate bulk container (IBC) // Plastic, HDPE // 1000 L Drum // Plastic, HDPE // 200 L Jerry can // Plastic, HDPE // 10 L; 20 L, 30 L and 60 L Bottles Plastic, HDPE // 1 L, 5 L

2.3.1.4.8 Use-specific instructions for use

See general directions for use of the products in the meta SPC.

2.3.1.4.9 Use-specific risk mitigation measures

1) The use is restricted to small cooling systems with a maximum blowdown of 2 m^3/h.
2) Waste water must be discharged to the municipal sewer or purified in an on-site industrial sewage treatment plant including a biological treatment step.

2.3.1.4.10 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of the products in the meta SPC.

2.3.1.4.11 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the products in the meta SPC.

2.3.1.4.12 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the products in the meta SPC.

2.3.1.5 General directions for use of the products in the meta SPC

2.3.1.5.1 Instructions for use

3) Microbiological validation of the treatment should be undertaken by the user of the product in order to determine the effective dose for the specific location/system. If needed, consult the authorisation holder of the product.

2.3.1.5.2 Risk mitigation measures

1) For loading the product the following risk mitigation measures shall be applied:
   - This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.
   - Wear protective chemical resistant gloves during product handling phase *(glove material to be specified by the authorisation holder within the product information).*
   - Wear protective chemical resistant boots during product handling phase.
   - A protective coverall (at least type 6, EN 13034) shall be worn.
   - The use of eye protection during handling of the product is mandatory.
2) The product may only be transferred/loaded with automatic pumps.
3) For inspection and maintenance of the cooling water system and cooling towers the following risk mitigation measures shall be applied:
   - ➢ This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.
   - ➢ Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required *(filter type (code letter, colour) to be specified by the authorisation holder within the product information).*
4) For repair or maintenance of dosing pumps the following risk mitigation measures shall be applied:
   - Prior to intervention in the pumps, existing product residues must be largely removed by flushing the pumps.
   - The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work:

- Wear protective chemical resistant gloves during product handling phase *(glove material to be specified by the authorisation holder within the product information).*
- Wear protective chemical resistant boots during product handling phase.
- A protective coverall (at least type 6, EN 13034) shall be worn.
- The use of eye protection during handling of the product is mandatory.

5) The product can only be applied when the cooling towers are equipped with drift eliminators that reduce drift with at least 99%.

2.3.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

1) IF SWALLOWED: Rinse mouth.If symptoms: Call 112/ambulance for medical assistance.If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

2) 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.Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

3) "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."

4) 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.
   Information to Healthcare personnel/doctor:
   The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid"
5) Do not discharge the biocidal product nor the diluted solution of the biocidal product into the sewage system or the environment.
6) Immediately take up spilled product mechanically and collect in suitable containers for disposal.
7) Dispose of in an incinerator approved for chemicals.
8) Inform respective authorities if the product contaminates rivers, lakes or drains.
9) Observe regulations on prevention of water pollution (collect, dam up, cover up).

2.3.1.5.4 Instructions for safe disposal of the product and its packaging

1) Residues of the biocidal product must be disposed of in accordance with the Waste Framework Directive (2008/98/EG) and the European Waste Catalogue (EWC) as well as national and regional regulations.
2) Leave biocidal products in original containers. Do not mix with other wastes. Containers containing residues of the product have to be handled accordingly.
3) Waste entry on pesticides: 20 01 19*
4) Waste entry on packaging containing residues of or contaminated by dangerous substances: 15 01 10*

2.3.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

1) Shelf-life: 15 months
2) Protect from frost.
3) Do not store above 30°C.

2.3.1.5.6 Other information

Use 1 - Preservation of cooling water in once-through systems: Curative efficacy against mussels, biofouling and other sessile target organisms has not been demonstrated.

2.3.2 Meta SPC 2

2.3.2.1 Administrative information

2.3.2.1.1 Meta SPC identifier

META SPC 2 - PERACLEAN GROUP 2

2.3.2.1.2 Suffix to the authorisation number

02

2.3.2.1.3 Product type(s) of the products in the meta SPC

PT 11 (Preservatives for liquid-cooling and processing systems)

PT 12 (Slimicides)

2.3.2.2 Composition and formulation of the products within the meta SPC

2.3.2.2.1 Qualitative and quantitative information on the composition of the products in the meta SPC

Table 5

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Peracetic acid		Active substance	79-21-0	201-186-8	3.8	5.0
Hydrogen peroxide	Hydrogen peroxide	Equilibrium partner of the active substance	7722-84-1	231-765-0	25.6	30.7
Acetic acid	Acetic acid	Equilibrium partner of the active substance	64-19-7	200-580-7	4.0	7.0

2.3.2.2.2 Type(s) of formulation of the products in the meta SPC

SL - soluble concentrate

2.3.2.3 Classification and Labelling according to the Regulation (EC) 1272/2008

Besides the active substance peracetic acid and the equilibrium partner of the active substancehydrogen peroxide, the other components do not affect the classification of the products in the meta SPC.

The current harmonised classification of the active substance peracetic acid is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). For the environment the currently available harmonised classification is aquatic acute 1. However, in the active substance Assessment Report (PT 11,12, 2016) it was stated that based on the data presented there, the classification would be required as aquatic acute 1, M=1 and aquatic chronic 1, M=10 for peracetic acid. This is taken into account for the classification of the biocidal products in the meta SPC.

The current harmonised classification of the equilibrium partner of the active substancehydrogen peroxide is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). The currently available harmonised classification states no classification for the environment. However, in the active substance Assessment Report for hydrogen peroxide (PT 11,12, 2017) it is stated, that according to the data presented there, a classification would be required with aquatic chronic 3 (H412) for hydrogen peroxide. This is taken into account for the classification of the biocidal products in the meta SPC.

Classification of the products in the meta SPC pursuant to the Regulation (EC) 1272/2008 is required.

Table 6

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Organic peroxide G	-
Oxidizing liquid 2	H272
Metal corr. 1	H290
Acute Tox. 4 (oral)	H302
Acute Tox. 4 (dermal)	H312
Acute Tox. 4 (inhalation)	H332
Skin Corr. 1A	H314
Eye Dam. 1	-
Aquatic chronic 1	H410

Table 7

Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS03	
	GHS05	

	GHS07	
	GHS09	
Signal word	-	Danger
Hazard statements	H272	May intensify fire; oxidiser
	H290	May be corrosive to metals.
	H302	Harmful if swallowed.
	H312	Harmful in contact with skin.
	H332	Harmful if inhaled.
	H314	Causes severe skin burns and eye damage.
	H410	Very toxic to aquatic life with long-lasting effects
Supplemental hazard information	EUH071	Corrosive to the respiratory tract.
Supplemental label elements	-	-
Precautionary statements	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P220	Keep away from clothing and other combustible materials.
	P234	Keep only in original packaging.
	P260	Do not breathe dust/fume/gas/mist/vapours/spray.
	P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
	P264	Wash … thoroughly after handling.
	P270	Do no eat, drink or smoke when using this product.
	P271	Use only outdoors or in a well-ventilated area.
	P273	Avoid release to the environment.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P301 + P312	IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell.
	P301 + P330 + P331 + P310	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/doctor.
	P302 + P352	IF ON SKIN: Wash with plenty of water.

	P303 + P361 + P353 + P310	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. Immediately call a POISON CENTER/doctor.
	P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
	P310	Immediately call a POISON CENTER/doctor/…
	P312	Call a POISON CENTRE/doctor if you feel unwell.
	P321	Specific treatment (see … on this label).
	P330	Rinse mouth.
	P362 + P364	Take off contaminated clothing and wash it before reuse.
	P363	Wash contaminated clothing before reuse.
	P370 + P378	In case of fire: Use ... to extinguish.
	P390	Absorb spillage to prevent material damage.
	P391	Collect spillage
	P405	Store locked up.
	P501	Dispose of contents/container to a hazardous waste disposal service in accordance with the statutory regulations.
Note	**-**	**-**

2.3.2.4 Use(s) of the products in the meta SPC appropriate for authorisation

2.3.2.4.1 Use 1 appropriate for authorisation – Preservation of cooling water in once-through systems

Product Type(s)	PT 11
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	Bacteria *Legionella spp.*
Field(s) of use	Indoor Curative action Preservation of cooling water in once-through systems.
Application method(s)	Automated dosing into cooling water stream
Application rate(s) and frequency	In-use concentration: Curative treatment against bacteria (incl. *Legionella spp*.): 10 ppm (w/w) PAA

	Dilution: The biocidal product is diluted down accordingly in order to achieve an in-use concentration of 10 ppm (w/w) PAA. Example for dilution: __ mL concentrate added up with water to 10L result in a solution of 10 ppm (w/w) PAA. [*The authorisation holder must indicate the relevant quantities on the label for the specific biocidal product*] Number and timing of application: Frequency: Max. 1 Operation/day, Max. 15 min/day; 220 days/year. Contact time: 15 min
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Intermediate bulk container (IBC) // Plastic, HDPE // 1000 L Drum // Plastic, HDPE // 200 L Jerry can // Plastic, HDPE // 10 L; 20 L, 30 L and 60 L Bottles Plastic, HDPE // 1 L, 5 L

2.3.2.4.2 Use-specific instructions for use

See general directions for use of the products in the meta SPC.

2.3.2.4.3 Use-specific risk mitigation measures

1) Application of the product is limited to cooling systems which use marine water as cooling water.
2) Blowdown water must be treated with sodium sulphite or a comparable reducing agent before release into marine water. The residential time before release should be sufficiently to achieve the desired reduction. The efficacy of treatment must be verified with control measurements to determine residual hydrogen peroxide and peracetic acid
3) The product can only be applied when the cooling towers are equipped with drift eliminators that reduce drift with at least 99%.

2.3.2.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of the products in the meta SPC.

2.3.2.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the products in the meta SPC.

2.3.2.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the products in the meta SPC.

2.3.2.4.7 Use 2 appropriate for authorisation – Preservation of cooling water in open recirculating systems

Product Type(s)	PT 11
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	Bacteria *Legionella spp*. Green algae
Field(s) of use	Indoor Preventive / curative action Preservation of cooling water in small open recirculating cooling systems. Small systems are characterized by a blowdown flow rate of ≤ 2 m^3/h.
Application method(s)	Automated dosing into cooling water stream
Application rate(s) and frequency	In-use concentration: Preventive treatment against bacteria (incl. *Legionella spp*.): 1.14 - 10 ppm (w/w) PAA Curative treatment of microbial contamination: • 15 min contact time: ➢ bacteria: 6 – 10 ppm (w/w) PAA ➢ *Legionella spp*.: 8.5 – 10 ppm (w/w) PAA • 3 h contact time: ➢ bacteria (incl. *Legionella* spp.): 5 – 10 ppm (w/w) PAA • 24 h contact time: ➢ bacteria 1.14 - 10 ppm (w/w) PAA ➢ *Legionella* spp.: 3.5 - 10 ppm (w/w) PAA ➢ green algae 8.5 - 10 ppm (w/w) PAA Dilution: The biocidal product is diluted down accordingly in order to achieve an in-use concentration of 1.14 – 10 ppm (w/w) PAA. Example for dilution: __ mL or __ mL concentrate added up with water to 10L result in a solution of 1.14 ppm (w/w) or 10 ppm (w/w) PAA respectively. [*The authorisation holder must indicate the relevant quantities on the label for the specific biocidal product*] Number and timing of application: Frequency: Max. 1 Operation/day, Max. 15 min/day; 220 days/year. Contact time: 15 min - 24 h
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Intermediate bulk container (IBC) // Plastic, HDPE // 1000 L Drum // Plastic, HDPE // 200 L Jerry can // Plastic, HDPE // 10 L; 20 L, 30 L and 60 L Bottles Plastic, HDPE // 1 L, 5 L

2.3.2.4.8 Use-specific instructions for use

See general directions for use of the products in the meta SPC.

2.3.2.4.9 Use-specific risk mitigation measures

1) The use is restricted to small cooling systems with a maximum blowdown of 2 m³/h.
2) Waste water must be discharged to the municipal sewer or purified in an on-site industrial sewage treatment plant including a biological treatment step.
3) The product can only be applied when the cooling towers are equipped with drift eliminators that reduce drift with at least 99%.

2.3.2.4.10 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of the products in the meta SPC.

2.3.2.4.11 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the products in the meta SPC.

2.3.2.4.12 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the products in the meta SPC.

2.3.2.4.13 Use 3 appropriate for authorisation – Slimicide in the pulp and paper industry

Product Type(s)	PT 12
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor Preventive action Slimicide in the pulp and paper industry closed System
Application method(s)	Automated dosing into closed water cycle/paper machine and process operation
Application rate(s) and frequency	In-use concentration: 34.5 – 75 ppm (w/w) PAA

	Dilution: The biocidal product is diluted down accordingly in order to achieve an in-use concentration of 34.5 – 75 ppm (w/w) PAA. Example for dilution: __ mL or __ mL concentrate added up with water to 10L result in a solution of 34.5 ppm (w/w) or 75 ppm (w/w) PAA respectively. [*The authorisation holder must indicate the relevant quantities on the label for the specific biocidal product*] Number and timing of application: Frequency: continuous dosing
Category(ies) of users	Industrial, Professional
Pack sizes and packaging material	Intermediate bulk container (IBC) // Plastic, HDPE // 1000 L Drum // Plastic, HDPE // 200 L Jerry can // Plastic, HDPE // 10 L; 20 L, 30 L and 60 L Bottles Plastic, HDPE // 1 L, 5 L

2.3.2.4.14 Use-specific instructions for use

See general directions for use of the products in the meta SPC.

2.3.2.4.15 Use-specific risk mitigation measures

See general directions for use of the products in the meta SPC.

2.3.2.4.16 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of the products in the meta SPC.

2.3.2.4.17 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the products in the meta SPC.

2.3.2.4.18 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the products in the meta SPC.

2.3.2.5 General directions for use of the products in the meta SPC

2.3.2.5.1 Instructions for use

1) Microbiological validation of the treatment should be undertaken by the user of the product in order to determine the effective dose for the specific location/system. If needed, consult the authorisation holder of the product.

2.3.2.5.2 Risk mitigation measures

1) For loading the product the following risk mitigation measures shall be applied:
    - This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.
    - Wear protective chemical resistant gloves during product handling phase *(glove material to be specified by the authorisation holder within the product information).*
    - Wear protective chemical resistant boots during product handling phase.
    - A protective coverall (at least type 6, EN 13034) shall be worn.
    - The use of eye protection during handling of the product is mandatory.
2) The product may only be transferred/loaded with automatic pumps.
4) For inspection and maintenance of the cooling water system and cooling towers the following risk mitigation measures shall be applied:
    - ➢ This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.
    - ➢ Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required *(filter type (code letter, colour) to be specified by the authorisation holder within the product information).*
5) For repair or maintenance of dosing pumps the following risk mitigation measures shall be applied:
    - Prior to intervention in the pumps, existing product residues must be largely removed by flushing the pumps
    - The following risk mitigation measures are without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work:
        - Wear protective chemical resistant gloves during product handling phase *(glove material to be specified by the authorisation holder within the product information).*
        - Wear protective chemical resistant boots during product handling phase.
        - A protective coverall (at least type 6, EN 13034) shall be worn.
        - The use of eye protection during handling of the product is mandatory.

2.3.2.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

1) IF SWALLOWED: Rinse mouth. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.
2) 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. Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.
3) IF ON SKIN: Wash skin with plenty of water. Take off all contaminated clothing and wash it before reuse. If symptoms: Call 112 /ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

4) 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. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid
6) Do not discharge the biocidal product nor the diluted solution of the biocidal product into the sewage system or the environment.
7) Immediately take up spilled product mechanically and collect in suitable containers for disposal.
8) Dispose of in an incinerator approved for chemicals.
9) Inform respective authorities if the product contaminates rivers, lakes or drains.
10) Observe regulations on prevention of water pollution (collect, dam up, cover up).

2.3.2.5.4 Instructions for safe disposal of the product and its packaging

1) Residues of the biocidal product must be disposed of in accordance with the Waste Framework Directive (2008/98/EG) and the European Waste Catalogue (EWC) as well as national and regional regulations.
2) Leave biocidal products in original containers. Do not mix with other wastes. Containers containing residues of the product have to be handled accordingly.
3) Waste entry on pesticides: 20 01 19*
4) Waste entry on packaging containing residues of or contaminated by dangerous substances: 15 01 10*

2.3.2.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

1) Shelf-life: 24 months
2) Protect from frost.
3) Do not store above 40 °C.

2.3.2.5.6 Other information

Use 1 - Preservation of cooling water in once-through systems: Curative efficacy against mussels, biofouling and other sessile target organisms has not been demonstrated.

2.3.3 Meta SPC 3

2.3.3.1 Administrative information

2.3.3.1.1 Meta SPC identifier

META SPC 3 - PERACLEAN GROUP 3

2.3.3.1.2 Suffix to the authorisation number

03

2.3.3.1.3 Product type(s) of the products in the meta SPC

PT 11 (Preservatives for liquid-cooling and processing systems) PT 12 (Slimicides)

2.3.3.2 Composition and formulation of the products within the meta SPC

2.3.3.2.1 Qualitative and quantitative information on the composition of the products in the meta SPC

Table 8

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Peracetic acid		Active substance	79-21-0	201-186-8	15.0	15.0
Hydrogen peroxide	Hydrogen peroxide	Equilibrium partner of the active substance	7722-84-1	231-765-0	14.3	23.3
Acetic acid	Acetic acid	Equilibrium partner of the active substance	64-19-7	200-580-7	15.8	16.3

2.3.3.2.2 Type(s) of formulation of the products in the meta SPC

SL - soluble concentrate

2.3.3.3 Classification and Labelling according to the Regulation (EC) 1272/2008

Besides the active substance peracetic acid and the equilibrium partner of the active substancehydrogen peroxide, the other components do not affect the classification of the products in the meta SPC.

The current harmonised classification of the active substance peracetic acid is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). For the environment the currently available harmonised classification is aquatic acute 1. However, in the active substance Assessment Report (PT 11,12, 2016) it was stated that based on the data presented there, the classification would be required as aquatic acute 1, M=1 and aquatic chronic 1, M=10 for peracetic acid. This is taken into account for the classification of the biocidal products in the meta SPC.

The current harmonised classification of the equilibrium partner of the active substancehydrogen peroxide is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). The currently available harmonised classification states no classification for the environment. However, in the active substance Assessment Report for hydrogen peroxide (PT 11,12, 2017) it is stated, that according to the data presented there, a classification would be required with aquatic chronic 3 (H412) for hydrogen peroxide. This is taken into account for the classification of the biocidal products in the meta SPC.

Classification of the products in the meta SPC pursuant to the Regulation (EC) 1272/2008 is required.

Table 9

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Organic peroxide F	H242
Metal corr. 1	H290
Acute Tox. 4 (oral)	H302
Acute Tox. 3 (dermal)	H311
Acute Tox. 4 (inhalation)	H332
Skin Corr. 1A	H314
Eye Dam. 1	-
Aquatic chronic 1	H410

Table 10

Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS02	
	GHS05	

	GHS06	
	GHS09	
Signal word	-	Danger
Hazard statements	H242	Heating may cause a fire.
	H290	May be corrosive to metals.
	H302	Harmful if swallowed.
	H311	Toxic in contact with skin.
	H332	Harmful if inhaled.
	H314	Causes severe skin burns and eye damage.
	H410	Very toxic to aquatic life with long-lasting effects
Supplemental hazard information	EUH071	Corrosive to the respiratory tract.
Supplemental label elements	-	-
Precautionary statements	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P234	Keep only in original packaging.
	P235	Keep cool.
	P240	Ground and bond container and receiving equipment
	P260	Do not breathe dust/fume/gas/mist/vapours/spray.
	P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
	P264	Wash … thoroughly after handling.
	P270	Do no eat, drink or smoke when using this product.
	P271	Use only outdoors or in a well-ventilated area.
	P273	Avoid release to the environment.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P301 + P312	IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell.
	P301 + P330 + P331 + P310	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/doctor.
	P302 + P352	IF ON SKIN: Wash with plenty of water.

	P303 + P361 + P353 + P310	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. Immediately call a POISON CENTER/doctor.
	P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310	Immediately call a POISON CENTER/doctor.
	P312	Call a POISON CENTRE/doctor if you feel unwell.
	P321	Specific treatment (see … on this label).
	P330	Rinse mouth.
	P361 + P364	Take off immediately all contaminated clothing and wash it before reuse.
	P363	Wash contaminated clothing before reuse.
	P390	Absorb spillage to prevent material damage.
	P391	Collect spillage
	P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
	P405	Store locked up.
	P501	Dispose of contents/container to a hazardous waste disposal service in accordance with the statutory regulations.
Note	-	-

2.3.3.4 Use(s) of the products in the meta SPC appropriate for authorisation

2.3.3.4.1 Use 1 appropriate for authorisation – Preservation of cooling water in once-through systems

Product Type(s)	PT 11
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	Bacteria *Legionella spp.*
Field(s) of use	Indoor Curative action Preservation of cooling water in once-through systems.
Application method(s)	Automated dosing into cooling water stream
Application rate(s) and frequency	In-use concentration: Curative treatment against bacteria (incl. *Legionella spp*.): 10 ppm (w/w) PAA

	Dilution: The biocidal product is diluted down accordingly in order to achieve an in-use concentration of 10 ppm (w/w) PAA. Example for dilution: __ mL concentrate added up with water to 10L result in a solution of 10 ppm (w/w) PAA. [*The authorisation holder must indicate the relevant quantities on the label for the specific biocidal product*] Number and timing of application: Frequency: Max. 1 Operation/day, Max. 15 min/day; 220 days/year. Contact time: 15 min
Category(ies) of users	Industrial, Professional[3]
Pack sizes and packaging material	Intermediate bulk container (IBC) // Plastic, HDPE // 1000 L Drum // Plastic, HDPE // 200 L Jerry can // Plastic, HDPE // 10 L; 20 L, 30 L and 60 L Bottles Plastic, HDPE // 1 L, 5 L

2.3.3.4.2 Use-specific instructions for use

See general directions for use of the products in the meta SPC.

2.3.3.4.3 Use-specific risk mitigation measures

1) Application of the product is limited to cooling systems which use marine water as cooling water.
2) Blowdown water must be treated with sodium sulphite or a comparable reducing agent before release into marine water. The residential time before release should be sufficiently to achieve the desired reduction. The efficacy of treatment must be verified with control measurements to determine residual hydrogen peroxide and peracetic acid.
3) The product can only be applied when the cooling towers are equipped with drift eliminators that reduce drift with at least 99%.

2.3.3.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of the products in the meta SPC.

2.3.3.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the products in the meta SPC.

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[3] In Germany only: Professional (Generally, training according to § 15c of the Hazardous Substances Ordinance (GefStoffV) is required)

2.3.3.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the products in the meta SPC.

2.3.3.4.7 Use 2 appropriate for authorisation – Preservation of cooling water in open recirculating systems (large)

Product Type(s)	PT 11
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	Bacteria *Legionella spp.* Green algae
Field(s) of use	Indoor Preventive / curative action Preservation of cooling water in large open recirculating cooling systems. Large systems are characterized by a blowdown flow rate of > 2 m^3/h.
Application method(s)	Automated dosing into cooling water stream
Application rate(s) and frequency	In-use concentration: Preventive treatment against bacteria (incl. *Legionella spp.*): 1.14 - 10 ppm (w/w) PAA Curative treatment of microbial contamination: • 15 min contact time: ➢ bacteria: 6 – 10 ppm (w/w) PAA ➢ *Legionella spp.*: 8.5 – 10 ppm (w/w) PAA • 3 h contact time: ➢ bacteria (incl. *Legionella* spp.): 5 – 10 ppm (w/w) PAA • 24 h contact time: ➢ bacteria 1.14 - 10 ppm (w/w) PAA ➢ *Legionella* spp.: 3.5 - 10 ppm (w/w) PAA ➢ green algae 8.5 - 10 ppm (w/w) PAA Dilution: The biocidal product is diluted down accordingly in order to achieve an in-use concentration of 1.14 – 10 ppm (w/w) PAA. Example for dilution: __ mL or __ mL concentrate added up with water to 10L result in a solution of 1.14 ppm (w/w) or 10 ppm (w/w) PAA respectively. [*The authorisation holder must indicate the relevant quantities on the label for the specific biocidal product*] Number and timing of application: Frequency: Max. 1 Operation/day, Max. 15 min/day; 220 days/year. Contact time: 15 min - 24 h

Category(ies) of users	Industrial, Professional[4]
Pack sizes and packaging material	Intermediate bulk container (IBC) // Plastic, HDPE // 1000 L Drum // Plastic, HDPE // 200 L Jerry can // Plastic, HDPE // 10 L; 20 L, 30 L and 60 L Bottles Plastic, HDPE // 1 L, 5 L

2.3.3.4.8 Use-specific instructions for use

See general directions for use of the products in the meta SPC.

2.3.3.4.9 Use-specific risk mitigation measures

1) Blowdown water must be treated with sodium sulphite or a comparable reducing agent before release into surface water. The residential time before release should be sufficiently to achieve the desired reduction. The efficacy of treatment must be verified with control measurements to determine residual hydrogen peroxide and peracetic acid.
2) The product can only be applied when the cooling towers are equipped with drift eliminators that reduce drift with at least 99%.

2.3.3.4.10 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of the products in the meta SPC.

2.3.3.4.11 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the products in the meta SPC.

2.3.3.4.12 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the products in the meta SPC.

2.3.3.4.13 Use 3 appropriate for authorisation – Preservation of cooling water in open recirculating systems

Product Type(s)	PT 11
Where relevant, an exact description of the use	-

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[4] In Germany only: Professional (Generally, training according to § 15c of the Hazardous Substances Ordinance (GefStoffV) is required)

Target organism(s) (including development stage)	Bacteria *Legionella spp.* Green algae
Field(s) of use	Indoor Preventive / curative action Preservation of cooling water in small open recirculating cooling systems. Small systems are characterized by a blowdown flow rate of ≤ 2 m^3/h.
Application method(s)	Automated dosing into cooling water stream
Application rate(s) and frequency	In-use concentration: Preventive treatment against bacteria (incl. *Legionella* spp.): 1.14 - 10 ppm (w/w) PAA Curative treatment of microbial contamination: • 15 min contact time: ➢ bacteria: 6 – 10 ppm (w/w) PAA ➢ *Legionella spp*.: 8.5 – 10 ppm (w/w) PAA • 3 h contact time: ➢ bacteria (incl. *Legionella* spp.): 5 – 10 ppm (w/w) PAA • 24 h contact time: ➢ bacteria 1.14 - 10 ppm (w/w) PAA ➢ *Legionella* spp.: 3.5 - 10 ppm (w/w) PAA ➢ green algae 8.5 - 10 ppm (w/w) PAA Dilution: The biocidal product is diluted down accordingly in order to achieve an in-use concentration of 1.14 – 10 ppm (w/w) PAA. Example for dilution: __ mL or __ mL concentrate added up with water to 10L result in a solution of 1.14 ppm (w/w) or 10 ppm (w/w) PAA respectively. [*The authorisation holder must indicate the relevant quantities on the label for the specific biocidal product*] Number and timing of application: Frequency: Max. 1 Operation/day, Max. 15 min/day; 220 days/year. Contact time: 15 min - 24 h
Category(ies) of users	Industrial, Professional[5]
Pack sizes and packaging material	Intermediate bulk container (IBC) // Plastic, HDPE // 1000 L Drum // Plastic, HDPE // 200 L Jerry can // Plastic, HDPE // 10 L; 20 L, 30 L and 60 L Bottles Plastic, HDPE // 1 L, 5 L

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[5] In Germany only: Professional (Generally, training according to § 15c of the Hazardous Substances Ordinance (GefStoffV) is required)

2.3.3.4.14 Use-specific instructions for use

See general directions for use of the products in the meta SPC.

2.3.3.4.15 Use-specific risk mitigation measures

1) The use is restricted to small cooling systems with a maximum blowdown of 2 m^3/h.
2) Waste water must be discharged to the municipal sewer or purified in an on-site industrial sewage treatment plant including a biological treatment step.
3) The product can only be applied when the cooling towers are equipped with drift eliminators that reduce drift with at least 99%.

2.3.3.4.16 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of the products in the meta SPC.

2.3.3.4.17 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the products in the meta SPC.

2.3.3.4.18 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the products in the meta SPC.

2.3.3.4.19 Use 4 appropriate for authorisation – Slimicide in the pulp and paper industry

Product Type(s)	PT 12
Where relevant, an exact description of the use	-
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor Preventive action Slimicide in the pulp and paper industry closed System
Application method(s)	Automated dosing into closed water cycle/paper machine and process operation
Application rate(s) and frequency	In-use concentration: 34.5 - 75 ppm (w/w) PAA Dilution:

	The biocidal product is diluted down accordingly in order to achieve an in-use concentration of 34.5 – 75 ppm (w/w) PAA. Example for dilution: __ mL or __ mL concentrate added up with water to 10L result in a solution of 34.5 ppm (w/w) or 75 ppm (w/w) PAA respectively. [*The authorisation holder must indicate the relevant quantities on the label for the specific biocidal product*] Number and timing of application: Frequency: continuous dosing
Category(ies) of users	Industrial, Professional[6]
Pack sizes and packaging material	Intermediate bulk container (IBC) // Plastic, HDPE // 1000 L Drum // Plastic, HDPE // 200 L Jerry can // Plastic, HDPE // 10 L; 20 L, 30 L and 60 L Bottles Plastic, HDPE // 1 L, 5 L

2.3.3.4.20 Use-specific instructions for use

See general directions for use of the products in the meta SPC.

2.3.3.4.21 Use-specific risk mitigation measures

See general directions for use of the products in the meta SPC.

2.3.3.4.22 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of the products in the meta SPC.

2.3.3.4.23 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the products in the meta SPC.

2.3.3.4.24 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the products in the meta SPC.

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[6] In Germany only: Professional (Generally, training according to § 15c of the Hazardous Substances Ordinance (GefStoffV) is required)

2.3.3.5 General directions for use of the products in the meta SPC

2.3.3.5.1 Instructions for use

1) Microbiological validation of the treatment should be undertaken by the user of the product in order to determine the effective dose for the specific location/system. If needed, consult the authorisation holder of the product.

2.3.3.5.2 Risk mitigation measures

1) For loading the product the following risk mitigation measures shall be applied:
   - This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.
   - Wear protective chemical resistant gloves during product handling phase *(glove material to be specified by the authorisation holder within the product information).*
   - Wear protective chemical resistant boots during product handling phase.
   - A protective coverall (at least type 6, EN 13034) shall be worn.
   - The use of eye protection during handling of the product is mandatory.
2) The product may only be transferred/loaded with automatic pumps.
3) For inspection and maintenance of the cooling water system and cooling towers the following risk mitigation measures shall be applied:
   This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.
4) Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).
5) For repair or maintenance of dosing pumps the following risk mitigation measures shall be applied:
   - This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.
   - Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).
   - Wear protective chemical resistant gloves during product handling phase *(glove material to be specified by the authorisation holder within the product information).*
   - Wear protective chemical resistant boots during product handling phase.
   - A protective coverall (at least type 6, EN 13034) shall be worn.

- The use of eye protection during handling of the product is mandatory.

6) Prior to intervention in the pumps, existing product residues must be largely removed by flushing the pumps.
7) Do not discharge the biocidal product nor the diluted solution of the biocidal product into the sewage system or the environment.
8) Immediately take up spilled product mechanically and collect in suitable containers for disposal
9) Dispose of in an incinerator approved for chemicals.
10) Inform respective authorities if the product contaminates rivers, lakes or drains.
11) Observe regulations on prevention of water pollution (collect, dam up, cover up).

2.3.3.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

1) IF SWALLOWED: Rinse mouth. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.
2) IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Immediately call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: Immediately initiate life support measures, thereafter call a POISON CENTRE.
3) IF ON SKIN: Immediately wash skin with plenty of water. Take off all contaminated clothing and wash it before reuse. After washing the skin: Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: Initiate life support measures, thereafter call a POISON CENTRE.
4) 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. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

2.3.3.5.4 Instructions for safe disposal of the product and its packaging

1) Residues of the biocidal product must be disposed of in accordance with the Waste Framework Directive (2008/98/EG) and the European Waste Catalogue (EWC) as well as national and regional regulations.
2) Leave biocidal products in original containers. Do not mix with other wastes. Containers containing residues of the product have to be handled accordingly.
3) Waste entry on pesticides: 20 01 19*

4) Waste entry on packaging containing residues of or contaminated by dangerous substances: 15 01 10*

2.3.3.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

1) Shelf-life: 6 months
2) Protect from frost.
3) Store in a well-ventilated place. Keep container tightly closed.
4) Do not store above 40 °C.

2.3.3.5.6 Other information

Use 1 - Preservation of cooling water in once-through systems: Curative efficacy against mussels, biofouling and other sessile target organisms has not been demonstrated.

2.4 Packaging

Table 11

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Bottle	1 L, 5 L	HDPE	HDPE	Professional	Yes
Jerry can	10 L, 20 L, 30 L and 60 L	HDPE	HDPE	Professional	Yes
Drum	200 L	HDPE	HDPE	Professional	Yes
IBC (intermediate BULK container)	1000 L	HDPE	HDPE	Professional	Yes

3 Assessment of the product family

3.1 *Intended use(s) as applied for by the applicant*

Table 12

Meta SPC	Use No.	Name of the use	PT	Target organism(s)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category of users	Pack sizes and packaging material	Conclusion
1, 2, 3	1	Preservation of cooling water in **once-through** systems	11	Bacteria (incl. Legionella)	Indoor Preservation of cooling water in-**once-through** systems **Curative** action	Automated dosing into cooling water stream	In-use concentration (PAA): 8.5 - 10 ppm (w/w) Number and timing of application: Frequency: Max. 1 Operation/day, Max. 15 min/day; 220 days/year. Contact time: 15 min	Professional Industrial	Intermediate bulk container (IBC) // Plastic, HDPE // 1000 L (1000 kg; 1100 kg, 1150 kg) Drum // Plastic, HDPE // 200 L (200 kg, 220 kg) Jerry can // Plastic, HDPE // 10 L; 20 L, 30 L and 60 L (10 kg; 20 kg, 25 kg, 60 kg; 65 kg) Bottles Plastic // 1 L, 5 L (1 kg, 5 kg)	**Acceptable** with further restrictions and RMM
3	2	Preservation of cooling water in **open recirculating** systems (**large**)		Bacteria (incl. Legionella) Algae	Indoor Preservation of cooling water in **large open recirculating** cooling systems **Preventive and curative** action		In-use concentration (PAA): Bacteria (incl. Legionella): 1 - 10 ppm (w/w) Algae: 3.5 - 10 ppm (w/w) Number and timing of application: Frequency: Max. 1 Operation/day, Max. 15 min/day; 220 days/year. Contact time: 15 min - 24 h			**Acceptable** with further restrictions and RMM
1, 2, 3	3	Preservation of cooling water in **open recirculating** systems (**small**)			Indoor Preservation of cooling water in **small open recirculating** cooling systems **Preventive and curative** action					**Acceptable** with further restrictions and RMM

2, 3	4	Slimicide in the pulp and paper industry	12	Bacteria Yeast	Indoor Slimicide in the pulp and paper industry **closed System** **Preventive** action	Automated dosing into closed water cycle/paper machine and process operation	In-use concentration (PAA): Bacteria: 5-75 ppm (w/w) Yeasts: 20.5-75 ppm (w/w)			**Acceptable** with further restriction or RMM

3.2 Physical, chemical and technical properties

Table 13: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	Meta SPC 1: PERACLEAN 2 WT, DEGACLEAN 20* Meta SPC 2: PERACLEAN 5 WT Meta SPC 3: PERACLEAN 15 WT, DEGACLEAN 150* *: please see table 14 (conclusion on the physical, chemical and technical properties) for more explanation	All products are colourless clear liquids	Evonik Resource Efficiency GmbH, 2018, “Product Appearance of peracetic acid containing biocidal products of the PERACLEAN® and DEGACLEAN® group”
Colour at 20 °C and 101.3 kPa	Visual	Meta SPC 1: PERACLEAN 2 WT, DEGACLEAN 20* Meta SPC 2: PERACLEAN 5 WT Meta SPC 3: PERACLEAN 15 WT,	All products are colourless clear liquids	Evonik Resource Efficiency GmbH, “Product Appearance of peracetic acid containing biocidal products of the PERACLEAN® and DEGACLEAN® group”

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		DEGACLEAN 150* *: please see table 14 (conclusion on the physical, chemical and technical properties) for more explanation		
Odour at 20 °C and 101.3 kPa	Waiver: The odour was not evaluated as the products in the family contain substances of concern, which are volatile.			
Acidity / alkalinity	OECD 122	Meta SPC 1: PERACLEAN 2 WT, DEGACLEAN 20* Meta SPC 2: PERACLEAN 5 WT Meta SPC 3: PERACLEAN 15 WT, DEGACLEAN 150* Also artificial test product „PERACLEAN 17" was tested. For more information on PERACLEAN 17 please refer	**pH-values** PERACLEAN 2 WT: -0.5 DEGACLEAN 20: -0.2 PERACLEAN 5 WT: 0.1 PERACLEAN 15 WT: 0.4 DEGACLEAN 150: 0.0 PERACLEAN 17: -0.1 **Acidity (in % H_2SO_4):** PERACLEAN 2 WT: 1.62% DEGACLEAN 20: 2.13% PERACLEAN 5 WT: 7.18% PERACLEAN 15 WT: 14.17%	**pH:** Evonik Resource Efficiency GmbH, 2018, „Determination of the pH-value of peracetic acid containing biocidal products of the 0PERACLEAN® and DEGACLEAN® group" **Acidity:** Evonik Resource Efficiency GmbH, 2018, „Determination of the apparent acidity of

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		to conclusions of PCT-data and the confidential annex. *: please see table 14 (conclusion on the physical, chemical and technical properties) for more explanation	DEGACLEAN 150: 15.68% PERACLEAN 17: 15.01%	peracetic acid containing biocidal products of the PERACLEAN® and DEGACLEAN® group"
Relative density / bulk density	OECD 109 (Oscillating density meter)	Meta SPC 1: PERACLEAN 2 WT, DEGACLEAN 20* Meta SPC 2: PERACLEAN 5 WT Meta SPC 3: PERACLEAN 15 WT, DEGACLEAN 150* Also artificial test product „PERACLEAN17" was tested. For more information on PERACLEAN 17 please refer to conclusions of PCT-data and the confidential annex. *: please see table 14 (conclusion on the physical, chemical and technical properties) for more explanation	PERACLEAN 2 WT: 1.1983 g/mL at 20°C D_4^{20} = 1.1983 DEGACLEAN 20: 1.2003 g/mL at 20°C D_4^{20} = 1.2003 PERACLEAN 5 WT: 1.1297 g/mL at 20°C D_4^{20} = 1.1297 PERACLEAN 15 WT: 1.1436 g/mL at 20°C D_4^{20} = 1.1436 DEGACLEAN 150: 1.1483 g/mL at 20°C D_4^{20} = 1.1483	Evonik Resource Efficiency GmbH, 2018, „Determination of the density of peracetic acid containing biocidal products of the PERACLEAN® and DEGACLEAN® group"

Property	**Guideline and Method**	**Purity of the test substance (% (w/w))**	**Results**	**Reference**
			PERACLEAN 17: 1.152 g/mL at 20°C D_4^{20} = 1.1152	
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Meta SPC 1: PERACLEAN 2 WT	The product was stored at 40°C for 8 weeks. Active substance content: 1.74% before storage 1.70% after storage Loss of 2.3%. H_2O_2 content: 47.4% before storage 47.2% after storage Loss of 0.4%. Before and after storage: colourless clear liquid	Evonik Resource Efficiency GmbH, Accelerated storage test of peracetic acid containing biocidal products of the PERACLEAN® and CLARMARIN®group
		Meta SPC 1: DEGACLEAN 20*	The product was stored at 40°C for 8 weeks. Active substance content: 2.01% before storage 1.74% after storage Loss of 13.4%. H_2O_2 content: 46.5% before storage	Evonik Resource Efficiency GmbH, Accelerated storage test of peracetic acid containing biocidal products of the DEGACLEAN® group

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		*: please see table 14 (conclusion on the physical, chemical and technical properties) for more explanation	45.9% after storage Loss of 1.3%. Before and after storage: colourless clear liquid	
		Meta SPC 2: PERACLEAN 5 WT	The product was stored at 40°C for 8 weeks. Active substance content: 5.1% before storage 5.0% after storage Loss of 2.0%. H_2O_2 content: 26.3% before storage 26.0% after storage Loss of 1.1%. Before and after storage: colourless clear liquid	Evonik Resource Efficiency GmbH, Accelerated storage test of peracetic acid containing biocidal products of the PERACLEAN® and CLARMARIN®group
		Meta SPC 2: PERACLEAN 5 WT	The product was stored at 20°C for 14 weeks in the presence of stainless steel (VA 1.4404) coupon. This material is common for transportation and storage of the biocidal products.. Active substance content: 5.1% before storage 5.0% after storage	Evonik Resource Efficiency GmbH, 2017 Storage test of peracetic acid containing biocidal products of the PERACLEAN®group with steel coupon

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Loss of 2.0%. H_2O_2 content: 26.3% before storage 25.9% after storage Loss of 1.5%. Before and after storage: colourless clear liquid	
		Meta SPC 3: PERACLEAN 15 BULK which is identical with PERACLEAN 15 WT	The product was stored at 40°C for 8 weeks. Active substance content: 14.8% before storage 13.9% after storage Loss of 6.1%. H_2O_2 content: 22.4% before storage 21.3% after storage Loss of 4.9%. Before and after storage: colourless clear liquid	Evonik Resource Efficiency GmbH, Accelerated storage test of peracetic acid containing biocidal products of the PERACLEAN® and CLARMARIN®group
		Meta SPC 3: PERACLEAN 15 BULK which is identical with PERACLEAN 15 WT	The product was stored at 20°C for 14 weeks in the presence of a stainless steel (VA 1.4404) coupon. This material is common for transportation and storage of the biocidal products.	Evonik Resource Efficiency GmbH, Storage test of peracetic acid containing biocidal products of the

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Active substance content: 14.8% before storage 14.2% after storage Loss of 4.1%. H_2O_2 content: 22.4% before storage 22.0% after storage Loss of 1.8%. Before and after storage: colourless clear liquid	PERACLEAN®group with steel coupon
		Meta SPC 3: DEGACLEAN 150* *: please see table 14 (conclusion on the physical, chemical and technical properties) for more explanation	The product was stored at 40°C for 8 weeks. Active substance content: 15.1% before storage 13.8% after storage Loss of 8.6%. H_2O_2 content: 21.5% before storage 20.4% after storage Loss of 5.1%. Before and after storage: colourless clear liquid	Evonik Resource Efficiency GmbH, Accelerated storage test of peracetic acid containing biocidal products of the DEGACLEAN® group

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		Also artificial test product „PERACLEAN17” was tested. For more information on PERACLEAN 17 please refer to conclusions of PCT-data and the confidential annex.	The product was stored at 20°C for 14 weeks in the presence of a stainless steel coupon. Active substance content: 16.5% before storage 15.9% after storage Loss of 3.5%. H_2O_2 content: 23.1% before storage 22.6% after storage Loss of 2.4%. Before and after storage: colourless clear liquid	
Storage stability test – **long term storage at ambient temperature**		Meta SPC 1: PERACLEAN 2 WT Batch 97104050	The product was stored at 20°C for 24 months in a 10L HDPE canister Packaging appearance befor and after storage: blue colour, smooth surface, stable material, no interaction between product and packaging, no leakage, no ballooning or panelling observed. Active substance content: 1.90% before storage 1.83% after storage Loss of 3.7%.	Evonik Resource Efficiency GmbH, „Long term storage test of peracetic acid containing biocidal products of the DEGACLEAN® and PERACLEAN® group”

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			H_2O_2 content: 47.2% before storage 46.5% after storage Loss of 1.5%. Before and after storage: colourless clear liquid After storage: pH: -0.7 dilution stability: 1500 mg/L: no phase separation or sedimentation after 18h at 20°C.	
eCA remark: The acidity should have been determined after storage as well. However, as neither pH nor active substance content change significantly during storage significant variations in acidity are also not expected. Additionally, weight change was not investigated during storage. This is considered acceptable because the packaging was shown to be stable troughout storage and no reactivity towards the container material was observed.				
		Meta SPC 1: DEGACLEAN 20* Batch 84301283 *: please see table 14 (conclusion on the physical, chemical and technical	The product was stored at 20°C for 15 months in a 10L HDPE canister Packaging appearance befor and after storage: blue colour, smooth surface, stable material, no interaction between product and packaging, no leakage, no ballooning or panelling observed. Active substance content:	Evonik Resource Efficiency GmbH 2018, Long term storage test of peracetic acid containing biocidal products of the DEGACLEAN® group

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		properties) for more explanation	1.94% before storage 1.75% after storage Loss of 9.8%. H_2O_2 content: 46.5% before storage 45.9% after storage Loss of 1.3%. Before and after storage: colourless clear liquid After storage: pH: -0.1 dilution stability: 1500 mg/L: no phase separation or sedimentation after 18h at 20°C.	
eCA remark: The acidity should have been determined after storage as well. However, as neither pH nor active substance content change significantly during storage significant variations in acidity are also not expected. Additionally, weight change was not investigated during storage. This is considered acceptable because the packaging was shown to be stable troughout storage and no reactivity towards the container material was observed.				
		Meta SPC 2: PERACLEAN 5 WT Batch 97968110	The product was stored at 20°C for 24 months in a 10L HDPE canister Packaging appearance befor and after storage: blue colour, smooth surface, stable material, no interaction between product and	Evonik Resource Efficiency GmbH, 2019, „Long term storage test of peracetic acid containing biocidal products of the DEGACLEAN® and PERACLEAN® group”

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			packaging, no leakage, no ballooning or panelling observed. Active substance content: 5.04% before storage 4.75% after storage Loss of 5.8%. H_2O_2 content: 26.2% before storage 24.8% after storage Loss of 5.3%. Before and after storage: colourless clear liquid After storage: pH: 0.0 dilution stability: 5000 mg/L: no phase separation or sedimentation after 18h at 20°C.	
eCA remark: The acidity should have been determined after storage as well. However, as neither pH nor active substance content change significantly during storage significant variations in acidity are also not expected. Additionally, weight change was not investigated during storage. This is considered acceptable because the packaging was shown to be stable troughout storage and no reactivity towards the container material was observed.				
		Meta SPC 3: PERACLEAN 15 BULK which is identical with PERACLEAN 15 WT	The product was stored at 20°C for 15 months in a 10L HDPE canister	Evonik Resource Efficiency GmbH, 2019, „Long term storage test of peracetic acid containing biocidal

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Packaging appearance befor and after storage: blue colour, smooth surface, stable material, no interaction between product and packaging, no leakage, no ballooning or panelling observed. Active substance content: 14.96% before storage 13.63% after storage Loss of 8.9%. H_2O_2 content: 22.5% before storage 20.6% after storage Loss of 8.4%. Before and after storage: colourless clear liquid After storage: pH: 0.4 dilution stability: 5000 mg/L: no phase separation or sedimentation after 18h at 20°C.	products of the DEGACLEAN® and PERACLEAN® group”
eCA remark: The acidity should have been determined after storage as well. However, as neither pH nor active substance content change significantly during storage significant variations in acidity are also not expected. Additionally, weight change was not investigated during storage. This is considered acceptable because the packaging was shown to be stable troughout storage and no reactivity towards the container material was observed.				

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		Meta SPC 3: DEGACLEAN 150* *: please see table 14 (conclusion on the physical, chemical and technical properties) for more explanation	The product was stored at 20°C for 6 months in a 10L HDPE canister Packaging appearance befor and after storage: blue colour, smooth surface, stable material, no interaction between product and packaging, no leakage, no ballooning or panelling observed. Active substance content: 14.90% before storage 14.11% after storage Loss of 5.3%. H_2O_2 content: 21.5% before storage 20.7% after storage Loss of 3.7%. Before and after storage: colourless clear liquid After storage: pH: 0.4 dilution stability: 75 mg/L: no phase separation or sedimentation after 18h at 20°C.	Evonik Resource Efficiency GmbH, 2019, „Long term storage test of peracetic acid containing biocidal products of the DEGACLEAN® and PERACLEAN® group”

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
eCA remark: The acidity should have been determined after storage as well. However, as neither pH nor active substance content change significantly during storage significant variations in acidity are also not expected. Additionally, weight change was not investigated during storage. This is considered acceptable because the packaging was shown to be stable troughout storage and no reactivity towards the container material was observed.				
		Also artificial test product „PERACLEAN17” was tested. For more information on PERACLEAN 17 please refer to conclusions of PCT-data and the confidential annex.	The product was stored at 20°C for 15 months in a 10L HDPE canister Packaging appearance befor and after storage: blue colour, smooth surface, stable material, no interaction between product and packaging, no leakage, no ballooning or panelling observed. Active substance content: 16.80% before storage 15.20% after storage Loss of 9.5%. H_2O_2 content: 22.9% before storage 21.4% after storage Loss of 6.6%. Before and after storage: colourless clear liquid After storage: pH: -0.3	Evonik Resource Efficiency GmbH, „Long term storage test of peracetic acid containing biocidal products of the DEGACLEAN® and PERACLEAN® group”

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			dilution stability: 5000 mg/L: no phase separation or sedimentation after 18h at 20°C.	
eCA remark: The acidity should have been determined after storage as well. However, as neither pH nor active substance content change significantly during storage significant variations in acidity are also not expected. Additionally, weight change was not investigated during storage. This is considered acceptable because the packaging was shown to be stable troughout storage and no reactivity towards the container material was observed.				
Storage stability test – **low temperature stability test for liquids**	Label claim „protect fom frost” will be established. Thus, test does not need to be addressed.			
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waiving		BP are stored and transported in opaque packaging and not exposed to light.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			Humidity: No significant effect expected as the products are water-based. Moreover, the packaging is watertight so that an exchange of humidity between product and surrounding is prevented. Temperature: The accelerated storage stability test at elevated temperatures show that the products in the family are stable exept one product in	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Meta SPC 1. Thus, Meta label claim „ do not store above 30°C shall be used for Meta SPC 1.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			Long tem storage at ambient temperature PERACLEAN® 2 WT PERACLEAN® 5 WT PERACLEAN® 15 Test Item: 10 L HDPE canister, temperature of 20 °C +/- 3°C and a relative humidity of 50% +/-10%. Results of all products: No interaction between product and packaging: no leakage, no balloning or panelling observed.	Evonik Resource Efficiency GmbH, 2019d, Report-Nr.: 2019-06-27
Wettability	Waiver.		Not applicable. Data is only required for solid preparations which are to be dispersed in water. The products of this family are water-based liquid formulations used as soluble concentrates.	
Suspensibility, spontaneity and dispersion stability	Waiver.		Not applicable. Data is required only for solid preparations and suspensions which are to be dispersed/diluted in water. The products of this family are water-based liquid formulations used as soluble concentrates.	
Wet sieve analysis and dry sieve test	Waiver.		Not applicable. Data is not required for water-based liquid formulations used as soluble concentrates.	
Emulsifiability, re-emulsifiability and emulsion stability	Waiver.		Not applicable. Data is not required for water-based liquid formulations used as soluble concentrates.	

Property	**Guideline and Method**	**Purity of the test substance (% (w/w))**	**Results**	**Reference**
Disintegration time	Waiver.		Not applicable. Data is not required for water-based liquid formulations used as soluble concentrates.	
Particle size distribution, content of dust/fines, attrition, friability	Waiver.		Not applicable. Data is not required for water-based liquid formulations used as soluble concentrates.	
Persistent foaming	CIPAC MT 47.2	Meta SPC 1: PERACLEAN 2 WT, DEGACLEAN 20* Meta SPC 2: PERACLEAN 5 WT Meta SPC 3: PERACLEAN 15 WT, DEGACLEAN 150* Also artificial test product „PERACLEAN17" was tested. For more information on PERACLEAN 17 please refer to conclusions of PCT-data and the confidential annex. *: please see table 14 (conclusion on the physical, chemical and technical properties) for more explanation	PERACLEAN 2 WT: 1mg/L: no foam detected after 60 seconds. 1500 mg/L: no foam detected after 60 seconds. DEGACLEAN 20: 1mg/L: no foam detected after 60 seconds. 1500 mg/L: no foam detected after 60 seconds. PERACLEAN 5 WT: 1mg/L: no foam detected after 60 seconds. 5000 mg/L: no foam detected after 60 seconds. PERACLEAN 15 WT: 1mg/L: no foam detected after 60 seconds. 5000 mg/L: no foam detected after 60 seconds. DEGACLEAN 150: 1mg/L: no foam detected after 60 seconds.	Evonik Resource Efficiency GmbH, 2018, Persistent foaming test of peracetic acid containing biocidal products of the PERACLEAN® and DEGACLEAN® group

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			5000 mg/L: no foam detected after 60 seconds. PERACLEAN 17: 1mg/L: no foam detected after 60 seconds. 5000 mg/L: no foam detected after 60 seconds.	
Flowability/Pourability/Dustability	Waiver.		Not applicable. Data is not required for water-based liquid formulations used as soluble concentrates.	
Burning rate — smoke generators	Waiver.		Not applicable. Data is not required for water-based liquid formulations used as soluble concentrates.	
Burning completeness — smoke generators	Waiver.		Not applicable. Data is not required for water-based liquid formulations used as soluble concentrates.	
Composition of smoke — smoke generators	Waiver.		Not applicable. Data is not required for water-based liquid formulations used as soluble concentrates.	
Spraying pattern — aerosols	Waiver.		Not applicable. Data is not required for water-based liquid formulations used as soluble concentrates.	
Physical compatibility	Waiver.		All products of this family are not intended to be used in combination with other products.	
Chemical compatibility	Waiver.		All products of this family are not intended to be used in combination with other products.	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Degree of dissolution and dilution stability	CIPAC MT 41	Meta SPC 1: PERACLEAN 2 WT, DEGACLEAN 20* Meta SPC 2: PERACLEAN 5 WT Meta SPC 3: PERACLEAN 15 WT, DEGACLEAN 150* Also artificial test product „PERACLEAN17” was tested. For more information on PERACLEAN 17 please refer to conclusions of PCT-data and the confidential annex. *: please see table 14 (conclusion on the physical, chemical and technical properties) for more explanation	PERACLEAN 2 WT: 1500 mg/L: no phase separation or sedimentation after 18h at 20°C. DEGACLEAN 20: 1500 mg/L: no phase separation or sedimentation after 18h at 20°C. PERACLEAN 5 WT: 5000 mg/L: no phase separation or sedimentation after 18h at 20°C. PERACLEAN 15 WT: 5000 mg/L: no phase separation or sedimentation after 18h at 20°C. DEGACLEAN 150: 5000 mg/L: no phase separation or sedimentation after 18h at 20°C. PERACLEAN 17: 5000 mg/L: no phase separation or sedimentation after 18h at 20°C.	Evonik Resource Efficiency GmbH, 2018, Dilution stability test of peracetic acid containing biocidal products of the PERACLEAN® and DEGACLEAN® group
Surface tension	pendant drop method	Meta SPC 1: PERACLEAN 2 WT	65.4 mN/m at 20°C	Krüss GmbH, 2017, Determination of surface tension of aqueous solutions using the pendant drop method

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	pendant drop method	Meta SPC 1: DEGACLEAN 20* Meta SPC 2: PERACLEAN 5 WT Meta SPC 3: PERACLEAN 15 WT, Also artificial test product „PERACLEAN17" was tested. For more information on PERACLEAN 17 please refer to conclusions of PCT-data and the confidential annex. *: please see table 14 (conclusion on the physical, chemical and technical properties) for more explanation	DEGACLEAN 20: 64.65 mN/m at 20°C PERACLEAN 5 WT: 55.68 mN/m at 20°C PERACLEAN 15 WT: 45.19 mN/m at 20°C PERACLEAN 17: 44.56 mN/m at 20°C	Evonik Resource Efficiency GmbH, 2017, Report No.: A170003713
	Ring method	Meta SPC 1: PERACLEAN® 2 WT Meta SPC 2: PERACLEAN® 5 Bulk (same as PERACLEAN® 5 WT) Meta SPC 3: PERACLEAN® 15 Bulk (same as PERACLEAN® 15 WT)	PERACLEAN® 2 WT: 35.6 mN/m at 20°C PERACLEAN® 5 Bulk: 54.6 mN/m at 20°C PERACLEAN® 15 Bulk: 46.5 mN/m at 20°C	Evonik, TI, PL Analytics, 2020, Report No.: R-200914-00017

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Viscosity	OECD 114 capillary viscometer (static)	Meta SPC 1: PERACLEAN 2 WT	PERACLEAN 2 WT: kinematic viscosity: 1.049 mm^2/s at 20°C 0.73 mm^2/s at 40°C	Evonik Resource Efficiency GmbH, 2017, Report No.: A170007171
	OECD 114 capillary viscometer (static)	Meta SPC 1: DEGACLEAN 20* Meta SPC 2: PERACLEAN 5 WT Meta SPC 3: PERACLEAN 15 WT Also artificial test product „PERACLEAN17" was tested. For more information on PERACLEAN 17 please refer to conclusions of PCT-data and the confidential annex.	DEGACLEAN 20 kinematic viscosity: 1.081 mm^2/s at 20°C 0.743 mm^2/s at 40°C PERACLEAN 5 WT: kinematic viscosity: 1.242 mm^2/s at 20°C 0.829 mm^2/s at 40°C PERACLEAN 15 WT: kinematic viscosity: 1.550 mm^2/s at 20°C 1.015 mm^2/s at 40°C PERACLEAN 17: kinematic viscosity: 1.559 mm^2/s at 20°C 1.021 mm^2/s at 40°C	Evonik Resource Efficiency GmbH, 2017, Report No.: A170003712

Table 14

Conclusion on the physical, chemical and technical properties
The data provided by the applicant was acceptable. Tested product PERACLEAN 5 Bulk is identical with PERACLEAN 5 WT, product PERACLEAN 15 Bulk is identical with PERACLEAN 15 WT. Products DEGACLEAN 20 (Meta SPC1) and DEGACLEAN 150 (Meta SPC3) are products that were initially part of the product authorisation and deleted during evaluation. Both products were not removed in the evaluation of the physical, chemical and technical properties as they support to represent the compositional ranges of their corresponding meta SPCs. Espacially for the evaluation of the storage stability DEGACLEAN 20 (Meta SPC1) and DEGACLEAN 150 (Meta SPC 3) both represent the lower conentration ranges of the stabilizers in their respective Meta SPC. This is why the results of the storage stabilitytests for both products are used in order to set storage conditions and shelf live for Meta SPCs 1 and 3. The family consists of colourless, clear liquids products that have an pH between -0.5 and 0.4. The acidity ranges from 1.62% (w/w) in H_2SO_4 to around 16%(w/w) in H_2SO_4. The density ranges from ca. 1.12 g/mL to 1.20 g/mL. The accelerated storage test for product „DEGACLEAN 20" which was part of meta SPC 1 showed an a.s. decrease of >10%. Therefore label claim „ do not store above 30°C will be necessary for meta SPC 1. Test results for all other meta SPCs did not show an active substance decrease above 10%. For Meta-SPC 2 and 3, „Do not store above 40 °C" will be added to the SPC Identity of test product „PERACLEAN17" is stated in the confidential annex. Long term storage at ambient temperature: The following shelf lifes can be assigned: Meta SPC 1: 15 months Meta SPC 2: 24 months Meta SPC 3: 6 months The label claim „protect fom frost" will be established. Thus, a low temperature stability test does not need to be addressed. The BPF does neither show any persistent foaming nor any phase separation. The surface tension ranges from 44.6 mN/m at 20°C to 64.7 mN/m at 20°C, the kinematic viscosity from 1.05 mm^2/s at 20°C to 1.56 mm^2/s at 20°C and from 0.73 mm^2/s at 40°C to 1.02 mm^2/s at 40°C.

3.3 Physical hazards and respective characteristics

Table 15: Physical hazards and respective characteristics of the product

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.1.	Explosives	Data waiving. According to the Guidance on the Application of the CLP Criteria (Version 5.0, July 2017) explosive properties do not have to be determined for organic peroxides, because they are incorporated in the respective decision logic.		
4.2.	Flammable gases	Not applicable – products are liquids.		
4.3.	Flammable aerosols			
4.4.	Oxidising gases			
4.5.	Gases under pressure			
4.6.	Flammable liquids	DIN EN ISO 2719 Pensky Martens closed cup	PERACLEAN 2 (This product is identical with Peraclean 2 WT)	Meta SPC 1:Not classified.At a temperature of > 85 °C the test was interrupted because of a strong foaming at this temperature. No flash point was observed up to this temperature.
		DIN EN ISO 2719 Pensky Martens closed cup	Meta SPC 2: PERACLEAN 5 (This product is identical with Peraclean 5 WT)	At a temperature of > 85 °C the test was interrupted because of a strong foaming at this temperature. No flash point was observed up to this temperature.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
		DIN EN ISO 2719 Pensky Martens closed cup	PERACLEAN 17 The composition of this product is stated in the confidential annex.	Flash point = 76 °C Not classified. The tested product is deemed acceptable to be representative for Meta SPC 3. The read-across justification is in the confidential annex.
4.7.	Flammable solids	Not applicable – products are liquids.		
4.8.	Self-reactive substances and mixtures	Data waiving. According to CLP Annex 1: 2.8.1.1., organic peroxides are excluded from the definition of self-reactive substances and mixtures. Information regarding SADT determination please refer to organic peroxides below.		
4.9.	Pyrophoric liquids	Data waiving. Experience in production and handling of the products has shown that the products exhibit no pyrophoric properties.		
4.10.	Pyrophoric solids	Not applicable – products are liquids.		
4.11.	Self-heating substances and mixtures	Not applicable – products are liquids. This hazard class applies only to solids.		
4.12.	Substances and mixtures which in contact with water emit flammable gases	Data waiving. The products are aqueous solutions containing > 40 % water.		
4.13.	Oxidising liquids	Meta SPC 1 Oxid. liquid, Category 2 More information is available under 4.15 “Organic peroxides.”		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
		Meta SPC 2 Oxid. liquid, Category 2 More information is available under 4.15 “Organic peroxides.”		
		Meta-SPC 3 is classified as organic peroxide type F. Therefore, according to the Guidance on the application of the CLP criteria section 2.13.3, the classification procedure and criteria for oxidising substances or mixtures is not applicable.		
4.14.	Oxidising solids	Not applicable – products are liquids.		
4.15.	Organic peroxides	UN-MTC, Part II, Section 28 H4	Meta-SPC 1 PERACLEAN 2 (This product is identical with Peraclean 2 WT)	SADT > 75 °C for a 50 kg package. Accordingly, no temperature control is necessary.
		UN-MTC, Part II, Section 28 H4	Meta SPC 2: PERACLEAN 5 (This product is identical with Peraclean 5 WT)	SADT > 75 °C for a 50 kg package. Accordingly, no temperature control is necessary.
		UN-MTC, Part II, Section 28 H4	PERACLEAN 2 WT Charge: V20.023	SADT representative for largest packaging: 1L Dewar with 18 mW/K·kg was used in

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				order to represent larger packaging than 50kg. SADT > 55 °C. Accordingly, no temperature control is necessary.
		UN-MTC, Part II, Section 28 H4	PERACLEAN 5 (This product is identical with Peraclean 5 WT) Charge: V20.025	SADT representative for largest packaging: 1L Dewar with 18 mW/K·kg was used in order to represent larger packaging than 50kg. SADT > 55 °C. Accordingly, no temperature control is necessary.
		UN-MTC, Part II, Section 28 H4	PERACLEAN 17 (Identity of this test product „PERACLEAN17" is stated in the confidential annex) and is representative for Meta SPC 3	SADT representative for largest packaging: 1L Dewar with 18 mW/K·kg was used in order to represent larger packaging than 50kg. SADT > 55 °C. Accordingly, no temperature control is necessary.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				Although other tests were conducted, see the two rows above, PERACLEAN 17 can be considered as representative for the whole BPF. A temperature control for the whole BPF can therefore be excluded.
		Test series according to the flow chart scheme according to CLP	PERACLEAN 5 (This product is identical with Peraclean 5 WT) Charge: 70277671	Organic peroxide Type F Box 1, test series A, detonation: BAM 50/60 steel tube test (cavitated version as the containment in IBCs exceeds a capacity of 450 L) Result: Fragmentation length: 13.2 cm and 13.4 cm; average: 13.3 cm. Comparative fragmentation length of inert substance (H20): 11.2 cm “**no detonation**”. Box 5; test series C, deflagration: Time/pressure test: in 3 measurements the gauge pressure did not reach 2070 kPa above atmospheric. Result: “**No**”

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				Deflagration test: The tested product could not be ignited. Result: “**no deflagration**” Box 9, test series E, heating under confinement: Koenen test: The tube remained unchanged, type “O” results in “**No**”. Dutch pressure vessel test: The limiting diameter is < 1.0 mm, no rupture was observed. Result: “**No**”. Box 11 (packaging size) is answered with yes Box 12, explosive power, test series F: BAM Trauzl test: two tests conducted with 7.1 cm³ expansion per 10g of sample resp. 7.7 cm³ expansion per 10g of sample. Result: “**No**” (expansion in both tests < 10cm³).

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				Following the flow chart the box 13 can be answered with no please see results for box 9 above. box 14 SADT <60°C can be answered with no please see result above. Box 16 “is diluent with a boiling point of < 150°C used” is answered with **yes**, as the product is a water based. However, the meta SPCs 1 and 2 profit from the UN3149 which foresees an assignment to organic peroxide Type G for “Hydrogen peroxide and peroxyacetic acid mixture with acid(s), water and not more than 5% peroxyacetic acid, stabilized.” All conditions for this assignment are fulfilled. Final result: organic peroxide Type G

Numbering according to Annex III of BPR	**Property**	**Guideline and Method**	**Tested product / batch (AS% (w/w)**	**Results**
		Test series according to the flow chart scheme according to CLP	PERACLEAN 15 (This product is identical with Peraclean 15 WT) Charge: 70708921	Organic peroxide Type F Box 1, test series A, detonation: BAM 50/60 steel tube test (cavitated version as the containment in IBCs exceeds a capacity of 450 L) Result: Fragmentation length: 14.2 cm and 15.1 cm; average: 14.7 cm. Comparative fragmentation length of inert substance (H20): 11.2 cm “**no detonation**”. Box 5; test series C, deflagration: Time/pressure test: in 3 measurements the gauge pressure did not reach 2070 kPa above atmospheric. Result: “**No**” Deflagration test: The tested product could not be ignited. Result: “**no deflagration**” Box 9, test series E, heating under confinement:

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				Koenen test: The tube remained unchanged, type “O” results in “**No**”. Dutch pressure vessel test: The limiting diameter is < 1.0 mm, no rupture was observed. Result: “**No**”. Box 11 (packaging size) is answered with yes Box 12, explosive power, test series F: BAM Trauzl test: two tests conducted with 9.0 cm³ expansion per 10g of sample resp. 8.9 cm³ expansion per 10g of sample. Result: “**No**” (expansion in both tests < 10cm³). Following the flow chart the box 13 can be answered with no, please see results for box 9 above. Box 14 SADT <60°C can be answered with no please see result above.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				However box 16 “is diluent with a boiling point of < 150°C used” is answered with **yes**, as the product is a water based. Final result: organic peroxide Type F
		Test series according to the flow chart scheme according to CLP	PERACLEAN 17 (Identity of this test product „PERACLEAN17” is stated in the confidential annex) and is representative for Meta SPC 3	Organic peroxide Type F Box 1, test series A, detonation: BAM 50/60 steel tube test (cavitated version as the containment in IBCs exceeds a capacity of 450 L) Result: Fragmentation length: 15.5 cm and 17.5 cm; average: 16.5 cm. Comparative fragmentation length of inert substance (H20): 11.2 cm “**no detonation**”. Box 5; test series C, deflagration: Time/pressure test: 3 measurements conducted. Twice the gauge pressure did not reach 2070 kPa above atmospheric. In

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				the third measurement a rupture of the busting disc was already detected at 1928kPa at a tise time of >8547ms. This leads to the result: “**yes slowly**” Deflagration test: The tested product could not be ignited. Result: “**no deflagration**” Overall according to test seriec C the result for box 5 is “**no**”. Box 9, test series E, heating under confinement: Koenen test: The tube remained unchanged, type “O” results in “**No**”. Dutch pressure vessel test: The limiting diameter is < 1.0 mm, no rupture was observed. Result: “**No**”. Box 11 (packaging size) is answered with yes Box 12, explosive power, test series F:

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				BAM Trauzl test: two tests conducted with 10.8 cm³ expansion per 10g of sample resp. 10.6 cm³ expansion per 10g of sample. Result: "**Low**" (expansion in both tests > 10cm³, < 25cm³). Final result: organic peroxide Type F
4.16.	Corrosive to metals	UN test C.1	Tested products are: "Oxypure 1.5 TE%", "Oxypure Bio-5%" and "Oxypure Bio-15%" The tested products represent compositions with the highest, the lowest and a medium PAA content. The products have comparable	Oxypure Bio-15%: Aluminium: The test lasted 168 hours. For this time of exposure calculated mass loss threshold based on a 6.25 mm/year is 13.5%. The mass loss of the most corroded aluminium sample : 1.29%. Corrosion rate of aluminium at 55ºC was below the threshold of 6.25mm/year. Steel: The test lasted 168 hours. The most corroded sample was the steel sample ½

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
			acidities, pH-Values and active oxygen content compared to the BPF. Thus the test of the three products is deemed representative for the BPF for this endpoint. The compositions of tested products are stated in the confidential annex.	immersed, with localised corrosion at the liquid/vapour space boundary. For this time of exposure deepest intrusion threshold based on a 6.25 mm/year is 120 µm. The depth of deepest hole determined for this sample with microscope was 440±10 µm. Corrosion rate of steel at 55ºC was above the threshold of 6.25mm/year. According to UN test C.1 criteria, the test material was considered to be corrosive to metals. **Oxypure Bio-5%** Aluminium The test lasted 168 hours. For this time of exposure calculated mass loss threshold based on a 6.25 mm/year is 13.5%. The mass loss of the most corroded aluminium sample : 1.29%. Steel

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				The test lasted 168 hours. The most corroded sample was the steel sample ½ immersed, with localised corrosion at the liquid/vapour space boundary. A total perforation was observed. According to UN test C.1 criteria, the test material was considered to be corrosive to metals. Oxypure 1.5 TE% Aluminium Uniform corrosion. The test lasted 168 hours. For this time of exposure calculated mass loss threshold based on a 6.25 mm/year is 13.5%. The mass loss of the most corroded aluminium sample : 3.98%. Steel Uniform corrosion. The test had to be terminated after 77 hours because of the

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				violent reaction which caused boiling the tested liquid over the test vessel. For this time of exposure calculated mass loss threshold based on a 6.25 mm/year is 6.81%. The mass loss of the most corroded steel sample: 10.36%. **All products of the BPF are considered as metal corrosive**
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	Data waiving. According to the Guidance on the Application of the CLP Criteria (Version 5.0, July 2017) the determination of the auto ignition temperature is not relevant for organic peroxides.		
4.17.2.	Relative self-ignition temperature for solids	Not applicable – products are liquids.		
4.17.3.	Dust explosion hazard	Not applicable – products are liquids.		

Table 16

Conclusion on the physical hazards and respective characteristics
The data provided by the applicant was acceptable. The classification in relation to physical hazards is: Meta-SPC 1: Metal Corr 1, Org Perox G, Oxidizing liquid 2 Meta-SPC 2: Metal Corr 1, Org Perox G, Oxidizing liquid 2 Meta-SPC 3: Metal Corr 1, Org Perox F

3.4 Methods for detection and identification

Table 17

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements[1]**	**Recovery rate (%)[1]**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Peracetic acid *(active substance);*	Iodometric titration	Demonstrated, no significant interferences were observed	0.97% - 22.5% (w/w) 5 measurements each at 4 concentrations $r^2 \geq 0.99$	4.97 % w/w (n=5)	99.8 – 100.2	100	0.2 %	Not determined	Anonymous, 2019, „Validation of the Determination of Peracetic Acid and Hydrogen Peroxide Content in biocidal Peracetic Acid Products.”,
				16.28 % w/w (n=5)	99.9 – 100.1	100	0.06%		
Hydrogen Peroxide *(equilibrium partner of the active substance)*	Cerimetric titration	Demontrated, no significant interferences were observed	1.37% - 37.1% (w/w) 5 measurements each at 4 concentrations $r^2 \geq 0.99$	25.95 % w/w (n=5)	99.96 – 100.04	100	0.04 %	Not determined	Anonymous., 2019, „Validation of the Determination of Peracetic Acid and Hydrogen Peroxide Content in biocidal Peracetic Acid Products.”,
				22.96 % w/w (n=5)	99.96 – 100.04	100	0.03%		

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements[1]**	**Recovery rate (%)[1]**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Acetic acid (equilibrium partner of the active substance)	HPLC-DAD method	No interferences detected	0.2 to 2 g acetic acid/L (n=6), R=0.99996	0.76 g/L (n=5)	100 – 102	101	1	0.283 g/L	Noack Laboratorien, 2017, „Method Validation for Acetic Acid”
				1.06 g/L (n=5)	101-103	102	1		

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[1] For PAA and hydrogen peroxide, Determination of accuracy is not technically feasible as the PAA exists always in equilibrium with the HP and AA. Instead, results for repeatability for the products PERACLEAN® 5 Bulk and PERACLEAN® 17 are reported here.

Table 18

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	no relevant residues expected	-	AR for PT 11 and 12, LoEP, chapter 2, 08/2016
Drinking water	peracetic acid	0.1 µg/L	minimal requirement of the Drinking Water Act
Surface water	peracetic acid	0.069 µg/L	PNEC$_{aquatic}$ based on NOEC *Danio rerio* (AF 10), AR for PT 11 and 12, chapter 2.2.2.2, 08/2016
Air	peracetic acid	0.5 mg/m³ (0.16 ppm)	AEC inhalation, AR for PT 11 and 12, LoEP, chapter 2, 08/2016
	hydrogen peroxide	1.25 mg/m³ (0.88 ppm)	AEC inhalation, AR for PT 11 and 12, LoEP, chapter 2, 08/2016
Animal and human body fluids and tissues	no relevant residues expected	-	not classified as T/T+ AR for PT 11 and 12, chapter 2.1.3, 08/2016
Food of plant and animal origin	no relevant residues expected	-	AR for PT 11 and 12, LoEP, chapter 2, 08/2016

Table 19

Analytical methods for drinking water and surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Peracetic acid (PAA)	Determi-nation as MTSO per LC-UV at 225 nm using Inertsil ODS-3 column	No interference	0.2 – 20 mg/L (MTSO) that means 0.1 – 10 mg/L PAA	0.1 – 5 mg/L	-	105	2.4	reported LOQ: 0.02 mg/L	CAR, doc IIIA, 4.2 c (01), Van Egdom (2006)

Table 20

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Peracetic acid (PAA)	Determination as MTSOO per LC-UV at 224 nm using C18 column	No interference	NA	1.61 ppm / 4 2.99 ppm / 4 0.23 ppm / 4 0.23 ppm / 4 0.47 ppm / 4		95 96 97 94 95	2.6 1.6 5.3 5.1 1.1	0.23 ppm	CAR, doc IIIA, 4.2 b (01), Hecht et al. (2004)
Hydrogen peroxide	Determination as titanium peroxysulfate per absorption spectrometry at 410 nm	No interference	NA	2.09 ppm / 4 3.75 ppm / 4 0.42 ppm / 4 0.32 ppm / 4 0.59 ppm / 4		93 95 87 93 92	4.2 8.0 9.0 7.2 3.5	0.32 ppm	CAR, doc IIIA, 4.2 b (01), Hecht et al. (2004)

Table 21

Analytical methods for animal and human body fluids and tissues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Peracetic acid (PAA)	Determination as MTSO per LC-UV at 225 nm using Inertsil ODS-3 column	No interference	0.2 – 20 mg/L (MTSO) that means 0.1 – 10 mg/L PAA	0.1 – 5 mg/L	-	105	2.4	reported LOQ: 0.02 mg/L	CAR, doc IIIA, 4.2 d (01), Van Egdom (2005)

Table 22

Data waiving was acceptable for the following information requirements	
Information requirement	1. 5.2.1. Soil 2. 5.3. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant
Justification	Analytical methods for monitoring purposes in **soil** and in/on **food of plant and animal origin or feeding stuffs** are not necessary since no relevant residues of peracetic acid are expected.

Table 23

Conclusion on the methods for detection and identification
Analytical methods for the analysis of the product as such are acceptable. The methods provided regarding the residues of peracetic acid in **water, air and blood** were acceptable even if the LOQ of the methods is not sufficiently low in comparison to the current lowest limits. In the respective AR for peracetic acid PT 11-12 the methods are accepted despite these deficiencies. The provided method regarding the residues of hydrogen peroxide in **air** is accepted.

3.5 Efficacy against target organisms

3.5.1 Function and field of use

Products of the “Evonik PAA BPF PT 11 PT 12” (further only referred to as “the BPF”) are used in PTs 11 and 12. They contain peracetic acid (PAA) as the sole active substance. The intended uses in PT 11 include curative preservation of cooling water in once-through systems and both preventive and curative preservation of cooling water in large and small open cooling systems. In PT 12 products are used as preventive slimicides in the pulp and paper industry. All products of the BPF are concentrates and used only by professional users.

3.5.2 Organisms to be controlled and products, organisms or objects to be protected

Products of the BPF are intended to act against microorganisms (bacteria, *Legionella*, algae, yeast). They are used to protect either cooling systems (PT 11) or pulp and paper production processes (PT12).

3.5.3 Effects on target organisms, including unacceptable suffering

PAA causes irreversible inactivation of microorganisms within a short timeframe.

3.5.4 Mode of action, including time delay

PAA is present in an equilibrium with hydrogen peroxide and acetic acid. Although these are known active substances themselves, it is known that PAA is substantially more active than either hydrogen peroxide or acetic acid, so PAA is considered to be the most relevant active component.
As described in the active substance CAR, PAA is a strong oxidant which is suspected to act via different mechanisms, including formation of hydroxyl radicals and organic radicals. Its action results in denaturation of proteins and disruption of cell membranes, which causes irreversible inactivation of the target organisms. There is no time delay in the action of PAA.

3.5.5 Efficacy data

General
Products within the family may contain different ratios of PAA and its equilibrium partners as well as different co-formulants (for detailed information please refer to conf PAR). To substantiate the choice of the worst case test product for the entire BPF, the applicant presented theoretical considerations and comparative experimental data. On the theoretical side, the ratio of PAA to other co-formulants, including its equilibrium partner hydrogen peroxide, was considered. This led to the selection of Peraclean 15 Bulk as putative representative worst case product. The selection was confirmed by bridging studies (EN 1040

and EN 1275 tests) that compared efficacy of different biocidal products within the BPF containing various amounts of co-formulants, which demonstrated that all products performed somewhat similarly, but Peraclean 15 Bulk tended to have the lowest log reductions.

The eCA agrees with the applicant's approach and considers Peraclean 15 Bulk to be a representative worst case product on which the entire efficacy assessment of the BPF can be based. When converting concentrations in % (v/v) to ppm (w/w), the relative density of the test product (1.14 g/ml) was taken into account. All ppm values are stated as ppm (w/w).

PT 11

All intended uses in PT 11 concern the preservation of cooling water and therefore could be covered by one efficacy assessment. The intended uses are either only curative or cover both curative and preventive applications. The submitted studies simulate practical conditions of use and therefore fulfil the definition of Tier 2 studies without additional ageing.

With regard to Use 1 (Preservation of cooling water in once-through systems), a restriction to only seawater-based systems was made after the efficacy assessment due to identified environmental risks when used in freshwater. In the absence of specific efficacy guidance on requirements for seawater-only uses, the available studies were accepted for the restricted claim, as before they were acceptable for a general, unspecified claim, which would have included seawater as well. The claimed target organisms for this use, (planktonic/suspended) bacteria and Legionellae, are considered potentially relevant in freshwater as well as saltwater [for *Legionella*, see references 1, 2, 3]. As in any case representative target organisms are tested, it is not assumed that representative saltwater strains of bacteria would behave fundamentally different from the tested freshwater bacteria. Activity against other target organisms, which may be more relevant in seawater than in freshwater (esp. general biofouling and mussels), was not claimed and consequently has not been demonstrated in the context of this authorisation dossier.

Preventive efficacy (no growth in treated samples) against bacteria in cooling water was demonstrated by two studies performed according to ASTM E645-13 (L20/0014.4, L20/0014.7) and at a product concentration of 0.0006% (1.14 ppm PAA). Curative bactericidal efficacy (≥3 logR) was demonstrated by the same studies for 0.0006% product (1.14 ppm PAA; 24 h contact time; L20/0014.4) and 0.003% product (5 ppm PAA; 3 h contact time; L20/0014.7), respectively. Both studies were valid for curative and preventive efficacy by demonstrating copious growth (>0.5 log) in the untreated controls. A further study performed according to ASTM E645-13 (J000800) demonstrated curative bactericidal efficacy within 15 min at a concentration of 0.0035% product (6 ppm PAA).

To substantiate efficacy against *Legionella* the applicant submitted a test performed according to EN 13623-2010 (L17/0802.2) and two studies performed according to ASTM E645-13 with *Legionella pneumophila* at contact times of 3 h (L20/0014.8) and 24 h (L20/0014.5). Preventive efficacy was demonstrated for a product concentration of 0.0006% (1.14 ppm PAA). Curative efficacy (≥3 logR) was demonstrated for product concentrations of 0.003% (5 ppm PAA; 3 h) and 0.002% (3 ppm PAA; 24 h). The additional study performed according to EN 13623-2010 demonstrated curative efficacy at 0.005%

product (8.5 ppm PAA) within 15 min. Population levels remained relatively stable in untreated controls, so the studies were valid for curative efficacy.

Two further studies were submitted to support algaecidal efficacy. One (J000799) was performed according to ASTM E645-13 against the green alga *Chlorella vulgaris* with a test duration of 24 h. This study was valid for curative efficacy (stable population in the untreated control) and demonstrated curative efficacy against green algae (≥95% reduction) within 24 h at 0.005% product concentration (8.5 ppm PAA). Preventive efficacy was not demonstrated, as no growth in the untreated controls was reported. The second study (J002126-5) was performed according to a modified ASTM E645-13 protocol against *Chlorella vulgaris* and the cyanobacterium *Anabaena* sp.. The main deviation from standard protocol was a transfer into liquid cultivation media after the contact time with the biocidal product was completed in synthetic cooling water. Analysis was performed only after the transfer, but not during the contact period with the biocide. The transfer included a 10-fold dilution, which was also supposed to act as neutralisation, but this was not validated. Quantification of growth after the transfer was attempted by spectrophotometry, but the provided calibration curves (OD640 vs. cells/ml) are of rather poor quality, especially for *Anabaena* sp., and more importantly do not cover the very low OD640 values recorded on the first measurement day (0.001 – 0.007) and also during most of the measuring period. This is critical, as spectrophotometric measurements are widely known to lack precision below OD ~ 0.05 due to measurement noise. Furthermore, there are no control samples taken for recovery evaluation at the beginning of the contact time and no OD640 measurements appear to have been conducted directly after transfer into cultivation medium. In total, the experimental setup and the reported data do not permit drawing any quantitative conclusion on events during the contact time. Consequently, it is neither possible to determine what level of reduction the biocidal treatment achieved nor what occurred in the untreated controls during contact time. Therefore, the second study is considered invalid. This means that only a curative claim against green algae is possible based on the first study (J000799). A general algaecidal claim cannot be made, as no valid data for cyanobacteria are available.

To conclude, the BPF can be authorised in PT 11 for preventive efficacy against bacteria and for curative efficacy against bacteria, *Legionella*, and green algae with the following concentrations:

Preventive application: bacteria (incl. *Legionella* spp.), 1.14 ppm PAA
Curative application (15 min): bacteria, 6 ppm PAA; *Legionella* spp., 8.5 ppm PAA
Curative application (3 h): bacteria (incl. *Legionella* spp.), 5 ppm PAA
Curative application (24 h): bacteria, 1.14 ppm PAA; *Legionella* spp., 3.5 ppm PAA; green algae, 8.5 ppm PAA.

PT 12

Six studies performed according to ASTM E1839-13 were submitted to support bactericidal and yeasticidal preventive efficacy. The submitted studies simulate practical conditions of use and therefore fulfil the definition of Tier 2 studies without additional ageing.

Four studies concerned bactericidal efficacy. Two of these (J002126-1 and J002126-2) are considered invalid for preventive efficacy, as the minimum requirement for growth in the untreated controls (+0.5 log) could not be demonstrated due to unsuitable dilutions used for plating. In the other two studies, *Pseudomonas aeruginosa*, *Klebsiella* (formerly *Enterobacter*) *aerogenes* and *Aeromonas hydrophila* were tested either in acidified paper pulp (J000896-1) or in alkaline paper pulp (J000896-2). All data for *A. hydrophila* was not valid due to a lack of growth in the controls, but this was accepted since the organism is not considered relevant for pulp and paper processes. In alkaline pulp (J000896-2), *K. aerogenes* was reduced by >2 log within 3 h at 0.0035% product (6 ppm PAA) and no surviving organisms were observed at 0.0065% product (11 ppm PAA). *P. aeruginosa* was reduced by >2 log at 0.013% product (22.5 ppm PAA) and no surviving organisms were observed at 0.02% (34.5 ppm PAA). Growth of *K. aerogenes* in the untreated control was rapid within 3 h, while *P. aeruginosa* alone reached a sufficient level of growth to achieve validity only after 24 h. As peracetic acid is known to promote microbial growth if the concentration is insufficient and as data on the treated samples is available for a maximum of 3 h, preventive efficacy during 24 h is not ensured for concentrations that did not achieve full kill of the challenge inoculum. Therefore, the minimum effective bactericidal concentration is 0.02% product (34.5 ppm PAA), which achieved a full kill both for *P. aeruginosa* and *K. aerogenes* and therefore ensures adequate preventive efficacy.

Based on the latest agreements of the EFF WG-II-2020 on the future efficacy guidance for PT 12, the eCA considers this data sufficient to cover the intended use with regard to bacteria without a need for restrictions concerning the pH of the pulp or paper process. The additional study performed in acidic pulp (J000896-1) is considered as supporting data, as it is valid only for *K. aerogenes*.

Yeasticidal efficacy is addressed in four studies. In alkaline pulp (Report J002126-4), 0.0006% product (1.14 ppm PAA) did not prevent increases in cell numbers of *Candida albicans* and *Rhodotorula mucilaginosa* within 24 h, but 0.003% (5 ppm PAA) did. Substantial growth (+0.9 log) was observed at the same time in untreated controls, so the test is valid. A corresponding test in acidic pulp (Report J002126-3) was not valid, as the dilution used for plating made it impossible to observe an increase of 0.5 log. However, as in the case of bacteria, the eCA considers the data for yeasticidal efficacy in alkaline pulp to be sufficient for authorisation of the use.

To conclude, the BPF can be authorised in PT 12 for preventive efficacy against bacteria and yeast at 34.5 ppm PAA in pulp and paper processes.

Table 24

Note: Only studies deemed relevant for the assessment result are listed in this table.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide (PT 11)	Preservation of cooling systems	Peraclean 15 Bulk (15% PAA)	*Pseudomonas aeruginosa* *Aeromonas hydrophila* *Enterobacter cloacae* *Micrococcus luteus*	ASTM E645-13	Test matrix: synthetic cooling water as described in EN 13623 Concentrations tested: 0.0006; 0.001; 0.002% product (1.14; 1.7; 3.4 ppm PAA) Test temperature: 30 °C Test duration: 24 h Challenges: 1 Replicates: 3 Neutralisation: validated	0.0006% product caused a log reduction >3. Untreated controls showed strong growth, so the test is valid.	Report L20/0014.4 **Key study**
Bactericide (PT 11)	Preservation of cooling systems	Peraclean 15 Bulk	*P. aeruginosa* *A. hydrophila* *Ent. cloacae* *M. luteus*	ASTM E645-13	Test matrix: synthetic cooling water as described in EN 13623 Concentrations tested: 0.0006; 0.003; 0.006% product (1.14; 5.1; 10.2 ppm PAA) Test temperature: 30 °C Test duration: 3 h Challenges: 1 Replicates: 3 Neutralisation: validated	0.0006% product caused a log reduction of 2.9. 0.003% product caused a log reduction >4. Untreated controls showed strong growth, so the test is valid.	Report L20/0014.7 **Key study**

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide (PT 11)	Preservation of cooling systems	Peraclean 15 Bulk	*P. aeruginosa* *A. hydrophila* *Ent. cloacae*	ASTM E645-13	Test matrix: synthetic cooling water as described in EN 13623 Concentrations tested: 0.0007; 0.002; 0.0035; 0.005% product (1.2; 3.4; 6; 8.5 ppm PAA) Test temperature: 30 °C Test duration: 3 h Sampling times: 15; 30; 180 min Challenges: 1 Replicates: 2 Neutralisation: validated	No effect on the test organisms was observed at 0.0007% product. 0.002% product did not achieve a ≥3 log reduction against *Ent. cloacae* within the test duration. 0.0035% product achieved a >5 log reduction against all test organisms within 15 min. Cell numbers stayed constant in untreated controls, so the test is valid for curative efficacy.	Report J000800 **Key study**
Algaecide (PT 11)	Preservation of cooling systems	Peraclean 15 Bulk	*Chlorella vulgaris* *Anabaena sp.*	ASTM E645-13 modified	Test matrix: synthetic cooling water as described in EN 13623 Concentrations tested: 0.002; 0.006; 0.008% product (3 h) (3.4; 10.2; 13.6 ppm PAA) 0.0006; 0.002; 0.006% product (24 h)	Due to the transfer step after contact time with the biocidal product, the low starting values in the culture medium, and the poor quality of the calibration curves for both test organisms,	Report J002126-5

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					(1.14; 3.4; 10.2 ppm PAA) Test temperature: 30 °C Test duration: 3 / 24 h Challenges: 1 Replicates: 3 Transfer into growth medium after completed contact time, investigation of growth afterwards via spectrophotometry. Neutralisation by dilution during transfer, not validated.	no quantitative assessment of the effect of the biocidal product is possible. As this issue also concerns the untreated controls, the study is not valid.	
Algaecide (PT 11)	Preservation of cooling systems	Peraclean 15 Bulk	*Chl. vulgaris*	ASTM E645-13	Test matrix: synthetic cooling water as described in EN 13623 Concentrations tested: 0.002; 0.005; 0.01; 0.02% product (3.4; 8.5; 17; 34 ppm PAA) Test temperature: 30 °C Test duration: 3 / 24 h Challenges: 1 Replicates: 2 Neutralisation: validated	Log reductions >2 were observed at 0.02% product after 3 h or 0.01% product after 24 h. Lower concentrations achieved reductions of 0.5 – 1.5 log. Slight reductions of approx. 0.2 log were observed in the water controls when compared to the inoculum (no recovery data	Report J000799 **Key study**

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						available). Therefore, the data is considered valid for curative efficacy, but invalid for preventive efficacy.	
Bactericide (PT 11)	Preservation of cooling systems	Peraclean 15 Bulk	*Legionella pneumophila*	ASTM E645-13	Test matrix: synthetic cooling water as described in EN 13623 Concentrations tested: 0.0006; 0.001; 0.002% product (1.14; 1.7; 3.4 ppm PAA) Test temperature: 30 °C Test duration: 24 h Challenges: 1 Replicates: 3 Neutralisation: validated	At product concentrations of 0.0006%, 0.001% and 0.002% log reductions of 0.98, 2.64 and >3 were observed, respectively. Cell counts in untreated controls increased by 0.3 log.	Report L20/0014.5 **Key study**
Bactericide (PT 11)	Preservation of cooling systems	Peraclean 15 Bulk	*L. pneumophila*	ASTM E645-13	Test matrix: synthetic cooling water as described in EN 13623 Concentrations tested: 0.0006; 0.003; 0.006% product (1.14; 5.1; 10.2 ppm PAA) Test temperature: 30 °C Test duration: 3 h Challenges: 1	No substantial reduction was observed at 0.0006% product. Log reductions >4 were observed both at 0.003% and 0.006%. Cell counts in untreated controls increased by 0.1 log.	Report L20/0014.8 **Key study**

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Replicates: 3 Neutralisation: validated		
Bactericide (PT 11)	Preservation of cooling systems	Peraclean 15 Bulk	*L. pneumophila*	EN 13623-2010	Concentrations tested: 0.002; 0.005; 0.015; 0.03% (15 min) (3.4; 8.5; 25.6; 51.2 ppm PAA) 0.002; 0.004; 0.01; 0.02% (30 min) (3.4; 6.8; 17.2; 34.2 ppm PAA) Test temperature: 30 °C Test duration: 15 / 30 min Challenges: 1 Replicates: 1 Neutralisation: validated	0.005% product achieved a >5 log reduction within 15 min. All controls were valid.	Report L17/0802.2 **Key study**
Bactericide, Yeasticide, Fungicide (PT 12)	Slimicide in pulp and paper industry	Peraclean 15 Bulk	*P. aeruginosa* *Klebsiella (ex Enterobacter) aerogenes* *A. hydrophila* *Aspergillus brasiliensis* *Candida albicans*	ASTM E1839-13	Test matrix: 0.33 g hardwood + 0.165 g softwood pulp, pH 5.0-5.5 (acid furnish) Concentrations tested: 0.0035; 0.0065; 0.013; 0.02; 0.03; 0.04; 0.05; 0.06% product (6; 11.1; 22.2; 34.2; 51.2; 68.4; 85.5; 102 ppm PAA) Test temperature: 35 °C Test duration: 180 min	Bacterial and yeast growth was prevented at 0.0035% product. Untreated controls of *K. aerogenes* and *C. albicans* showed growth. No growth was demonstrated for *P. aeruginosa*, *A. hydrophila* and *Asp. brasiliensis*, so the	Report J000896-1 **Supporting study**

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Sampling times: 0; 30; 60; 120; 180 min Challenges: 1 Replicates: 2 Neutralisation: -	study is just partially valid for bacteria and invalid for filamentous fungi.	
Bactericide, Yeasticide, Fungicide (PT 12)	Slimicide in pulp and paper industry	Peraclean 15 Bulk	*P. aeruginosa* *K. aerogenes* *A. hydrophila* *Aspergillus brasiliensis* *Candida albicans*	ASTM E1839-13	Test matrix: 0.33 g hardwood + 0.165 g softwood pulp, pH 8.0-8.5 (alkaline furnish) Concentrations tested: 0.0035; 0.0065; 0.013; 0.02; 0.03; 0.04; 0.05% product (6; 11.1; 22.2; 34.2; 51.3; 68.4; 85.5 ppm PAA) Test temperature: 35 °C Test duration: 180 min Sampling times: 0; 30; 60; 120; 180 min Additional sampling of controls at 24 h (bacteria, yeast) or 7 d (*Asp. brasiliensis*) Challenges: 1 Replicates: 2 Neutralisation: -	Growth of bacteria was inhibited at 0.013% product and full kill was achieved at 0.02% product. Growth of yeast was inhibited at 0.0035% product. Growth in untreated alkaline controls was observed for *P. aeruginosa (24 h), K. aerogenes* (3 h) and *C. albicans* (24 h). The study is valid for preventive efficacy for these organisms. No growth was observed in case of *A. hydrophila* and *Asp. brasiliensis*.	Report J000896-2 **Key study**
Bactericide (PT 12)	Slimicide in pulp and	Peraclean 15 Bulk	*P. aeruginosa* *K. aerogenes*	ASTM E1839-13	Test matrix: 0.33 g hardwood + 0.165 g softwood pulp, pH 5.0-5.5 (acid furnish)	All tested concentrations	Report J002126-1

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
	paper industry				Concentrations tested: 0.0006; 0.003; 0.006; 0.012% product (1.14; 5.1; 10.2; 20.4 ppm PAA) Test temperature: 30 °C Test duration: 24 h Challenges: 1 Replicates: 3 Neutralisation: validated	resulted in reductions >3 log. Due to the analysed dilutions and upper quantification limits, no growth could be observed in untreated controls. Therefore, the study is invalid for preventive efficacy.	
Bactericide (PT 12)	Slimicide in pulp and paper industry	Peraclean 15 Bulk	*P. aeruginosa* *K. aerogenes*	ASTM E1839-13	Test matrix: 0.33 g hardwood + 0.165 g softwood pulp, pH 8.0-8.5 (alkaline furnish) Concentrations tested: 0.0006; 0.003; 0.006; 0.012% product (1.14; 5.1; 10.2; 20.4 ppm PAA) Test temperature: 30 °C Test duration: 24 h Challenges: 1 Replicates: 3 Neutralisation: validated	All tested concentrations resulted in reductions >2 log. Due to the analysed dilutions and upper quantification limits, no growth could be observed in untreated controls. Therefore, the study is invalid for preventive efficacy.	Report J002126-2

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Yeasticide (PT 12)	Slimicide in pulp and paper industry	Peraclean 15 Bulk	*C. albicans* *Rhodotorula mucilaginosa*	ASTM E1839-13	Test matrix: 0.33 g hardwood + 0.165 g softwood pulp, pH 5.0-5.5 (acid furnish) Concentrations tested: 0.0006; 0.003; 0.006; 0.012% product (1.14; 5.1; 10.2; 20.4 ppm PAA) Test temperature: 30 °C Test duration: 24 h Challenges: 1 Replicates: 3 Neutralisation: validated	No growth was observed at all tested product concentrations. Slight increases in cell counts occurred in the untreated control. However, due to the upper quantification limit at the chosen dilution the increases are too low to qualify as growth. Therefore, the study is not valid for preventive efficacy.	Report J002126-3
Bactericide, Yeasticide, Fungicide (PT 12)	Slimicide in pulp and paper industry	Peraclean 15 Bulk	*C. albicans* *R. mucilaginosa*	ASTM E1839-13	Test matrix: 0.33 g hardwood + 0.165 g softwood pulp, pH 8.0-8.5 (alkaline furnish) Concentrations tested: 0.0006; 0.003; 0.006; 0.012% product (1.14; 5.1; 10.2; 20.4 ppm PAA) Test temperature: 30 °C Test duration: 24 h Challenges: 1	Slight increases in cell numbers were observed at 0.0006% product. 0.003% product and higher concentrations prevented growth. Strong growth was reported in the untreated controls, so the study is valid for preventive efficacy.	Report J002126-4 **Key study**

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Replicates: 3 Neutralisation: validated		

3.5.6 Occurrence of resistance and resistance management

Due to the unspecific mode of action of peracetic acid and its strong oxidative properties, the development of resistance appears rather unlikely. Furthermore, there are no conclusive literature reports on acquired microbial resistance against peracetic acid which the eCA is aware of. Therefore, no resistance management strategies are considered necessary at the current stage.

3.5.7 Known limitations

None.

3.5.8 Evaluation of the label claims

The label claims have to reflect the use conditions as specified in the SPC.

3.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The products of the BPF are not intended to be used with other biocidal products.

3.5.10 Conclusion

Table 25

Conclusion on the efficacy
Products of the BPF are expected to be efficacious at the following minimum in-use concentrations: PT 11, preservation of cooling water in cooling systems: Preventive application: bacteria (incl. *Legionella* spp.), 1.14 ppm PAA Curative application (15 min): bacteria, 6 ppm PAA; *Legionella*, 8.5 ppm PAA Curative application (3 h): bacteria (incl. *Legionella*), 5 ppm PAA Curative application (24 h): bacteria, 1.14 ppm PAA; *Legionella*, 3.5 ppm PAA; green algae, 8.5 ppm PAA PT 12, slimicide in pulp and paper industry: Preventive application: bacteria and yeasts, 34.5 ppm PAA

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 26

Peracetic acid	**Value**	**Study**	**Safety factor**
Systemic effects			
AEL long-term	n.a.; PAA does not cause systemic effects[1]	-	-
AEL medium-term	n.a.; PAA does not cause systemic effects[1]	-	-
AEL acute	n.a.; PAA does not cause systemic effects[1]	-	-
Local effects			
Dermal NOAEC short- and medium-term	0.2 %	Human volunteer study, Assessment-Report, RMS Finland (2015/2016)	-
Dermal NOAEC long-term	0.1 %	rabbit one year study, Assessment-Report, RMS Finland (2015/2016)	2
AEC inhalation	0.5 mg/m^3 (0.16 ppm)	Human data (NOAEC 0.5 ppm), Assessment-Report, RMS Finland (2015/2016)	3.16

[1] Assessment-Report, RMS Finland (2015/2016)

Table 27

Peracetic acid	**Value**	**Reference**
Oral absorption	Not determined, 100 % - default	Assessment-Report, RMS Finland (2015/2016)
Dermal absorption	See chaper 3.6.2.7	

3.6.2 Assessment of effects of the product on human health

Based on the similarity of the products of the biocidal product family, the following assessment includes all meta SPC 1, 2 and 3.

3.6.2.1 Skin corrosion and irritation

Table 28

Data waiving was acceptable for the following information requirements	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	Studies on potential skin corrosive or skin irritating properties of the BPF are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), “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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” The composition of the BPF is known. Sufficient data on the intrinsic properties of the components are available through safety data sheets and other information for each of the individual components in the products. There is no information or indications on synergistic effects between any of the components (e.g. surfactants). In addition, information on the physico-chemical properties of representative products (e.g. pH) is available. Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the BPF is not required.

Table 29

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Meta SPC 1, 2 and 3: Corrosive to the skin.
Justification for the value/conclusion	Meta SPC 1, 2 and 3: Based on the additivity approach in accordance with the Regulation (EC) No 1272/2008. For details refer to the Confidential annex.
Classification of the product according to CLP	Meta SPC 1, 2 and 3: Skin Corr. 1A, H314

3.6.2.2 Eye irritation

Table 30

Data waiving was acceptable for the following information requirements	
Information requirement	8.2. Eye irritation
Justification	Studies on potential eye damaging or eye irritating properties of the BPF are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), “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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” The composition of the BPF is known. Sufficient data on the intrinsic properties of the components are available through safety data sheets and other information for each of the individual components in the products. There is no information or indications on synergistic effects between any of the components. In addition,

	information on the physico-chemical properties of representative products (e.g. pH) is available. Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the BPF is not required.

Table 31

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Meta SPC 1, 2 and 3: Corrosive and damaging to the eye.
Justification for the value/conclusion	Meta SPC 1, 2 and 3: Based on the additivity approach in accordance with the Regulation (EC) No 1272/2008. For details refer to the confidential annex.
Classification of the product according to CLP	Meta SPC 1, 2 and 3: Eye Dam. 1 Note that labelling with H318 is not required, since the products of BPF are already labelled with H314.

3.6.2.3 Respiratory tract irritation

Table 32

Data waiving	
Information requirement	8.10 Other data
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the BPF has to be made according to the rules of the Regulation (EC) No 1272/2008.

Table 33

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Meta SPC 1, 2 and 3: Corrosive to the respiratory tract.
Justification for the value/conclusion	Meta SPC 1, 2 and 3: The BPF contains components classified for STOT SE 3, H335 in relevant concentrations to trigger classification for respiratory tract irritation, according to the Regulation (EC) No 1272/2008. However, all meta SPCs have a corrosive pH < 2 and are classified for acute inhalation toxicity, which requires labelling with label EUH071 'Corrosive to the respiratory tract' in accordance with the Regulation (EC) No 1272/2008, Annex I, section 1.2.6. Hence, labelling of the BPF with H335 is abandoned in favour of the more severe supplemental hazard label EUH071. For details refer to the confidential annex.
Classification of the product according to CLP	Meta SPC 1, 2 and 3: EUH071

3.6.2.4 Skin sensitisation

Table 34

Data waiving was acceptable for the following information requirements	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin sensitising properties of the BPF are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), “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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” The composition of the BPF is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information or indications on synergistic effects between any of the components. Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the BPF is not required.

Table 35

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Meta SPC 1, 2 and 3: Not sensitising to the skin.
Justification for the value/conclusion	Meta SPC 1, 2 and 3: The BPF does not contain any components, which are known to have senitising properties. Hence, classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Meta SPC 1, 2 and 3: Not classified for skin sensitisation.

3.6.2.5 Respiratory sensitisation (ADS)

Table 36

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the BPF or their components are not available.

Table 37

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Meta SPC 1, 2 and 3: Not sensitising to the respiratory tract.
Justification for the value/conclusion	Meta SPC 1, 2 and 3: The BPF does not contain any components, which are known to have senitising properties for the respiratory tract. Hence, classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Meta SPC 1, 2 and 3: Not classified for respiratory sensitisation.

3.6.2.6 Acute toxicity

3.6.2.6.1 Acute toxicity by oral route

Table 38

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.1. By oral route
Justification	Studies on potential acute toxicity by oral route of the BPF are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The composition of the BPF is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information or indications on synergistic effects between any of the components. Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the BPF is not required.

Table 39

Value used in the Risk Assessment – Acute oral toxicity	
Value	Meta SPC 1: LD_{50} (oral): 697 mg/kg bw Meta SPC 2: LD_{50} (oral): 758 mg/kg bw Meta SPC 3: LD_{50} (oral): 431 mg/kg bw
Justification for the selected value	Meta SPC 1, 2 and 3: Based on the additivity approach in accordance with the Regulation (EC) No 1272/2008. For details refer to the confidential annex.
Classification of the product according to CLP	Meta-SPC 1, 2 and 3: Acute Tox. 4 (oral), H302

3.6.2.6.2 Acute toxicity by inhalation

Table 40

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	Studies on potential acute toxicity by inhalation route of the BPF are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The composition of the BPF is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the

Data waiving was acceptable for the following information requirements	
	individual components in the products. There is no information or indications on synergistic effects between any of the components. Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the BPF is not required.

Table 41

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Meta SPC 1: LC_{50} (inhalation): not assignable, Acute Tox. 4 Meta SPC 2: LC_{50} (inhalation): not assignable, Acute Tox. 4 Meta SPC 3: LC_{50} (inhalation): not assignable, Acute Tox. 4
Justification for the selected value	Meta SPC 1, 2 and 3: Based on the additivity approach in accordance with the Regulation (EC) No 1272/2008. Since LC_{50} from dust/mist and vapour from single components have to be combined for the additivity approach, LC_{50} for the single Meta-SPCs could not be derived. Instead, the equation provided in sections 3.1.3.3.4 and 3.1.5.5.1 of the Guidance on the Application of the CLP Criteria, Version 5.0 - July 2017 was applied. For details refer to the confidential annex.
Classification of the product according to CLP	Meta SPC 1, 2, and 3: Acute Tox. 4 (inhalation), H332

3.6.2.6.3 Acute toxicity by dermal route

Table 42

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.3. By dermal route
Justification	Studies on potential acute toxicity by dermal route of the BPF are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), “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 Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” The composition of the BPF is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information or indications on synergistic effects between any of the components. Consequently, classification of the mixtures was made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the BPF is not required.

Table 43

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Meta SPC 1: LD_{50} (dermal): > 2000 mg/kg bw Meta SPC 2: LD_{50} (dermal): 1111 mg/kg bw Meta SPC 3: LD_{50} (dermal): 372 mg/kg bw
Justification for the selected value	Meta SPC 1, 2 and 3: Based on the additivity approach in accordance with the Regulation (EC) No 1272/2008. For details refer to the confidential annex.
Classification of the product according to CLP	Meta SPC 1: Not classified for acute dermal toxicity. Meta SPC 2: Acute Tox. 4 (dermal), H312 Meta SPC 3: Acute Tox. 3 (dermal), H311

3.6.2.7 Information on dermal absorption

Table 44

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	Dermal absorption studies with the biocidal products of this family are not required. According to the safety data sheets, all products of the BPF have a pH-value below 2, thus being corrosive. According to the EFSA Guidance on dermal absorption (2017) and BPC-WG-III-2016, TAB, version 2.0, 2018 – TOX 21, the dermal absorption of the active substance and the respective co-formulant is 100 % by default. In addition, the following justification for dermal penetration is extracted from the CAR Doc. IIB: ***Peracetic acid*** *No standard dermal penetration studies with equilibrium peracetic acid have been successfully conducted. Basically it is acceptable to use default values instead of a test result to describe dermal penetration for the purpose of risk characterisation. Other available studies do provide the overall information that dermally applied peracetic acid penetrates the skin. It was also demonstrated with human skin (penetration of tritiated water through human skin in vitro) that cocentrations of up to 1 % peracetic acid did not to impair the skin barrier function (refer to Doc. IIIB, 6.04/01).* *Based on the physico-chemical properties (molecular weight not >500 and logPow not <-1 or >3) of PAA, 100 % dermal penetration should be used in the absence of more accurate information. However, in this particular case, in the absence of clear systemic effects, no dermal penetration parameter is needed in order to conclude on human health risks from the presented uses of peracetic acid.* *Peracetic acid is believed not to penetrate skin and dermal absorption is therefore considered to be not relevant at non-irritant/non-corrosive concentrations, i.e. when the integrity of the skin is kept intact. During mixing/loading operations and during application, no damage to the skin is anticipated as well since appropriate protective equipment such as gloves and coverall are considered to be used consistently during these procedures especially when handling the concentrated products. … (for details please refer to Document IIA and IIC).* ***Hydrogen peroxide*** *The limitation of dermal exposure is triggered by the hydrogen peroxide concentration, since hydrogen peroxide is recognized as skin irritant and therefore skin*

Data waiving was acceptable for the following information requirements	
	contact should be avoided. Hydrogen peroxide has been shown not to exert systemic effects in repeated dose toxicity studies and for this reason, a dermal penetration of hydrogen peroxide after dermal exposure is not considered to be relevant in the exposure and risk assessment. In summary it can be concluded for both substances, that in the absence of systemic effects and corresponding reference values, dermal penetration data is not necessary. If required, a default of 100 % can be used.

Table 45

Value(s) used in the Risk Assessment – Dermal absorption		
Substance exposure scenario(s) (e.g. undiluted formulation or 1:100 in-use dilution, etc.)	Peracetic acid, all meta SPC, all scenarios and dilutions	Hydrogen peroxide, all meta SPC, all scenarios and dilutions
Value(s)	100 %	100 %
Justification for the selected value(s)	Default according to the CAR (2015) / Default for corrosive substances (BPC-WG-III-2016, TAB, version 2.0, 2018 – TOX 21)	

3.6.2.8 Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

For relevant information on the equilibrium partner of the active substance refer also to the confidential annex.

Hydrogen peroxide (CAS.-No.: 7722-84-1)

Threshold Limits and other Values for Human Health Risk Assessment

Table 46

Summary		
	Value	Source
AEC inhalation long-term	1.25 mg/m^3	Assessment-Report (RMS FI (2015))
AEC inhalation medium-term	1.25 mg/m^3	Assessment-Report (RMS FI (2015))
AEC inhalation acute	1.25 mg/m^3	Assessment-Report (RMS FI (2015))
ADI	Not established, substance systemically not available	Assessment-Report (RMS FI (2015))
ARfD	Not established	Assessment-Report (RMS FI (2015))

Summary		
	Value	Source
Inhalative absorption	100 %	Default value
Oral absorption	No significant absorption, local effects	Assessment-Report (RMS FI (2015))
Dermal absorption	100 %	Default value for corrosive stubances

Classification	
Current, according to Annex VI of Reg. 1272/2008	Acute Tox. 4, H302, Acute Tox. 4, H332, Skin Corr. 1A, H314

3.6.2.9 Endocrine disrupting properties

Based on the information available from ECHA databases (e.g. SVHC-candidate list) there are no indications for endocrine disrupting properties of any of the single components of the biocidal product. Nevertheless, the active substance peracedic acid is listed in the endocrine disruptor assessment list and is currently under investigation for endocrine disrupting properties by Austria. According to the AR of peracetic acid (FI, 2016) there is no evidence of any endocrine disrupting potential of the active substance. Also the BPC opinions for PT11 and PT12 for active substance approval indicate that peracedic acid is not considered to have endocrine disrupting properties. According to the assessment reports and BPC opinions for PT 3 to PT 6 (2015), there is also no evidence for hydrogen peroxide to have any endocrine disrupting properties. More information is provided in the confidantial annex.

3.6.2.10 Summary of effects assessment

Table 47

Endpoint	Brief description
Skin corrosion and irritation	Meta SPC 1, 2 and 3: Skin Corr. 1A, H314 Based on the additivity appoach according to Regulation (EC) No 1272/2008. Refer to the confidential annex.
Eye irritation	Meta SPC 1, 2 and 3: Eye Dam. 1 Based on the additivity appoach according to Regulation (EC) No 1272/2008. Refer to the confidential annex.
Respiratory tract irritation	Meta SPC 1, 2 and 3: EUH071 Refer to the confidential annex.
Skin sensitisation	Meta SPC 1, 2 and 3: Not sensitising to the skin. Based on information for the single components.
Respiratory sensitization (ADS)	Meta SPC 1, 2 and 3: Not sensitising to the respiratory tract. Based on information for the single components.

Endpoint	Brief description
Acute toxicity by oral route	Meta SPC 1, 2 and 3: Acute Tox. 4 (oral), H302 Based on the additivity appoach according to Regulation (EC) No 1272/2008. Refer to the confidential annex.
Acute toxicity by inhalation	Meta SPC 1, 2, and 3: Acute Tox. 4 (inhalation), H332 Based on the additivity appoach according to Regulation (EC) No 1272/2008. Refer to the confidential annex.
Acute toxicity by dermal route	Meta SPC 1: Not classified Meta SPC 2: Acute Tox. 4 (dermal), H312 Meta SPC 3: Acute Tox. 3 (dermal), H311 Based on the additivity appoach according to Regulation (EC) No 1272/2008. Refer to the confidential annex.
Information on dermal absorption	Meta SPC 1, 2 and 3 (all scenarios and dilutions): Peracetic acid: 100 % Hydrogen peroxide: 100 % Default for corrosive substances (BPC-WG-III-2016, TAB, version 2.0, 2018 – TOX 21) and default according to the respective CAR (2015) for peracetic acid and hydrogen peroxide.
Available toxicological data relating to non-active substance(s)	For relevant information on substances of concern/equilibrium partner of the active substance, refer to the confidential annex.
Available toxicological data relating to a mixture	Not relevant
Other relevant information	Not relevant

3.6.3 Exposure assessment

3.6.3.1 Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Table 48

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	yes	yes	n.a.	yes	yes	Yes	n.a.
Dermal	yes	yes	n.a.	no	no	No	n.a.
Oral	no	no	n.a.	no	no	No	n.a.

List of scenarios

Table 49

Summary table: scenarios					
Scenario number	**Intended use**	**Meta SPC**	**Scenario**	**Description of scenario**	**Exposed group**
FB4-1a	1	1-3	Automated loading	Primary exposure of workers during connecting/disconnecting the b.p. containers (e.g., IBC or drum) and during automated dosing of the b.p. into the process waters.	Professional user Industrial user
	2	3			
	3	1-3			
	4	2-3			
FB4-1b	1	1-3	Automated loading	Primary exposure of workers during connecting/disconnecting the bulk containers used for delivery (e.g., a truck) to the storage tank and during transfer („pumping”) of the b.p.	Professional user Industrial user
	2	3			
	3	1-3			
	4	2-3			
FB4-2	1	1-3	Inspection / maintenance	Secondary exposure of workers from inspection and maintenance of the cooling water system and cooling towers (PT 11).	Professional user Industrial user
	2	3			
	3	1-3			
FB4-3	4	2-3	process operation	Secondary exposure of workers from operating and/or inspecting/maintaining the paper production process, in which the b.p. is present (PT12).	Professional user Industrial user
FB4-4	1	1-3		Post application exposure occuring from maintaining or repairing dosing pumps	Professional user
	2	3			

	3	1-3	Maintenance / repair of dosing pumps		Industrial user
	4	2-3			
BfR 1	1-3	1-3	General public (all age groups) – Chronic inhalation of aerosols	Secondary exposure The preservative is added to wet cooling system. Exposure to volatilised peracedic acid and hydrogen peroxide by drift due to uncontrolled windage or blowdown.	General public (all age groups) – Chronic inhalation of aerosols

3.6.3.1.1 Professional and industrial exposure

- **General considerations**

Note: After the commenting phase of the PAR by member states the concentration of peracetic acid in Meta SPC 3 was reduced from 16.7% to 15%. Since this lower concentration of peracetc acid had no impact on the conclusion for the professional use, the figures of the calculated exposure were not adopted.

The products of the BPF are liquid concentrates containing the active substanc peracetic acid (PAA; up to 2.4 % (w/w) in biocidal products of meta SPC 1, 5.0 % (w/w) in biocidal products of meta SPC 2 and 16.7 % (w/w) in biocidal products of meta SPC 3).
In addition, hydrogen peroxide (HP) has been identified as a relevant equilibrium partner of the active substance. It is present in concentrations of up to 48.4 % (w/w) in biocidal products of meta SPC 1, 30.7 % (w/w) in biocidal products of meta SPC 2 and 23.3 % (w/w) in biocidal products of meta SPC 3. The product is delivered in IBCs (1000 L), drums (200 L), jerry cans (10 L, 20 L, 30 L and 60 L) and plastic bottles (1 L and 5 L). The draft PAR provided by the applicant also mentions the possibility of bulk deliveries, where the product is unloaded on site into IBCs or tanks.

For PT 11, the biocidal products of the BPF are intended for preservation of cooling water in once-through systems (Use 1 in meta SPCs 1-3) and in large (Use 2 in meta SPC 3) or small (Use 2 in meta SPCs 1 and 3, Use 3 in meta SPC 3) open recirculating systems.

For PT 12, the biocidal products of meta SPCs 2-3 are intended to be used as slimicide in the pulp and paper industry (Use 3 in meta SPC 2, Use 4 in meta SCP 3).

In this PAR, inhalation exposure to the active substance peracetic acid and to the equilibrium partner of the active substancehydrogen peroxide is assessed quantitatively for the different scenarios. In all cases, the assessment was modelled using the Advanced Reach Tool (ART). All scenarios are also expected to result in dermal exposure, which was assessed semi-quantitatively for the active substance peracetic acid and qualitatively for the active substance peracetic acid and the equilibrium partner of the active substancehydrogen peroxide via product classification (see chapter 3.6.4 for details).

For all foreseen uses, the products are pumped with automatic dosing pumps from the storage containers into the systems to which they are applied. Thus, *primary exposure* of workers is expected to result only from attachment of transfer lines and operation of the pumps, which is assessed in Scenarios FB4-1a (dosing) and FB4-1b (transfer from bulk transporters into storage tanks). The use of these pumps makes a maintenance and/or repair of these pumps likely, which is assessed as *post-application* in Scenario FB4-4. For these scenarios, as a worst-case the highest concentrations of the active substance peracetic acid (16.7 % in meta SPC 3) and the equilibrium partner of the active substancehydrogen peroxide (48.4 % in meta SPC 1) are considered.

In addition, *secondary exposure* of employees working in areas where the products are applied has to be considered, which is assessed in Scenarios FB4-2 (inspection/maintenance of cooling systems/cooling towers) and FB4-3 (process operation and inspection/maintenance in the pulp and paper industry). In contrast to the other scenarios, here the diluted application liquids have to be considered. According to the applicant, the product has to be diluted to final concentrations of peracetic acid of up to 0.0010 % (“10 ppm”) for Uses 1 - 3 or 0.0075 % (“75 ppm”) for Use 4, respectively. However, the applicant has requested the authorisation of concentration ranges of the active substance peracetic acid and the equilibrium partner of the active substancehydrogen peroxide. For the assessment laid out in this PAR, it is assumed that the user dilutes the products correctly to the indicated concentrations of peracetic acid. To ensure this in actual workplaces, the authorisation holder shall give specific advice on the correct dilution factor on the product label, considering the concentrations and the density of the product. Thus, for the risk assessment the concentrations of the active substance peracetic acid are fixed to desired target concentrations.
For the equilibrium partner of the active substancehydrogen peroxide, the concentrations were derived as follows: For each meta SPC, the smallest dilution factor (based on the lowest concentration of peracetic acid in the frame formulation) was calculated. This dilution factor was then considered together with the highest possible hydrogen peroxide concentration within the frame formulation. For Uses 1 - 3, the highest hydrogen peroxide concentration results for meta SPC 1 (dilution factor 1:1700, giving as final hydrogen peroxide concentration of up to 0.0285 % (w/w)). For Use 4, the highest hydrogen peroxide concentration of 0.0606 % (w/w) results for meta SPC 2 with a dilution factor of 1:507.

For all scenarios, the worst-case concentrations (across all meta SPCs) described here were used for the initial exposure estimates. It was then checked if these figures are representative for all meta SPCs, i.e., it was approved that these considerations will not result in overprotective packages of risk mitigation measures for other meta SPCs. Details on these considerations can be found in the following descriptions of these scenarios

- **Scenario FB4-1a: Primary Exposure: Automated loading (from storage containers into the process waters)**

Table 50

Description of Scenario FB4-1a: Primary Exposure: Automated loading (from storage containers into the process waters)
For this assessment, the highest concentrations of peracetic acid and hydrogen peroxide that may occur in this BPF were considered as a worst case, i.e., 16.7 % (w/w) peracetic acid (as in products of meta SPC 3) and 48.4 % (w/w) hydrogen peroxide (as in products of meta SPC 1). Thus, this worst-case scenario is based on a fictive worst-case product which covers all products of this biocidal product family. As every use applied for includes a dosing step, this scenario is applicable to all uses. It should be mentioned that products of meta SPC 1, which contain the highest hydrogen peroxide concentration, are not foreseen for Use 4. However, for better readability, an additional assessment of this scenario for the lower concentrations found in meta SPCs 2-3, which are intended for Use 4, was omitted from this PAR, but it was ascertained that this simplification does not result in unnecessary measures. The biocidal product is stored in the delivery containers (e.g., IBC or drum) or in storage tanks. These vessels are attached to the transfer lines and the biocidal product is dosed with automated dosing pumps into the cooling water stream (Uses 1-3) or into the paper mill (Use 4) to generate the final in-use concentrations of up to 0.001 % peracetic acid in Uses 1-3 or of up to 0.0075 % peracetic acid in Use 4. Inhalation exposure The inhalation exposure of workers resulting from this task was assessed based on the approach described in the CAR for peracetic acid (PT 11, 12). The approach assesses inhalation exposure based on the ART model using the parameters shown below. Activity coefficients of the active substance peracetic acid and the equilibrium partner of the active substancehydrogen peroxide were calculated using AIOMFAC (http://www.aiomfac.caltech.edu/). For calculation of the activity coefficients, only the major compounds water, PAA and HP have been considered. For details on the calculations of the activity coefficients and the ART calculations, see documents attached to the annex (section 4.3.1) of this PAR. Dermal exposure Dermal exposure was assessed semi-quantitatively or qualitatively for the active substance peracetic acid and the equilibrium partner of the active substancehydrogen peroxide. For details, see chapter 3.6.4. Summary Regarding inhalation exposure, no risk was identified in Tier 1. In agreement with information provided by the applicant, the assessment considers only loading tasks using automated pumps. In order to exclude manual loading tasks, which have not been assessed, the use of automated dosing pumps is included in the RMMs for this biocidal product family. For informational purposes, a Tier 2 assessment was performed considering RPE with an assigned protection factor (APF) of 10. The local risk assessment (see chapter 3.6.4 of this PAR) has indicated risks resulting from contact with skin (hands, body, feet) as well as from eye contact. Thus, **chemical protective gloves**, a **coverall**, **protective boots** and **eye protection** are required for safe use in scenario 1a. *Considerations regarding product compositions with lower concentrations than the worst-case*

As outlined above, the assessment is based on worst-case assumptions regarding the concentrations of peracetic acid and hydrogen peroxide. Nevertheless, the quantitative risk assessment did not demonstrate risks and thus did not trigger any risk mitigation measures.

The local risk assessment is based on the classification of the products and the dermal NOAEC of peracetic acid. The NOAEC of peracetic acid is exceeded for all meta SPCs, so the same risk mitigation measures result for all meta SPCs.

Thus, the presented risk assessment is expected to be representative for the entire biocidal product family.

Scenario FB4-1a: Primary Exposure: Automated loading (from storage containers into the process waters)

Inhalation exposure was calculated with ART model using the following parameters.

	Parameters	**Value**
Tier 1	peracetic acid concentration (max. conc. in meta SPC 3) molar fraction activity coefficient (calculated for meta SPC 1) vapour pressure	 16.7 % 0.0613 0.3011 1410 Pa
	hydrogen peroxide concentration (max. conc. in meta SPC 1) molar fraction activity coefficient (calculated for meta SPC 1) vapour pressure	 48.4 % 0.3975 0.9317 214 Pa
	ART scenario parameters Emissions sources Duration Process temperature	 (only) near field 15 min 293 K
	Activity class	Falling liquids
	Situation	Transfer of liquid product with flow of 1 - 10 l/minute
	Containment level	Open process
	Loading type	Submerged loading, where the liquid dispenser remains below the fluid level reducing the amount of aerosol formation
	Process fully enclosed?	No
	Effective housekeeping practices in place?	Yes
	Work area	Indoors
	Room size	Any size workroom
	Localised controls: Primary	Medium level containment (99% reduction)
	Localised controls: Secondary	No localised controls (0% reduction)
	Ventilation rate	Only good natural ventilation

Tier 2	Respiratory protective equipment	APF 10

Scenario FB4-1b: bulk transporter into storage tank or IBC)

Table 51

Description of Scenario FB4-1b: Automated loading (from bulk transporter into storage tank or IBC)

The product is marketed not only in containers such as IBCs or barrels, but may also be delivered as bulk product, e.g., with trucks. In this case, the product must be transferred into the storage tanks or empty IBCs at the plant. For this process, higher loading rates of 100-1000 L/min may be expected, which is much higher than the transfer rates of 1-10 L/min considered in Scenario FB4-1a. For this reason, in this Scenario FB4-1b an assessment of automated loading was performed considering the higher transfer rates of 100 – 1000 L/min. Except from this parameter, all other parameters are identical with those used in Scenario FB4-1a which is referenced here. The assessment of the dermal exposure performed for Scenario FB4-1a is also applicable to this Scenario FB4-1b.

Summary

Regarding inhalation exposure, no risk was identified in Tier 1. In agreement with information provided by the applicant, the assessment considers only loading tasks using automated pumps. In order to exclude manual loading tasks, which have not been assessed, the use of automated pumps is included in the RMMs for this biocidal product family.

For informational purposes, a Tier 2 assessment was performed considering RPE with an assigned protection factor (APF) of 10.

The local risk assessment (see chapter 3.6.4 of this PAR) has indicated risks resulting from contact with skin (hands, body, feet) as well as from eye contact. Thus, **chemical protective gloves**, a **coverall**, **protective boots** and **eye protection** are required for safe use in scenario 1b.

Considerations regarding product compositions with lower concentrations than the worst-case

As outlined above, the assessment is based on worst-case assumptions regarding the concentrations of peracetic acid and hydrogen peroxide. Nevertheless, the quantitative risk assessment did not demonstrate risks and thus did not trigger any risk mitigation measures.

The local risk assessment is based on the classification of the products and the dermal NOAEC of peracetic acid. The NOAEC of peracetic acid is exceeded for all meta SPCs, so the same risk mitigation measures result for all meta SPCs.

Thus, the presented risk assessment is expected to be representative for the entire biocidal product family.

Scenario FB4-1b: Automated loading (from bulk transporter into storage tank or IBC)

Inhalation exposure was calculated with ART model using the following parameters.

	Parameters	**Value**
Tier 1	peracetic acid	
	concentration (max. conc. in meta SPC 3)	16.7 %
	molar fraction	0.0613
	activity coefficient (calculated for meta SPC 1)	0.3011
	vapour pressure	1410 Pa
	hydrogen peroxide	
	concentration (max. conc. in meta SPC 1)	48.4 %
	molar fraction	0.3975
	activity coefficient (calculated for meta SPC 1)	0.9317
	vapour pressure	214 Pa
	ART scenario parameters	

	Emissions sources Duration Process temperature	(only) near field 15 min 293 K
	Activity class	Falling liquids
	Situation	Transfer of liquid product with flow of 100 - 1000 l/minute
	Containment level	Open process
	Loading type	Submerged loading, where the liquid dispenser remains below the fluid level reducing the amount of aerosol formation
	Process fully enclosed?	No
	Effective housekeeping practices in place?	Yes
	Work area	Indoors
	Room size	Any size workroom
	Localised controls: Primary	Medium level containment (99% reduction)
	Localised controls: Secondary	No localised controls (0% reduction)
	Ventilation rate	Only good natural ventilation
Tier 2	Respiratory protective equipment	APF 10

- **Scenario FB4-2: Secondary Exposure: inspection/maintenance of cooling systems/cooling towers (PT 11)**

Table 52

Description of Scenario FB4-2: Secondary exposure: inspection/maintenance of cooling systems/cooling towers
This scenario applies to applications of PT 11 (Uses 1-3), but not to applications within PT 12 (Use 4). The biocidal product is automatically dosed into the water cycle. While no direct exposure of workers is expected to occur from this automated dosing process, exposure may occur during inspection and for maintenance of the cooling water system/cooling towers. In agreement with the CAR for peracetic acid (PT 11,12), it is assumed that exposure might occur towards the liquid and aerosols or vapours of the diluted product. As a worst case approach, the highest in-use concentration of up to 0.001 % (w/w) of peracetic acid described by the applicant for Uses 1-3 was assessed. For the equilibrium partner of the active substancehydrogen peroxide, various concentrations may occur due to the different compositions of the products within the product family and consequently different dilution factors. As a worst case approach, the highest concentration of hydrogen peroxide which may occur for these uses after dilution was assessed. This is the case for products of meta SPC 1. These products have at least 1.7 % of peracetic acid and at most 48.4 % hydrogen peroxide, thus a dilution factor of 1:1700 would be used to produce a final concentration of 0.001 % peracetic acid. In this case, a final concentration for hydrogen peroxide of 0.0285 % results, which was used for this assessment.

Inhalation exposure

The inhalation exposure of workers resulting from this task was assessed based on the approach described in the CAR for peracetic acid (PT 11, 12). The approach assesses inhalation exposure based on the ART model using the parameters shown below. Activity coefficients of the active substance peracetic acid and the equilibrium partner of the active substancehydrogen peroxide were calculated using AIOMFAC (http://www.aiomfac.caltech.edu/). For calculation of the activity coefficients, only the major compounds water, PAA and HP have been considered.

For details on the calculations of the activity coefficients and the ART calculations, see documents attached to the annex (section 4.3.1) of this PAR.

Dermal exposure

Dermal exposure was assessed semi-quantitatively or qualitatively for the active substance peracetic acid and the equilibrium partner of the active substancehydrogen peroxide. For details, see chapter 3.6.4.

Summary

Regarding inhalation exposure, a risk was identified in Tier 1. Therefore, a refined assessment was performed in Tier 2, taking **RPE with an assigned protection factor (APF) of 10** into account. With this measure, no risk was identified with regard to inhalation exposure.

The local risk assessment (see section see 3.6.4 of this PAR) has not indicated any additional risks, thus no additional RMMs are required for mitigation of local risks.

Considerations regarding product compositions with lower concentrations than the worst-case

As outlined above, the assessment is based on worst-case assumptions regarding the concentrations of peracetic acid and hydrogen peroxide, the latter being based on meta SPC 1. In Tier 1, a risk from inhalation exposure towards peracetic acid as well as towards hydrogen peroxide was identified, which triggers RMMs. However, even if a lower concentration of hydrogen peroxide was considered for the meta SPCs 2-3, the risk resulting from peracetic acid remains in Tier 1, as the application concentration of this substance is the same for all meta SPCs. Consequently, the RMM package (RPE with an APF of 10) is required for all meta SPCs.

The local risk assessment is based on the classification of the application liquid and the dermal NOAEC of peracetic acid. Even for the worst-case, the NOAEC of peracetic acid is not exceeded in this scenario, and the diluted product handled here is not classified.

Thus, the presented risk assessment is expected to be representative for the entire biocidal product family.

Scenario FB4-2: Secondary exposure: inspection/maintenance of cooling systems/cooling towers

Inhalation exposure was calculated with ART model using the following parameters.

	Parameters	**Value**
Tier 1	peracetic acid	
	concentration (max. conc. in meta SPC 2)	0.001 %
	molar fraction	$2.37 \cdot 10^{-6}$
	activity coefficient (calculated for meta SPC 1)	2.474
	vapour pressure	1410 Pa
	hydrogen peroxide	
	concentration (max. conc. in meta SPC 1)	0.0285 %
	molar fraction	$1.51 \cdot 10^{-4}$
	activity coefficient (calculated for meta SPC 1)	1.200

	vapour pressure	214 Pa
	ART scenario parameters Emissions sources Duration Process temperature	 (only) near field 30 min 293 K
	Activity class	Spraying of liquids in a space
	Situation	Large scale space spraying
	Process fully enclosed?	No
	Effective housekeeping practices in place?	Yes
	Work area	Indoors
	Room size	Large workrooms only
	Localised controls: Primary	No localised controls (0 % reduction)
	Localised controls: Secondary	No localised controls (0 % reduction)
	Ventilation rate	Only good natural ventilation
Tier 2	Respiratory protective equipment	APF 10

- **Scenario FB4-3: Secondary exposure: process operation (240 min/day) and inspection/maintenance (120 min/day) (PT 12)**

Table 53

Description of Scenario FB4-3: Secondary exposure: process operation (240 min/day) and inspection/maintenance (120 min/day)
This scenario applies to Use 4 (PT 12), but not to the applications of PT 11 (Uses 1-3). The biocidal product is automatically dosed into the water cycle of the paper machine. While no direct exposure of workers is expected to occur from this automated dosing process, exposure may occur during process operation or maintenance of the paper machine, which contains the diluted product. In agreement with the CAR for peracetic acid (PT 11,12), it is assumed that exposure might occur towards the liquid and aerosols or vapours of the diluted product. The assessment of inhalation exposure is based on the ART model (*vide infra)*. The CAR distinguishes two scenarios, the process operation and inspection/maintenance work at the paper machine. Both scenarios are assessed with the same parameters with exception of the duration, which is 240 min for process operation and 120 min for inspection/maintenance. Since this parameter does not show any influence on the air concentrations estimated by ART, and no (duration dependent) systemic effects are assessed for peracetic acid or hydrogen peroxide, this scenario covers both tasks. As a worst case approach, the highest in-use concentration of up to 0.0075 % (w/w) of peracetic acid described by the applicant for Use 4 was assessed. For the equilibrium partner of the active substancehydrogen peroxide, various concentrations may occur due to the different compositions of the products within meta SPCs 2 -3 of the BPF which are foreseen for Use 4, and consequently different dilution factors. As a worst case approach, the highest concentration of hydrogen peroxide which may occur for these uses after dilution was assessed. This is the case for products of meta SPC 2. These products have at least 3.8 % of peracetic acid and at most 30.7 % hydrogen

peroxide, thus a dilution factor of 1:507 would be used to produce a final concentration of 0.0075 % peracetic acid. In this case, a final concentration for hydrogen peroxide of 0.0606% would result, which was used for this assessment.

Inhalation exposure

The inhalation exposure of workers resulting from this task was assessed based on the approach described in the CAR for peracetic acid (PT 11, 12). The approach assesses inhalation exposure based on the ART model using the parameters shown below. Activity coefficients of the active substance peracetic acid and the equilibrium partner of the active substancehydrogen peroxide were calculated using AIOMFAC (http://www.aiomfac.caltech.edu/). For calculation of the activity coefficients, only the major compounds water, PAA and HP have been considered.

For details on the calculations of the activity coefficients and the ART calculations, see documents attached to the annex (section 4.3.1) of this PAR.

Dermal exposure

Dermal exposure was assessed semi-quantitatively or qualitatively for the active substance peracetic acid and the equilibrium partner of the active substancehydrogen peroxide. For details, see chapter 3.6.4.

Summary

Regarding inhalation exposure, no risk was identified in Tier 1. Nevertheless, for informational purposes, a Tier 2 assessment was performed considering RPE with an assigned protection factor (APF) of 10.

The local risk assessment (see section 3.6.4 of this PAR) has not indicated any additional risks, thus no additional RMMs are required for mitigation of local risks.

Considerations regarding product compositions with lower concentrations than the worst-case

As outlined above, the assessment is based on worst-case assumptions regarding the concentrations of peracetic acid and hydrogen peroxide. Nevertheless, the quantitative risk assessment did not demonstrate risks and thus did not trigger any risk mitigation measures.

The local risk assessment is based on the classification of the application liquid and the dermal NOAEC of peracetic acid. Even for the worst-case, the NOAEC of peracetic acid is not exceeded in this scenario, and the diluted product handled here is not classified.

Thus, the presented risk assessment is expected to be representative for the entire biocidal product family.

Scenario FB4-3: Secondary exposure: process operation (240 min/day) and inspection/maintenance (120 min/day)

Inhalation exposure was calculated with ART model using the following parameters.

	Parameters	**Value**
Tier 1	peracetic acid	
	concentration (max. conc. in meta SPC 2)	0.0075 %
	molar fraction	$1.78 \cdot 10^{-5}$
	activity coefficient (calculated for meta SPC 1)	2.471
	vapour pressure	1410 Pa
	hydrogen peroxide	
	concentration (max. conc. in meta SPC 1)	0.0606 %
	molar fraction	$3.21 \cdot 10^{-4}$
		1.200

	activity coefficient (calculated for meta SPC 1) vapour pressure	214 Pa
	<u>ART scenario parameters</u>	
	Emissions sources	(only) far field
	Duration	240 min
	Process temperature	293 K
	Activity class	Spraying of liquids in a space
	Situation	Small scale space spraying
	Process fully enclosed?	No
	Effective housekeeping practices in place?	Yes
	Work area	Indoors
	Room size	Large workrooms only
	Localised controls: Primary	No localised controls (0 % reduction)
	Localised controls: Secondary	No localised controls (0 % reduction)
	Localised controls: Segregation	No segregation (0 % reduction)
	Localised controls: Personal enclosure	No personal enclosure (0 % reduction)
	Ventilation rate	Only good natural ventilation
Tier 2	Respiratory protective equipment	APF 10

- ### <u>Scenario FB4-4: Secondary exposure: Maintenance/repair of dosing pumps</u>

Table 54

Description of Scenario FB4-4: Post application exposure: Maintenance/repair of dosing pumps
This scenario applies to all uses of this biocidal product family. All uses employ dosing pumps which automatically dose the biocidal product into the respective systems. While no direct exposure of workers is expected to occur from this automated dosing process, exposure may occur when work at these pumps is required, i.e., maintenance or repair of the dosing pumps. These pumps may contain concentrated product. However, according to the pattern of use for PT 12 described in the *biocides human health exposure methodology* (BHHEM) document, version 1, p. 65, "*maintenance and repair of dosing pumps require decontamination before handling as protective equipment is not practicable for this task*". While the requirements regarding risk mitigation measures are subject to the risk assessment, this note underlines that decontamination of the pumps and the concentrate pipes is common practice. The concentrations were chosen as for scenarios FB4-1a and FB4-1b, taking a fictive worst-case product containing 16.7 % peracetic acid and 48.4 % hydrogen peroxide into account. For the Tier 2 assessment, it is assumed that the pumps are flushed prior to maintenance/repair. Even after decontamination, some diluted product might be left in the pumps and/or pipes. As a worst case, a dilution factor of 100 is assumed, which might represent a rather conservative figure if thorough decontamination and/or flushing of the system is expected.

Inhalation exposure

The inhalation exposure of workers resulting from this task was assessed using the ART model. The chosen activity class (handling of contaminated objects) and the situation (activities with treated/contaminated objects (surface 1-3 m²)) are representative for "maintenance of fuel pumps" in ART. In order to have a conservative approach, a contamination of 10-90 % of the surface was chosen.

Activity coefficients of the active substance peracetic acid and the equilibrium partner of the active substancehydrogen peroxide were calculated using AIOMFAC (http://www.aiomfac.caltech.edu/), taking only the major compounds water, PAA and HP into account.

For details on the calculations of the activity coefficients and the ART calculations, see documents attached to the annex (section 4.3.1) of this PAR.

Dermal exposure

Dermal exposure was assessed semi-quantitatively or qualitatively for the active substance and the equilibrium partner of the active substance. For details, see chapter 3.6.4.

Summary

For Tier 1, the quantitative risk assessment has indicated risks resulting from inhalation exposure. In addition, local risk assessment (see section 3.6.4 of this PAR) has indicated risks resulting from contact with skin (hands, body, feet) as well as from eye contact. As an organisational measure, flushing of the pumps prior to maintenance and/or repair is therefore required, which is assessed in Tier 2.

For Tier 2, the quantitative risk assessment has still indicated a risk resulting from inhalation exposure. Therefore, a Tier 3 assessment considering RPE with an APF of 10 was performed.

Even when it is considered that the pumps are flushed prior to maintenance/repair, the local risk assessment has indicated risks resulting from contact with skin (hands, body, feet) as well as from eye contact. Thus, the use of chemical protective gloves, a coverall, protective boots and eye protection is additionally required for safe use in scenario FB4-4.

Considerations regarding product compositions with lower concentrations than the worst-case

As outlined above, the initial assessment is based on worst-case assumptions regarding the concentrations of peracetic acid and hydrogen peroxide, i.e., the highest concentration of peracetic acid (from meta SPC 3) and of hydrogen peroxide (from meta SPC 1) have been considered. In Tier 1, a risk from inhalation exposure towards peracetic acid as well as towards hydrogen peroxide was identified. The exceedance of the AEC is substantial even for the lower concentrations of the products in the other meta SPCs, so the worst-case Tier 1 calculation is considered representative for the entire biocidal product family.

In Tier 2, a dilution factor of 1:100 resulting from flushing the pumps is considered. For the worst-case concentrations, only a risk from peracetic acid is observed in Tier 2. This calculation is based on the peracetic acid concentration found in meta SPC 3 (16.7 % diluted 1:100 = 0.167 %), but calculations performed for the other meta SPCs have shown that for the respective lower concentrations there is no risk.For the lower concentration in meta SPC 2 (0.05 % after dilution) no risk was identified. The latter calculation is expected to cover the even lower concentration of peracetic acid in meta SPC 1 (0.024 % after dilution).

Consequently, only the biocidal products of meta SPCs 3 require the use of **RPE** for repair or maintenance of the pumps, while for meta SPCs 1 and 2 this PPE is dispensable.

The local risk assessment is based on the classification of the diluted products in Tier 2/3 and the dermal NOAEC of peracetic acid. The dermal NOAEC is exceeded for the diluted products in meta SPC 3, but not for the diluted products in meta SPCs 1 and 2. Additionally the classifications Skin Corr. 1, and Eye Dam. 1 and hazard category very high result from the fact that it cannot be excluded that the pH value is < 2. Consequently, risk mitigation measures preventing dermal or eye contact, i.e., **chemical protective gloves**, a **coverall**, **protective boots** and **eye protection,** are mandatory for products of all meta SPCs for this scenario.

Scenario FB4-4: Post application exposure: Maintenance/repair of dosing pumps Inhalation exposure was calculated with ART model using the following parameters.		
	Parameters	**Value**
Tier 1	peracetic acid concentration (max. conc. in meta SPC 2) molar fraction activity coefficient (calculated for meta SPC 1) vapour pressure	 16.7 % 0.0613 0.3011 1410 Pa
	hydrogen peroxide concentration (max. conc. in meta SPC 1) molar fraction activity coefficient (calculated for meta SPC 1) vapour pressure	 48.4 % 0.398 0.9317 214 Pa
	ART scenario parameters Emissions sources Duration Process temperature	 (only) near field 120 min 293 K
	Activity class	Handling of contaminated objects
	Situation	Activities with treated/contaminated objects (surface 1-3 m²)
	Contamination level	Contamination 10-90 % of surface
	Process fully enclosed?	No
	Effective housekeeping practices in place?	Yes
	Work area	Indoors
	Room size	Any size workroom
	Localised controls: Primary	No localised controls (0 % reduction)
	Localised controls: Secondary	No localised controls (0 % reduction)
	Ventilation rate	Only good natural ventilation
Tier 2	peracetic acid *meta SPC 3* concentration molar fraction activity coefficient *meta SPC 1 (covers also meta SPC 2)* concentration molar fraction	 0.167 % $3.97 \cdot 10^{-4}$ 2.4262 0.050 % $1.19 \cdot 10^{-4}$ 2.4457

	activity coefficient	
	<u>hydrogen peroxide</u> concentration (max. conc. in meta SPC 1) molar fraction activity coefficient (calculated for meta SPC 1)	 0.484 % $2.57 \cdot 10^{-3}$ 1.1957
Tier 3	Respiratory protective equipment	APF 10

Table 55

Quantitative inhalation exposure resulting from use of the biocidal product <u>Note:</u> The dermal exposure is assessed semi-quantitatively considering the dermal NOAEC for peracetic acid, and qualitatively for the equilibrium partner of the active substancehydrogen peroxide (for details, see chapter 3.6.4.).					
		inhalation exposure [mg/m³]		**Dermal exposure (concentration in handled solutions) [% (w/w)]**	
Exposure scenario	**Tier/RMMs**	**Active substance peracetic acid (PAA)**	**Equilibrium partnerhydrogen peroxide (HP)**	**Active substance peracetic acid (PAA)**	**Equilibrium partner hydrogen peroxide (HP)**
FB4-1a	Tier 1 Automatic dosing pump	$1.7x10^{-2}$	$5.3x10^{-2}$	16.7 %	48.4 %
	Tier 2* RPE w. APF 10	$1.70x10^{-3}$	$5.30x10^{-3}$	16.7 %	48.4 %
FB4-1b	Tier 1 Automatic dosing pump	0.17	0.53	16.7 %	48.4 %
	Tier 2* RPE w. APF 10	$1.7x10^{-2}$	$5.30x10^{-2}$	16.7 %	48.4 %
FB4-2	Tier 1	0.56	2.70	0.0010 %	0.0285 %
	Tier 2 RPE w. APF 10	$5.6x10^{-2}$	0.27	0.0010 %	0.0285 %
FB4-3	Tier 1	0.20	0.26	0.0075 %	0.0606 %
	Tier 2* RPE w. APF 10	$2.0x10^{-2}$	$2.6x10^{-2}$	0.0075 %	0.0606 %
FB4-4	Tier 1	18.0	53.0	16.7 %	48.4 %
	Tier 2 (meta-SPC 3) flushing pump	0.91	0.44	0.167 %	0.484 %
	Tier 2 (meta-SPC 2, covers also meta-SPC 1) flushing pump	0.28	Covered by meta SPC 3	0.050 %	
	Tier 3 (meta-SPC 2, covers also meta-SPC 1) RPE w. APF 10	0.03	0.044	See respective values indicated for Tier 2	
	Tier 3 (meta-SPC 3) RPE w. APF 10	$9.1x10^{-2}$	$4.4x10^{-2}$	See respective values	

				indicated for Tier 2	

[*] Values for Tier 2 for this scenario are displayed for informational purposes, only (Safe scenario already in Tier 1).

3.6.3.1.2 Non-professional exposure

Not relevant. The BPF is intended for use in industrial settings.

3.6.3.1.3 Secondary exposure of the general public

For PT 11 products of the family chronic secondary exposure of non-users/bystanders via the inhalation route due to blowdown or uncontrolled windage from cooling towers is relevant for the treatment of open re-circulating cooling water systems within this assessment. In contrast to this, the disinfection of once-through cooling systems is not relevant as no cooling towers are connected to the latter type of cooling systems. Therefore, no exposure estimations for chronic secondary exposure need to be performed following the disinfection of once-through cooling systems.
Consequently, the human health secondary exposure assessment presented for PT 11 (Treatment of cooling water in open re-circulating systems) is the worst case scenario. The in-use concentrations of open re-circulating systems are used in the calculations although values are lower than in once-through cooling systems.

Therefore worst-case in use concentrations of 0.001 % PAA and 0.028 % HP are used for the secondary exposure assessment.
According to the CAR for peracetic acid (PT11 and 12 (DocIIB, 2016, CA FI), secondary exposure to PT12 products is not relevant.
In accordance with the CAR for peracetic acid (PT 11 and 12), secondary exposure scenarios of humans and a systemic exposure towards peracetic acid and hydrogen peroxide following dermal contact with treated surfaces, equipment or media is considered to be not relevant for the following reasons (CAR PAA PT11 and 12 DocIIB, 2016, CA FI):

- After application of aqueous peracetic acid solutions, peracetic acid and hydrogen peroxide are used in a very diluted form only and concentrations applied are below a skin-irritating concentration. Therefore, no skin damage occurs after incidental or inadvertent dermal contact with treated surfaces and/or equipment. The concentration-dependent irritant/corrosive properties of peracetic acid and hydrogen peroxide have been substantiated in various animal studies as well as in investigations in humans.
- Owing to the chemical properties of peracetic acid and considering the mechanism of action as well as its function as a strong oxidant, peracetic acid is highly unstable and will rapidly degrade at the site of first contact, i.e. on treated surfaces and equipment. These properties and behaviour also apply to hydrogen peroxide. Even in the case, that higher concentrated peracetic acid solutions might cross the skin barrier as a consequence of skin damage, peracetic acid will not become systemically available or will be systemically distributed in the organism due to its rapid degradation in the blood. Thus, in light of the known high reactivity of peracetic acid, systemic exposure towards peracetic acid after dermal contact is not likely to occur and the substance will not become systemically available as a consequence thereof.

- Hydrogen peroxide solutions below skin irritating concentrations as well do not penetrate the skin, since it reacts rapidly at the site of first contact and degrades to form water and oxygen. In the unlikely case, that hydrogen peroxide penetrates skin it will not become systemically available as it is enzymatically degraded within the body (catalase, glutathione peroxidase). Therefore, systemic exposure towards hydrogen peroxide is not likely to occur after dermal contact since it will not become systemically available.
- In applications of peracetic acid solutions as a slimicide in the paper industry, peracetic acid and hydrogen peroxide will have degraded on contact with paper and other organic matter present. Therefore, secondary dermal exposure of consumers to peracetic acid and hydrogen peroxide via paper is not considered to be relevant as both substances degrade rapidly following application and no residues are expected in paper. The absence of peracetic acid in slurries of a paper-mill using representative conditions has been demonstrated by measurements relevant for applications as an in-can preservative within PT 6. The same samples were also analysed for residual amounts of hydrogen peroxide and were in the range between 0.8 and 1.0 mg/L (0.8 – 1 ppm). However, dermal exposure towards hydrogen peroxide is not relevant and has not to be taken into consideration since the measured residual amounts of the substance are below skin irritating concentrations and diluted hydrogen peroxide does not penetrate skin. Thus, no systemic exposure toward hydrogen peroxide is to be expected. Furthermore, hydrogen peroxide is very reactive and degrades rapidly at the site of first contact with organic material to form water and oxygen. According to the TNsG, no inhalation exposure has to be preconceived for reactive substances as they are considered to have disappeared by the time the paper is used (Technical Notes for Guidance, part 2, page 98). Thus, dermal exposure towards residues of peracetic acid and hydrogen peroxide in treated paper is considered to be not relevant due to the high reactivity and fast degradation of both substances.

It can therefore be concluded that secondary exposure of humans following dermal contact is not relevant after application of aqueous peracetic acid solutions.

Chronic secondary exposure

Inhalation of volatilised peracetic acid and hydrogen peroxide

During uses of peracetic acid (PAA) solutions for the disinfection of cooling water systems, a potential chronic secondary exposure of non-users/bystanders via the inhalation route of exposure might occur towards vapours or mist of PAA and hydrogen peroxide (HP) containing cooling water released from cooling towers. The exposure to airborne PAA and HP by uncontrolled windage or blowdown is considered to be a chronic scenario since it cannot be excluded that non-users/bystanders will be continuously exposed (CAR PAA PT11 and 12 DocIIB, 2016, CA FI).

For the estimation of the secondary inhalation exposure of non-users/bystanders, no measurements have been performed. This scenario was discussed in the BPC-WG-II-2016 with the conclusion that PECair values from the CAR can be used as a worst case scenario for the assessment of the exposure of a non-user/bystander towards vapours or mist of PAA and HP released from a cooling tower. Nevertheless, in the exposure estimations from the risk assessment for the environment (part 3.8.4) of this PAR, PECair values for the BPF products were derived. The values are estimated from worst-case assumptions and are therefore used in this risk assessment for the gereral public. A few other ways of calculations were also proposed but PECair values were considered as the most appropriate approach, giving also the highest value (the worst case) here (CAR PAA PT11 and 12 DocIIB, 2016, CA FI). The TNsG of Human exposure (2002, part 3) suggests to calculate a spray drift model for preservatives used in liquid-cooling and processing systems. This chronic reference scenario gives adult systemic exposure. However, systemic exposure is not relevant for PAA and HP.

- **Scenario [BfR1]**

Table 56

Description of Scenario [BfR1]		
Secondary exposure General public (all age groups) – Chronic inhalation of aerosols The biocidal products of the BPF are used for the preservation of cooling water in open recirculating systems of cooling towers. The concentrate is added into the cooling water stream by automated dosing. The maximal in use concentrations is 0.001 % PPA and 0.028 % HP. After application of peracetic acid within PT 11 for the disinfection of cooling water in open re-circulating systems, people walking by or living near to a cooling tower may be potentially exposed to vapours or mist of airborne peracetic acid and hydrogen peroxide by uncontrolled windage or blowdown. In Tier 1 the exposure values from environmental exposure assessment of the active substance peracetic acid (PAA) and the equilibrium partner of the active substancehydrogen peroxide (HP) are used in the assessment for the chronic secondary inhalation exposure of a non-user/bystander following inhalation of aerosols and vapours of peracetic acid and hydrogen peroxide due to uncontrolled windage or blowdown from a cooling tower. The PECair values are 0. 006589 mg PAA/m^3 and 0.011 mg HP/m^3 (according to the exposure assessment of risk assessment for the environment part 3.8.4).		
	Parameters	Value
Tier 1	PAA PEC_{air} (according to the exposure assessment for the environment part 3.8.4.5 Table 95)	0. 006589 mg/m^3
	HP PEC_{air} (according to the exposure assessment for the environment part 3.8.4.5Table 92)	0.011 mg/m^3

Table 57

Summary table: local exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake in mg/m^3**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake in mg/m^3**
Scenario [BfR1]	1	PAA: 0.006589 HP: 0.011	Not relevant	Not relevant	PAA: 0.006589 HP: 0.011

3.6.3.2 Dietary exposure

Table 58

Intended use(s) (critical application with regard to dietary exposure)	
Active substance(s)	peracetic acid
Type of formulation	soluble concentrate
Equilibrium partner of the active substance	hydrogen peroxide
Field(s) of use	**1) Preservation of cooling water in once-through systems** (Meta SPC 1 Use 1, Meta SPC 2 Use 1, Meta SPC 3 Use 1) **2) Preservation of cooling water in open recirculating systems** (Meta SPC 1 Use 3, Meta SPC 2 Use 3, Meta SPC 3 Use 2-3) **3) Slimicide in pulp and paper industry** (Meta SPC 2 Use 4; Meta SPC 3 Use 4)
Target organism(s)	Bacteria (incl. Legionella) Algae Yeast (slimicide use only) Slime (slimicide use only)
Application rate(s) and frequency	**1) Preservation of cooling water in once-through systems** In-use concentration a.s. 8.5-10 ppm (w/w) Frequency: max. 15 min/day (max. 220 days/year) **2) Preservation of cooling water** In-use concentration a.s. 1-10 ppm Frequency: max. 15 min/day (max. 220 days/year) **3) Slimicide in pulp and paper industry** In-use concentration a.s. 30-75 ppm Frequency: continuous dosing
Category(ies) of users	Professional and industrial user
Waiting periods after treatment	/
Further information	/

<u>Representative dietary exposure scenarios</u>

Critical scenarios with respect to consumer dietary intake for the BPF are presented in the following table. They have been selected based on the information on the intended uses given in Table 58.

Table 59

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
Transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)			
1.	Slimicide in pulp and paper industry	Transfer of residues from contaminated food contact materials (FCM, like packaging paper and board, and cooking papers) onto food or feed	Food and feed

Conclusion

At active substance approval it was noticed that equilibrium peracetic acid is composed of acetic acid, peracetic acid, hydrogen peroxide and water. Moreover, after application of equilibrium peracetic acid the relevant substances, which have to be considered in human health exposure assessment, are peracetic acid (a.s.) and hydrogen peroxide (equilibrium partner of the active substance). Both are highly reactive and degrade rapidly at the site of first contact with organic material. Therefore, the application of disinfectant solutions containing peracetic acid and hydrogen peroxide as slimicide is not expected to lead to the formation of residues in food items (AR section 2.2.1.4, Peracetic acid, PT 11 and 12, eCA: FI, 2015).

The contamination of food and feed in contact with contaminated FCM is foreseen to be negligible. Therefore, no consumer or livestock exposure assessment was considered necessary.

Consequently, for the intended uses of the BPF no relevant residues of peracetic acid and hydrogen peroxide in food are anticipated. Human dietary exposure to peracetic acid and hydrogen peroxide from the intended uses is not considered to be relevant.

3.6.3.2.1.1 Information of non-biocidal use of the active substance

Information on the residue definitions is provided in Table 18 (Maximum residue limits or equivalent).

Table 60

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Veterinary use	Uterus disinfectant and control of foot-rot in ruminants	No MRL required[a]
2.	Plant protection products	Not approved as active substance, however national authorisations apply in individual MS[c]	default MRL of 0.01 mg/kg[b]

		- disinfection of glasshouses, warehouses, agricultural equipment/tools and irrigation pipes (FR, PL) - treatment of flower bulbs (NL)	
3.	Food contact materials	(1) Slimicide in food packaging paper and board, and cooking papers (2) Preservative for artificial sausage casings	No legally binding reference values, but recommendations: (1) max 0.1 % based on dry fibers[d] (2) 0.5 % aqueous solution (no preserving effect on foodstuff)[e]

[a] CVMP summary report EMEA/MRL/060/96-FINAL, February 1996, https://www.ema.europa.eu/documents/mrl-report/peracetic-acid-summary-report-committee-veterinary-medicinal-products_en.pdf

[b] according to Commission Regulation (EC) No. 396/2005

[c] Commission Decision 2007/442/EC

[d] Database BfR Recommendations on Food Contact Materials: No. XXXVI. Paper and Board for Food Contact and XXXVI/1. Cooking Papers, Hot Filter Papers and Filter Layers

[e] Database BfR Recommendations on Food Contact Materials: XLIV. Artificial Sausage Casings

3.6.3.3 Exposure associated with production, formulation and disposal of the biocidal product

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR.

3.6.3.4 Summary of exposure assessment

Table 61

Scenarios and values to be used in quantitative risk assessment for professional and industrial use				
Scenario number	**Exposed group** **(e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total external inhalation exposure towards active substance peracetic acid, considering the duration of the task** **[mg/m³]**	**Estimated total external inhalation exposure towards equilibrium partner of the active substance hydrogen peroxide, considering the duration of the task** **[mg/m³]**
FB4-1a (all meta SPCs)	Professionals*	Tier 1 (no RPE, but automatic dosing	$1.7x10^{-2}$	$5.3x10^{-2}$

		pumps have been considered)		
FB4-1b (all meta SPCs)	Professionals*	Tier 1 (no RPE, but automatic dosing pumps have been considered)	0.17	0.53
FB4-2 (all meta SPCs)	Professionals*	Tier 2 (RPE w. APF 10)	5.6×10^{-2}	0.27
FB4-3 (meta SPCs 2-4)	Professionals*	Tier 1 (no RPE)	0.20	0.26
FB4-4 (meta SPCs 1 + 2)	Professionals*	Tier 2 (no RPE, but initial flushing of pumps has been considered)	0.28	0.44
FB4-4 (meta SPCs 3)	Professionals*	Tier 3 (RPE w. APF 10, also initial flushing of pumps has been considered)	9.1×10^{-2}	4.4×10^{-2}

*including industrial user

Table 62

Summary table: local exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake in mg/m^3**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake in mg/m^3**
Scenario [BfR1]	1	PAA: 0. 006589 HP: 0.011	Not relevant	Not relevant	PAA: 0.006589 HP: 0.011

3.6.4 Risk characterisation for human health

3.6.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report(s) as in Table 63.

Table 63

Reference values of the active substance peracetic acid					
Reference	**Study**	**NOAEC**	**AF**	**Correction for oral absorption**	**Value**
AEC inhalation	Human data, Assessment-Report, RMS Finland (2015/2016)	1.56 mg/m^3 (0.5 ppm)	3.16	-	0.5 mg/m^3 (0.16 ppm)

Reference values of hydrogen peroxide					
Reference	**Study**	**NOAEC**	**AF**	**Correction for oral absorption**	**Value**
AEC inhalation	90-day rat inhalation study, Assessment-Report PT 1-5 (RMS FI (2015))	10mg/m^3 (7ppm)	8	-	1.25 mg/m^3

3.6.4.2 Maximum residue limits or equivalent

Table 64

MRLs or other relevant reference values	**Reference**	**Relevant commodities**	**Value**
MRL (peracetic acid)	Commission Regulation (EC) No. 396/2005	All commodities	0.01 mg/kg
MRL (hydrogen peroxide)	Reg. (EU) 2017/1777	All commodities	No MRL required

3.6.4.3 Specific reference value for groundwater

No specific reference values for groundwater have been derived.

3.6.4.4 Risk for industrial users

For all scenarios, more than one group of exposed users with identical exposure patterns exist. For clarity, the risk assessment of all scenarios is only described in detail in section 3.6.4.5 Risk for professional users.

3.6.4.5 Risk for professional users

The BPF comprises three meta SPCs. An overview of the applications applied for the three meta SPCs is given in Table 49 in chapter 3.6.3. All members of the BPF contain peracetic acid (CAS No.: 79-21-0) as active substance and the equilibrium partner of the active substance hydrogen peroxide.

The occupational risk assessment for local effects of the active substance peracetic acid and the equilibrium partner of the active substance hydrogen peroxide is based on the external reference value (inhalation $AEC_{long\text{-}term}$) and for peracetic acid also with the derived dermal $NOAEC_{long\text{-}term}$. These reference values are compared with external inhalation exposure values for peracetic acid and hydrogen peroxide as well as with the external dermal exposure value for peracetic acid.

Local effects – quantitative

Peracetic acid

Peracetic acid has corrosive properties (skin, eye and respiratory tract). Since there is an $AEC_{inhalation}$ (based on sensory irritation symptoms in humans) available a quantitative risk characterisation for professional users is carried out. Since there is an dermal NOAEC (based on irritation symptoms in humans) available also a semi-quantitative risk characterisation for professional users is carried out.

Quantitative inhalation risk characterisation

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from inhalation exposure of professional users the local reference value $AEC_{inhalation}$ (0.5 mg/m^3) of peracetic acid is used as external inhalation reference value and directly compared with airborne concentrations of peracetic acid.

Calculation of AEC exhaustion (%)

The exposure-to-AEC ratio (%) referring to the active substance peracetic acid is determined according to the equation:

Exposure-to-AEC ratio (%) = inhalation exposure to peracetic acid (in mg/m^3) / $AEC_{inhalation}$ of peracetic acid (in mg/m^3) x 100 %.

A risk for professional users is unlikely if the AEC exhaustion (%) for each scenario is below the value of 100 %. Table 65 gives a detailed overview of the risk assessment results. It is noted that for clarity reasons all values are rounded to an appropriate number of decimal places. However, the underlying calculations are based on unrounded values.

As shown in Table 65, for scenarios FB4-1a, FB4-1b and FB4-3 a risk for the professional user is unlikely already in Tier 1. By contrast, for scenarios FB4-2 and FB4-4 risks are identified after Tier 1 and partly Tier 2 consideration. However when risk mitigation measures are implemented a risk for the professional user is unlikely at the latest in Tier 3.

Table 65: Overview of detailed local risk assessment results for inhalation route referring to the active substance peracetic acid

Scenario number	**Meta-SPC**	**Scenario**		**reference value inhalation $AEC_{long-term}$** mg/m^3	**inhalation exposure** mg/m^3	**inhalation exposure/ AEC** %	**Acceptable** (yes/no)
FB4-1a	1-3	Primary Exposure: Automated loading (from storage containers into the process waters)	Tier 1	0.50	1.70×10^{-2}	3	**yes**
FB4-1b	1-3	Primary Exposure: Automated loading (from bulk transporter into storage tank or IBC)	Tier 1	0.50	0.17	34	**yes**
FB4-2	1-3	Secondary exposure: inspection/maintenance of cooling systems/cooling towers	Tier 1	0.50	0.56	112	no
			Tier 2	0.50	5.60×10^{-2}	11	**yes**
FB4-3	2-3	Secondary exposure: process operation (240 min/day) and inspection/maintenance (120 min/day)	Tier 1	0.50	0.20	40	**yes**
FB4-4	1-3	Post application exposure:	Tier 1	0.50	18.0	3600	**no**
	1+2		Tier 2	0.50	0.28	56	**yes**

	3	Maintenance/repair of dosing pumps		0.50	0.91	182	no
	1+2		Tier 3	0.50	0.03	6	yes
	3			0.50	$9.1x10^{-2}$	18	**yes**

Conclusion

Based on the risk assessment of the active substance peracetic acid via the inhalation route, a risk for professional users resulting from all uses is unlikely at the latest after Tier 3 consideration. Regarding occupational safety, there are no objections against the uses as well as secondary exposure taking into account the provisions described in chapter 2.3 of this PAR.

Hydrogen peroxide

For the equilibrium partner of the active substance hydrogen peroxide irritation is considered as primary toxic effect with respect to inhalation exposure. A quantitative risk characterisation for professional users is carried out since there is a harmonised reference value (AEC) of 1.25 mg/m^3 for hydrogen peroxide.

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from inhalation exposure of professional users the local reference value $AEC_{inhalation}$ (1.25 mg/m^3) of hydrogen peroxide is used as external inhalation reference value and directly compared with airborne concentrations of hydrogen peroxide.

Calculation of AEC exhaustion (%)

The exposure-to-AEC ratio (%) referring to the equilibrium partner of the active substance hydrogen peroxide is determined according to the equation:

Exposure-to-AEC ratio (%) = inhalation exposure to hydrogen peroxide (in mg/m^3) / $AEC_{inhalation}$ of hydrogen peroxide (in mg/m^3) x 100 %.

A risk for professional users referring to the equilibrium partner of the active substance hydrogen peroxide is unlikely if the AEC exhaustion (%) for each scenario is below the value of 100 %. Table 109 gives a detailed overview of the risk assessment results. It is noted that for clarity reasons all values are rounded to an appropriate number of decimal places. However, the underlying calculations are based on unrounded values.

As shown in Table 66, for scenarios FB4-1a, FB4-1b and FB4-3 a risk for the professional user is unlikely already in Tier 1. By contrast, for scenario FB4-2 and FB4-4 risks are identified after Tier 1 consideration. However when risk mitigation measures are implemented a risk for the professional user is unlikely at the latest in Tier 2.

Table 66: Overview of detailed local risk assessment results for inhalation route referring to the equilibrium partner of the active substance hydrogen peroxide

Scenario number	**Meta-SPC**	**Scenario**		**reference value inhalation $AEC_{long-term}$** mg/m^3	**inhalation exposure** mg/m^3	**inhalation exposure/ AEC** %	**Acceptable** (yes/no)
FB4-1a	1-3	Primary Exposure: Automated loading (from storage containers into the process waters)	Tier 1	1.25	5.30×10^{-2}	4	**yes**
FB4-1b	1-3	Primary Exposure: Automated loading (from bulk transporter into storage tank or IBC)	Tier 1	1.25	0.53	42	**yes**
FB4-2	1-3	Secondary exposure: inspection/maintenance of cooling systems/cooling towers	Tier 1	1.25	2.70	216	no
			Tier 2	1.25	0.27	22	**yes**
FB4-3	2-3	Secondary exposure: process operation (240 min/day) and inspection/maintenance (120 min/day)	Tier 1	1.25	0.26	21	**yes**
FB4-4	1-3	Post application exposure: Maintenance/repair of dosing pumps	Tier 1	1.25	53.0	4240	no
			Tier 2	1.25	0.44	35	**yes**

Conclusion

Based on the risk assessment of the equilibrium partner of the active substance hydrogen peroxide via the inhalation route, a risk for professional users resulting from all uses is unlikely at the latest after TIER 2 consideration. Regarding occupational safety, there are no objections against the uses as well as secondary exposure taking into account the provisions described in chapter 2.3 of this PAR.

Local effects – semi-quantitative

Peracetic acid

Semi-quantitative dermal risk characterisation

<u>Details of risk characterisation</u>
<u>Reference values</u>
For the purpose of risk characterisation resulting from dermal exposure of professional users the local reference value $NOAEC_{dermal,\ long\text{-}term}$ (0.1 %) of peracetic acid is directly compared with dermal concentrations of peracetic acid.

In case the dermal exposure (as concentration [%] of the application solution) falls below the $NOAEC_{dermal,\ long\text{-}term}$ a risk for professional users is unlikely, in case the dermal exposure exceeds the $NOAEC_{dermal,\ long\text{-}term}$ a risk for professional user can not be excluded

A risk for professional users referring to the active substance peracetic acid is unlikely if the dermal exposure falls below the $NOAEC_{dermal,\ long\text{-}term}$ for each scenario. Table 67 gives a detailed overview of the risk assessment results. It is noted that for clarity reasons all values are rounded to an appropriate number of decimal places. However, the underlying comparisons are based on unrounded values.

As shown in Table 67, for the scenarios FB4-2 and FB4-3 a risk for the professional user is unlikely. By contrast, for the scenarios FB4-1a, FB4-1b and FB4-4 inacceptable risks are identified. However when risk mitigation measures are implemented a risk for the professional user is unlikely. For details see part "Local risk – qualitative" of this section, Table 70.

Table 67: Overview of risk assessment results for dermal route and the active substance peracetic acid

Scenario number	Meta-SPC	Task/scenario		Dermal NOAEC	Concentration peracetic acid (max.) in application solution	Concentration peracetic acid exceeds dermal NOAEC?	RMM
FB4-1a	1-3	Primary Exposure: Automated loading (from storage containers into the process waters)	Tier 1	0.1%	16.70 %	yes	*
			Tier 2	0.1%	16.70 %	yes	*
FB4-1b	1-3	Primary Exposure: Automated loading (from bulk transporter into storage tank or IBC)	Tier 1	0.1%	16.70 %	yes	*
			Tier 2	0.1%	16.70 %	yes	*

FB4-2	1-3	Secondary exposure: inspection/maintenance of cooling systems/cooling towers	Tier 1	0.1%	0.001 %	no	-
FB4-3	2-3	Secondary exposure: process operation (240 min/day) and inspection/maintenance (120 min/day)	Tier 1	0.1%	0.0075 %	no	-
FB4-4	1-3	Post application exposure: Maintenance/repair of dosing pumps	Tier 1	0.1%	16.70 %	yes	*
	1+2		Tier 2	0.1%	0.050 %	no	-
	3			0.1%	0.167 %	yes	*
	1+2		Tier 3	0.1%	0.050 %	no	-
	3			0,1%	0.167 %	yes	*

* Skin protection needed, see section Local risks

Conclusion

Based on the risk assessment of the active substance peracetic acid via the dermal route a risk for professional users resulting from the scenarios FB4-1a, FB4-1b and FB4-4 is unlikely taking into account the provisions described in part “Local risk – qualitative” (Table 69 and Table 70) and in chapter 2.3 of this PAR.

Equilibrium partner of the active substance hydrogen peroxide

The equilibrium partner of the active substance hydrogen peroxide exerts local effects in the biocidal products of the BPF. In Table 68 the classification and assigned band according to the banding evaluation scheme of the SoC Guidance (Annex A to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (Version 4.0, December 2017)) are shown.

Table 68: Overview of the relevant classification and assigned band from the banding evalution scheme

Substance	Resulting classification according to Regulation (EC) No. 1272/2008	Relevant band from Banding evaluation scheme	Associated evaluation/risk management requirements	Implementation
Hydrogen peroxide	Contributes to classification of products with: Acute Tox. 4, H332 Skin Corr. 1A, H314	A B	a) b)	See section 2.3.1.3

				*

a) Application of P-statements normally associated with concerned H statements

b) Qualitative exposure and risk assessment to determine whether P-statements normally associated with concerned H statements are sufficient or whether other risk mitigation measures should be applied

* See chapter Local effects - qualitative

Local effects – qualitative

Qualitative risk characterisation for local effects

The active substance peracetic acid as well as the equilibrium partner of the active substance hydrogen peroxide contribute to the classification of the products of the BPF with H314 (Causes severe skin burns and eye damage), H318 (Causes serious eye damage) and EUH071 (Corrosive to the respiratory tract). Therefore a qualitative risk assessment for local effects regarding contact with the skin, eye and the respiratory tract is necessary. The qualitative risk assessment for local effects takes into account the concentrated biocidal product as well as the different dilutions thereof. The Table 69 gives an overview of the relevant classifications for the qualitative risk assessment for local effects. Furthermore, the allocated hazard categories according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017) are plotted against the respective classification.

Table 69: Relevant classification and resulting hazard categories

Biocidal product concentration in application solution [%]	Resulting classification according to Regulation (EC) No. 1272/2008	Resulting hazard category according to Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017)
100	Skin Corr. 1A, H314 Eye Dam. 1, H318 EUH071	Very high
1	Skin Corr. 1A, H314 Eye Dam. 1, H318	Very high
0.001	-	-
0.0075	-	-

For the concentrated biocidal product qualitative risk assessment is triggered by the corrosive effects (Skin Corr. 1A, H314) as this classification is allocated to the hazard category “very high”. The classifications for eye damage and respiratory corrosion are allocated to the hazard category “high”.

For biocidal product concentration in application solution of 0.001 % and 0.0075 % no qualitative risk assessment for local effects is triggered as no classification and therefore no hazard categories are allocated .

Concluding qualitatively on the acceptability of risk, the frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017) the following tables are prepared to carry out the qualitative risk assessment for local effects regarding contact with the skin, the eye and the respiratory tract (Table 70). With the proposed risk mitigation measures the reduction of dermal and eye contact minimises the anticipated health risk to an acceptable level for the intended uses and for secondary exposure.

Conclusion

Concerning the irritating and corrosive properties for products of the BPF, exposure should be minimised with risk mitigation measures. If the proposed risk mitigation measures are implemented, the intended uses as well as secondary exposure do not lead to concern for professional users.

Overall conclusion

In summary, a risk for professional users resulting from the use of products of the BPF is unlikely. Risk mitigation measures described in chapter 2.3 of this PAR have to be taken into account in order to ensure safe use.

Table 70: Summary of qualitative conclusions for local risk assessment for scenarios FB4-1a, FB4-1b, FB4-2, FB4-3 and FB4-4

Tasks, uses, processes	**Concentration b.p. (max.) in application solution**	**Concentration a.s. PAA (max.) in application solution**	**Local effects in terms of C&L**	**Hazard category**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM & PPE**	**Acceptability**
Scenario FB4-1a: Primary Exposure: Automated loading (from storage containers into the process waters) and Scenario FB4-1b: Primary Exposure: Automated loading (from bulk transporter into storage tank or IBC)	100 %	16.7%	Meta SPC 1-3: Skin Corr. 1A, H314 Eye Dam. 1, H318 EUH071	Very high	daily	dermal, hands: incidental contact to skin is likely dermal, body: incidental contact to skin is possible dermal, feet: incidental contact to skin is possible eyes: contact is possible	Technical measures: - Containment as appropriate; - Good standard of general ventilation; - highly automated process, in particular: **product is only transferred using automatic pumps** - Regular cleaning of equipment and work area; - Avoidance of contact with contaminated tools and objects Organisational measures: - Minimise number of staff exposed; - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice; - Good standard of personal hygiene. PPE: **- Substance/task appropriate gloves;** **- Skin coverage with appropriate barrier material based on potential for contact with the chemicals (coverall (min. type 6, EN 13034) , boots);** **- Eye protection (goggles)**	Acceptable low exposure (high degree of technical RMMs (avoiding splashes, connecting lines only) + professionals using appropiate PPE

Scenario FB4-2: Secondary exposure: inspection /maintenance of cooling systems/ cooling towers	various, depending on product	0.0010 %	Meta SPC 1-3: -	**-**	daily	dermal, hands: frequent contact to skin is to be expected dermal, body: incidental contact to skin is likely dermal, feet: incidental contact to skin is possible eyes: contact is possible	Technical measures: - Good standard of general ventilation; - Regular cleaning of equipment and work area; Organisational measures: - Minimise number of staff exposed; - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice; - Good standard of personal hygiene. PPE: none	Acceptable

Scenario FB4-3: Secondary exposure: process operation (240 min/day) and inspection/ maintenance (120 min/day)	various, depending on product	0.0075 %	Meta SPC 1-3: -	**-**	daily*	dermal, hands: frequent contact to skin is to be expected dermal, body: incidental contact to skin is likely dermal, feet: incidental contact to skin is possible eyes: contact is possible	Technics: - Good standard of general ventilation; - Regular cleaning of equipment and work area; Organisation: - Minimise number of staff exposed; - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice; - Good standard of personal hygiene. PPE: none	Acceptable

Scenario FB4-4: Post application exposure: Maintenance/repair of dosing pumps	1 %	0.024-0.167 %	Meta SPC 1-3: ** Skin Corr. 1, H314 Eye Dam. 1, H318	Very high	monthly	dermal, hands: frequent contact to skin is to be expected dermal, body: incidental contact to skin is likely dermal, feet: incidental contact to skin is possible eyes: contact is possible	Technics: - Good standard of general ventilation; - Regular cleaning of equipment and work area; Organisation: - Minimise number of staff exposed; - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice; - Good standard of personal hygiene. - decontamination/flushing of pumps before start of maintenance/repair PPE: - Substance/task appropriate gloves; - Skin coverage with appropriate barrier material based on potential for contact with the chemicals (coverall (min. type 6, EN 13034) , boots); - Eye protection (goggles)	Acceptable professionals using appropiate PPE

* "manuel dosing in case of interrupted production, 2-10 times/year (from research report F1703: "Arbeitsplatzbelastung bei der Verwendung von bioziden Produkten")

** the classification and hazard category result from the fact that it cannot be excluded that the pH value is < 2, as the concentrates have a pH value around "0"

3.6.4.6 Risk for non-professional users

Non-professional exposure is not relevant. The BPF is for industrial and professional use only.

3.6.4.7 Risk for the general public

- **Local effects**

Oral

Secondary exposure scenarios of humans and a systemic exposure following oral uptake from treated areas, surfaces, material, or equipment is considered to be not relevant. Therefore, a risk assessment for oral exposure is not necessary.

Dermal

Secondary exposure scenarios of the general public following dermal contact with the biocidal product and its dilutions on treated areas, surfaces, material, or equipment is considered to be not relevant. Therefore, a risk assessment for dermal exposure is not necessary.

Inhalation

Secondary exposure of humans via the inhalation route has been identified in the exposure assessment. After and during application of peracetic acid within PT 11 for the disinfection of cooling water in open re-circulating systems, people walking by or living near to a cooling tower may be potentially exposed to vapours or mist of airborne peracetic acid and hydrogen peroxide by uncontrolled windage or blowdown. This scenario is described in Table 59 (General public (all age groups) – Chronic inhalation of aerosols) and is considered to represent a worst case for all other potential exposure scenarios of the general public. Exposure is considered to be of longer duration for people in the vicinity of a cooling tower and to occur under conditions related to a chronic exposure scenario. Environmental PEC_{air} values for the active substance PAA and the equilibrium partner of the active substance HP are derived according to the exposure assessment for the environment part 3.8.4.5Table Table 92for the BfR1 scenario tier 1.

Scenario, Tier	**Substance**	**Default PEC_{air} values mg/m^3**	**Relevant reference value mg/m^3 (AEC)**	**PEC_{air} values/reference value (%)**	**Acceptable (yes/no)**
BfR1a	PAA	0. 006589	0.5	1.3	Yes
	HP	0.011	1.25	0.9	Yes

According to the CAR for peracetic acid (PT11 and 12 (DocIIB, 2016, CA FI), secondary exposure after and during the use in PT12 including inhalation exposure products is not relevant.

Conclusion

Exposure of the general public to the biocidal products of the BPF, with a maximal in use concentration of 0.001 % PAA and 0.028 % HP, is considered acceptable, if the biocidal product is used as intended. No risk has been identified and no risk mitigation measures or safety instruction are required for the general public.

3.6.4.8 Risk for consumers via residues in food

No relevant residues of peracetic acid (a.s.) and hydrogen peroxide (equilibrium partner of the active substance) in food are anticipated.

3.6.4.9 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

No cumulative risk assessment is necessary as no systemically active substance or substance of concern is contained.

3.6.4.10 Summary of risk characterisation

3.6.4.10.1 Summary of risk characterisation for industrial user

See Summary of risk characterisation for professional user

3.6.4.10.2 Summary of risk characterisation for professional user

In summary, a risk for professional users resulting from the use of the biocidal products of the BPF is unlikely for all intended uses.

For details see chapter 3.6.4.5 (Table 65 to Table 70).

3.6.4.10.3 Summary of risk characterisation for non-professional user

Not relevant.

3.6.4.10.4 Summary of risk characterisation for indirect exposure

Table 71

Scenario, Tier	**Substance**	**Default PEC$_{air}$ values mg/m^3**	**Relevant reference value mg/m^3 (AEC)**	**PEC$_{air}$ values/reference value (%)**	**Acceptable (yes/no)**
BfR1	PAA	0. 006589	0.5	1.3	Yes
	HP	0.011	1.25	0.9	Yes

3.7 Risk assessment for animal health[7]

Risk of exposure of domestic animals and pets is covered by human health effect assessment for the general public. Species-dependent differences particularly to humans are considered not relevant, due to the local mode of action of the active substance peracetic acid and the equilibrium partner of the active substance hydrogen peroxide.

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[7] Pets and domestic animals. Regarding wild animals, please refer to chapter 3.9.

3.8 Risk assessment for the environment

3.8.1 General information

The BPF “Evonik PAA BPF PT 11 PT 12” for use in PT 11 and 12 contains the active substance peracetic acid (PAA). Peracetic acid is only present as a chemical equilibrium mixture with hydrogen peroxide (H_2O_2), acetic acid and water. The requested PAA-concentration in the final BP can be achieved by a variety of mixing ratios between both starting components hydrogen peroxide and acetic acid. In PT 11 the content of peracetic acid varies between 1.7% and 15.0% (w/w), in PT 12 between 3.8% and 15.0%. The associated concentrations of H_2O_2 vary between 14.3% and 48.4% for PT 11 and 14.3% and 30.7% for PT 12. The applied in-use-concentration for the PT 11-applications is 1-10 g/m^3 or 8.5-10 g/m^3, for PT 12-applications 5-75 g/m^3 and will be achieved by dilution of the particular biocidal product with water.

While PAA is the active substance, hydrogen peroxide is an equilibrium component as well as a biocidal active substance itself. Therefore, it has to be evaluated like a substance of concern (SoC) for the environment in this biocidal product family. Acetic acid should not be considered as SoC because it is an Annex I substance under BPR which can be exempted from SoC identification according to the Guidance on BPR Vol. IV Part B and C (2017, p.358). In addition, the WG agreed not to consider acetic acid as SoC (agreed documents: WGIV2019_ENV_6-3_Harmonisation of UA cases_PAA and WGIII2020_ENV_8-3a_Harmonisation of assessment for PAA). No other substances of concern were identified for the environment.

No new ecotoxicological studies were submitted for the products, so the environmental risk assessment is based on data from the active substance Assessment Reports (PAA, PT 11 and 12: FI, August 2016 and Hydrogen peroxide PT 11 and 12: FI, October 2017). The application of the BPF is intended for professional use only.

3.8.2 Effects assessment

The effects assessment for environment is based on sufficient data available from the active substance Assessment Reports (PAA, PT 11 and 12: FI, August 2016 and Hydrogen peroxide PT 11 and 12: FI, October 2017).

3.8.2.1 Mixture toxicity

PAA is formed by reaction of H_2O_2 with acetic acid in an aqueous solution. Thereby is PAA not obtained as pure substance but in form of aqueous solution containing PAA and acetic acid in a specific chemical equilibrium. As acetic acid is not considered as SoC , the risk assessment for the environment is done for PAA as active substance and H_2O_2 as equilibrium substance evaluated like a SoC.

Screening step

- **Screening Step 1: Identification of the concerned environmental compartments**

The BPF affects the aquatic and the terrestrial environment as well as the atmosphere. For further information on the release pathways and the relevant compartments for the assessment of the product family, see chapters 3.8.4.2 and 3.8.4.3.

- **Screening Step 2: Identification of relevant substances**

The BPF is composed of the active substance peracetic acid, hydrogen peroxide and acetic acid, which are considered as parts of the active substance equilibrium mixture. Peracetic acid as active substance and hydrogen peroxide as equilibrium substance evaluated like a SoC are relevant substances for the mixture toxicity. No other substances are included, which would lead to an environmental classification of the products of the family according to CLP.

- **Screening Step 3: Screen on synergistic interactions**

Synergistic interactions between the components of the product are not expected according to current knowledge.

Table 72

Screening step	
Y	Significant exposure of environmental compartments? (Y/N)
Y	Number of relevant substances >1? (Y/N)
N	Indication for synergistic effects for the product or its constituents in the literature? (Y/N)

Tiered approach

According to the available data for the relevant substances identified above, tier 1 of the mixture toxicity assessment, the PEC/PNEC summation, has to be followed. In subsequent sections, all values for the two relevant substances are presented in parallel and mixture toxicity assessment is performed conjointly in the risk assessment section.

3.8.2.2 Aquatic compartment (including sediment and STP)

Available PNEC values for surface water, seawater and STP from the respective ARs of the active substances (PAA FI, 2016 & H_2O_2 FI, 2017) are summarised in the following tables.

Table 73: Summary table of PNEC values for surface water and for seawater

Substance	PNEC	Based on
PAA	0.069 µg/L (freshwater)	NOEC for *D. rerio* 0.69 µg/L, AF 10
PAA	0.0069 µg/L (seawater)	NOEC for *D. rerio* 0.69 µg/L, AF 100
H_2O_2	12.6 µg/L (freshwater)	NOEC for *D. magna* 0.63 mg/L, AF 50
H_2O_2	1.26 µg/L (seawater)	NOEC for *D. magna* 0.63 mg/L, AF 500

A PNECsediment for PAA and H_2O_2 was derived by equilibrium partitioning method in the active substance ARs. However, a separate risk assessment for sediment is not necessary, as adsorption potential of both PAA and H_2O_2 are very low, both substances degrade rapidly and the risk assessment for freshwater is considered to cover the risks for sediment.

Table 74: Summary table of PNEC values for STP

Substance	PNEC	Based on
PAA	0.051 mg/L	EC_{50} = 5.1 mg/L, AF 100
H_2O_2	4.66 mg/L	EC_{50} = 466 mg/L, AF100

3.8.2.3 Terrestrial compartment (including groundwater)

Available PNEC values for soil from the respective ARs of the active substances (PAA FI, 2016 & H_2O_2 FI, 2017) are summarised in the following table.

Table 75: Summary table of PNEC values for soil

Substance	PNEC	Based on
PAA	0.282 mg/kg_{ww}	seedling emergence test with non-target plants (*Brassica napus*), AF 1000
H_2O_2	0.0018 mg/kg_{ww}	EPM

Birds and mammals are not anticipated to be directly exposed to peracetic acid or hydrogen peroxide. Thus, risk assessment for bird and mammals is not considered necessary according to the respective ARs.

3.8.2.4 Atmosphere

The measured Henry's Law constants of 0.217 Pa m^3 mol^{-1} for peracetic acid at 25°C and 7.5 × 10^{-4} Pa·m^3 mol^{-1} for hydrogen peroxide at 20°C indicate that volatilisation of both substances from surface water as well as from water in cooling towers into atmosphere is not expected to be an important process.

Therefore, air is not expected as an environmental compartment of concern.

3.8.2.5 Non-compartment specific effects

An assessment of secondary poisoning has to be performed if a substance has a potential for bioaccumulation. According to the AR (2016) for peracetic acid and the AR (2017) for hydrogen peroxide both substances do not have any potential for bioaccumulation and thus, no further assessment of secondary poisoning is considered necessary.

3.8.2.6 Summary of effects assessment

Table 76: Summary table of PNEC values for effects assessment

Compartment	PNEC PAA	PNEC H_2O_2
Surface water	0.069 µg/L	12.6 µg/L
Seawater	0.0069 µg/L	1.26 µg/L
STP	0.051 mg/L	4.66 mg/L
Soil	0.282 mg/kg_{ww}	0.0018 mg/kg_{ww}

3.8.3 Fate and behaviour

Peracetic acid decomposes rapidly in all environmental compartments, i.e. in surface water, seawater, soil, active sludge and air. The following processes are involved in the decomposition/ degradation of peracetic acid in the environment:

- Abiotic degradation:
    - hydrolysis,
    - spontaneous decomposition,
    - metal (Fe, Cr, Mn) catalysed decomposition,
    - oxidation of organic substance,
- Biotic degradation by micro-organisms.

Resulting degradation products of peracetic acid are oxygen, acetic acid and hydrogen peroxide. Spontaneous decomposition results in the formation of acetic acid and oxygen, while hydrolysis yields acetic acid and hydrogen peroxide. The degradation pathway by which hydrogen peroxide can be formed from peracetic acid is by hydrolysis ($CH_3C(O)OOH + H_2O \rightarrow CH_3COOH + H_2O_2$). However, this reaction is negligible in aquatic ecosystems. The predominant degradation pathway in aquatic ecosystems, which are loaded with organic matter, is the reaction of peracetic acid with organic matter and metal cations, leading to the formation of acetic acid and oxygen. Acetic acid and hydrogen peroxide are further degraded to H_2O, CO_2 and oxygen.

Hydrogen peroxide decomposes rapidly in different environmental compartments, i.e. in surface water, seawater, soil, active sludge and air. The following processes are involved in the decomposition/ degradation of hydrogen peroxide in the environment:

- Biotic degradation catalysed by microbial catalase and peroxidase enzymes,
- Abiotic degradation by:
    - transition metal (Fe, Mn, Cu) and heavy metal catalysed decomposition,
    - oxidation or reduction reactions with organic compounds or formation of addition compounds with organic or inorganic substances.

Hydrogen peroxide decomposes into water and oxygen ($2H_2O_2 \rightarrow 2H_2O + O_2$). The rate of this reaction depends on the contact with catalytic materials and other factors such as heat and sunlight.
Standard ready biodegradability tests are not suitable for inorganic substances. Nevertheless, hydrogen peroxide shows a very rapid degradation with organic matter in sewage sludge (DT_{50} = 2 min, 20° C). Rapid degradation of hydrogen peroxide has also been observed in surface water and soil compartments. This degradation has been considered to be mainly microbial derived based on the difference in degradation rates between the natural and filtered/sterilised samples.

At WG-III-2020 the following half-lives for peracetic acid and hydrogen peroxide for the environmental exposure assessment were agreed (document WGIII2020_ENV_8-3a):

Table 77: Summary table on half-lives of peracetic acid

Compartment	DT50 measured/ estimated in tests	Remarks	Reference
STP – effluent stream (also transferable to sewer system and liquid manure)	<< 5 min (<< 9.5 min at 12°C)	Measured at 20° C, pH 7.03	AR for PAA (PT 1-6, Nov 2015 p. 18) (PT 11 & 12, Aug 2016 p.17)
STP – aeration tank	< 3 min (< 4.48 min at 15°C)	Measured at 20° C, pH 7	
Surface water (hydrolysis)	31.7 h (89.7 h at 12°C)	Measured at 25° C, pH 7	AR for PAA (PT 1-6, Nov 2015, LoEP) (PT 11 & 12, Aug 2016, LoEP)
Seawater	50 % degradation within 2 minutes		AR for PAA (PT 1-6, Nov 2015, LoEP) (PT 11 & 12, Aug 2016, LoEP)
Soil	12 h	The default DT50 value based on a conclusion of WG-II-2016 should be used (12 h). The value should not be temperature corrected. It was agreed in the BPC WG ENV-II-2016 to use the DT50 from hydrogen peroxide of 12 h in the absence of a DT50 for PAA. Worst case DT50 estimate based on	AR for PAA (PT 11 & 12, Aug 2016, LoEP)

Compartment	DT50 measured/ estimated in tests	Remarks	Reference
		the literature sources; used for environmental exposure assessment without temperature correction.	
Air	DT50 of 3.969 days (based on a 24-hour day), corresponding to 95.26 h	According to an Atkinson calculation of the atmospheric residence time, peracetic acid degrades in the atmosphere with a DT50 of 3.969 days (based on a 24-hour day), corresponding to 95.26 hours. As the molecule does not contain olefin carbon-carbon double or acetylic triple bonds, peracetic acid is not expected to react with ozone.	AR for PAA (PT 1-6, Nov 2015, LoEP) (PT 11 & 12, Aug 2016, LoEP)

The adsorption of peracetic acid to aerosol particles, the volatilisation from water into air and the adsorption of peracetic acid to soil (K_{OC}=1.46 L kg^{-1} (QSAR)) can be considered to be very low. Thus, peracetic acid mainly distributes in the aqueous phase if released into the environment.

Table 78: Summary table on half-lives of hydrogen peroxide

Compartment	DT50 measured/ estimated in tests	Remarks	Reference
STP – effluent stream	89 min (169 min at 12°C)	Measured at 20° C, pH 7.03	CAR II-B of PAA (PT 1-6, Jan 2015, Table 8.3-2), (PT 11 & 12, Aug 2016, Table 8.3-2)
activated sludge stage of sewage treatment plants	2 min	Measured at 20° C, pH 7.8	AR of H_2O_2 (PT 1-6, Jan 2015, LoEP), (PT 11 & 12, Oct 2017, LoEP)
Raw sewage (also transferable to sewer system), liquid manure	6 min (11.4 min at 12°C)	Measured at 20° C, pH not reported; (Worst-case DT50 determinate for hydrogen peroxide in microbial communities present in an infiltration gallery of a contaminated soil remediation site.)	CAR II-A of H_2O_2 (PT 1-6, July 2013, Table 4.1.1-2), (PT 11 & 12, Oct 2017, Table 4.1.1-2)
activated sludge of a pulp and paper mill	14 min	Measured at 25°C	CAR II-A of H_2O_2 (PT 1-6, July 2013, Table 4.1.1-2), (PT 11 & 12, Oct 2017, Table 4.1.1-2)
Surface water (hydrolysis)	Hydrolysis is not applicable based on the nature of the compound.		AR of H_2O_2 (PT 1-6, Jan 2015, LoEP), (PT 11 & 12, Oct 2017, LoEP)
Surface water (abiotic catalysis and biotic degradation)	5 days	Estimated (An extreme worst case DT_{50} estimate to take account for unfavourable conditions, i.e. oligotrophic cold waters with low microbial density and low transition metal concentration)	AR of H_2O_2 (PT 1-6, Jan 2015, LoEP), (PT 11 & 12, Oct 2017, LoEP)
Soil	12 h	Rapidly decomposed in soil to water and oxygen. Worst case DT50 estimate based on the literature sources; used for environmental exposure assessment without temperature correction.	AR of H_2O_2 (PT 1-6, Jan 2015, LoEP), (PT 11 & 12, Oct 2017, LoEP)

Compartment	DT50 measured/ estimated in tests	Remarks	Reference
Air	24 hrs	Estimated Worst case DT50 estimate based on the literature sources; used for environmental exposure assessment without temperature correction.	AR of H_2O_2 (PT 1-6, Jan 2015, LoEP), (PT 11 & 12, Oct 2017, LoEP)

Since hydrogen peroxide is miscible with water in all ratios, and considering the estimated log K_{OC} of 0.2036 (QSAR, corresponds to K_{OC} of 1.598 L kg^{-1}), it is expected that hydrogen peroxide has a low potential for adsorption to soil and dispersion to suspended matter or sediment (AR of H_2O_2 PT 1-6, Jan 2015 and PT 11 & 12, Oct 2017).

3.8.3.1 Bioconcentration

Peracetic acid: The low logKow of -0.6 indicates that peracetic acid has a negligible potential for bioconcentration and bioaccumulation. Moreover, peracetic acid dissipates rapidly in the environment. This is a further indication of low accumulation potential (AR, 2016).
Hydrogen peroxide: The estimated low log-Kow of –1.57 indicates negligible potential of bioconcentration of hydrogen peroxide in biota. The BCFs calculated according to BPR Vol. IV Part B and C (2017) for fish and earthworm are 1.4 and 0.84, respectively. Therefore, no accumulation of hydrogen peroxide in the food chain is expected either (AR, 2017).

3.8.4 Exposure assessment

3.8.4.1 General information

The biocidal products of the BPF are intended to be used

- for the preservation of liquid cooling water systems (PT 11), the foreseen Meta SPCs are Meta SPC 1-3 and
- as slimicides in process water in the paper and cardboard industry, the foreseen Meta SPCs are Meta SPC 2-3.

Table 79: Intended uses in PT 11

Assessed PT	PT 11
Assessed scenarios	Scenario 11.1: Once-through cooling systems (use 11.1) Scenario 11.2: Large open recirculating cooling systems (use 11.2) Scenario 11.3: Small open recirculating cooling systems (use 11.3)

ESD(s) used	Harmonisation of Environmental Emission Scenarios for biocides used as preservatives for liquid cooling systems (product type 11) (2003) EUSES 2.1 background report, chapter III model calculations
Approach	Scenario 11.1 – 11.3: Average consumption
Distribution in the environment	Calculated based on ECHA-Guidance (2017) BPR, Vol. IV, ENV – Part B+C. WGIII2020_ENV_8-3a_Harmonisation of assessment for PAA
Groundwater simulation	• no groundwater assessment for H_2O_2 is necessary according to the Technical Agreements for Biocides (TAB) – ENV, February 2021; ENV-208 and • no groundwater assessment for PAA and H_2O_2 is needed according to the agreed documents of WGIV2019_ENV_6-3_Harmonisation of UA cases_PAA and WGIII2020_ENV_8-3a_Harmonisation of assessment for PAA
Confidential annexes	No
Life cycle steps assessed	Scenario 11.1 – 11.3 Production: No Formulation: No Use: Yes Service life: No
Remarks	

Table 80: Intended uses in PT 12

Assessed PT	PT 12
Assessed scenarios	Scenario PT 12: Slimicide in the pulp and paper industry – continuous dosing
ESD(s) used	• Harmonisation of the Environmental Emission Scenarios for Slimicides (PT 12) (EUBEES, 2003) • Technical Agreements for Biocides (TAB) – ENV, February 2021; ENV-128 • Technical Agreements for Biocides (TAB) – ENV, February 2021; ENV-203
Approach	Scenario PT 12: average consumption
Distribution in the environment	Calculated based on ECHA-Guidance (2017) BPR, Vol. IV, ENV – Part B+C. WGIII2020_ENV_8-3a_Harmonisation of assessment for PAA
Groundwater simulation	• no groundwater assessment for H_2O_2 is necessary according to the Technical Agreements for Biocides (TAB) – ENV, February 2021; ENV-208 and • no groundwater assessment for PAA and H_2O_2 is needed according to the agreed documents of WGIV2019_ENV_6-3_Harmonisation of UA cases_PAA and WGIII2020_ENV_8-3a_Harmonisation of assessment for PAA
Confidential annexes	No
Life cycle steps assessed	Scenario PT 12: Production: No

	Formulation No Use: Yes Service life: No

In PT 11 for scenario 11.1 (once-through cooling systems) the in-use concentration of peracetic acid is given with 8.5-10 g/m^3, for scenario 11.2 (large open recirculating cooling systems) and scenario 11.3 (small open recirculating cooling systems) the in-use concentration of peracetic acid is given with 1-10 g/m^3. Cooling systems with a blowdown flow rate > 2 m^3/h are considered as large systems, whereas cooling systems with a flow rate ≤ 2 m^3/h are considered as small systems.
For the scenario PT 12 the in-use concentration of peracetic acid is given with 5-75 g/m^3.

The concentration of the equilibrium substance hydrogen peroxide varies in the Meta SPCs and depends on the specific use. The applicant has calculated for every Meta SPC the worst case H_2O_2/PAA ratio to deduce a worst case hydrogen peroxide in-use concentration which covers every PAA and H_2O_2 combination. The worst case H_2O_2/PAA-ratios are shown in the following table.

Table 81: Worst case H_2O_2/PAA – ratios for the assessed Meta SPCs

Meta SPC	Minimum PAA concentration [%; w/w]	Maximum H_2O_2 concentration [%; w/w]	Worst case H_2O_2/PAA - ratio	Remarks
1	1.70	48.4	28.5	This H_2O_2/PAA – ratio is used for calculations in PT 11 for use 11.1 and 11.3 for all Meta SPCs
2	3.80	30.7	8.08	This H_2O_2/PAA – ratio is used for calculations in PT 12 for Meta SPC 2 and 3.
3	15.0	23.3	1.55	This H_2O_2/PAA – ratio is used for calculations in PT 11 for use 11.2.

The resulting worst case in-use concentration of hydrogen peroxide for every intended use are deduced by multiplying the worst case H_2O_2/PAA – ratio with the use-specific peracetic acid in-use concentration. For PT 11 the ratio of Meta SPC 1 is the worst case ratio for the uses 11.1 once-through cooling systems and 11.3 small open recirculating cooling systems. Therefore, it is applied for the calculation of the in-use concentration of hydrogen peroxide for both scenarios. Since use 11.2 large open recirculating cooling systems is applied for only in Meta SPC 3, this ratio is used.
As for PT 12 only Meta SPCs 2-3 are of relevance, the worst case is represented by the ratio for Meta SPC 2.

The biocidal products of the Evonik BPF are liquid concentrates and must be diluted to the final in-use concentration. The density of the diluted solutions can be regarded equal to the density of water due to strong dilution and is assumed to be 1 mg/l at ambient temperature. Therefore, in diluted solutions, both units 1ppm (w/w) and 1 mg/l can be regarded as equivalent and used for calculations.
However, when calculating the preparation of the final application solution, the density of the individual biocidal product must be considered to achieve the required a.s. concentration of 10 ppm.
Since peracetic acid exists only as an equilibrium mixture of hydrogen peroxide, acetic acid, peracetic acid and water, the target peracetic acid concentration in the final biocidal product (chemical equilibrium state) can be achieved with various mixing ratios between both starting components. Therefore, for the environment assessment, the final in-use concentration in the different applications is applied to include all products of the BPF.

3.8.4.2 Fate and distribution in exposed environmental compartments

Parameters according to ARs (LoEP) of peracetic acid and hydrogen peroxide which describe the fate and distribution of PAA and H_2O_2 in the environment are summarised in the following table. The partitioning coefficients for the aquatic and terrestrial compartments, which are relevant for the environmental emission estimation and exposure assessment are based on these input values. Input parameters and PT depended rate constants, which have been harmonised at BPC WGIII2020_ENV_8-3a, are presented in Table 82 as well.

Table 82: Input parameters (only set values) for calculating the fate and distribution in the environment of peracetic acid and hydrogen peroxide

Input	PAA	H_2O_2	Unit	Remarks
Molecular weight	76.05	34.01	g/mol	
Vapour pressure at 20°C (Vapour pressure at 12°C)	1410 (793)	214 (120)	Pa	
Water solubility	1.0E+06	1.0E+06	mg/L	complete miscible; without temperature correction
pKa	8.24	---		
Log octanol/water partition coefficient	-0.6	-1.57	Log 10	
Organic carbon/water partition coefficient (Koc)	1.46	1.598	L/kg	
Henry's Law Constant	0.217 (at 25°C)	0.00075 (at 20°C)	Pa×m^3/mol	
Biodegradability	ready biodegradable	ready biodegradable		
Rate constant for STP	13.86 (DT_{50}=3 min) 9.28 (DT_{50}=4.48 min)	20.79 (DT50=2 min) 13.96 (DT50=2.98 min)	h^{-1} (at 20°C) h^{-1} (at 15°C)	

Input	PAA	H_2O_2	Unit	Remarks
	7.31 (DT_{50}=5.69 min)	10.97 (DT50=3.79 min)	h^{-1} (at 12°C)	
DT_{50} for biodegradation in surface water	---	5	d (at 12ºC)	Estimated (an extreme worst case DT_{50} estimate to take account for unfavourable conditions, i.e. oligotrophic cold waters with low microbial density and low transition metal concentration)
DT_{50} for hydrolysis in surface water	31.7 (89.7 (at 12°C))	---	h (at 25ºC, pH 7)	
DT_{50} for photolysis in surface water	---	---		
DT_{50} for biodegradation in seawater	2	---	min	
DT_{50} for degradation in soil	12	12	h	without temperature correction
DT_{50} for degradation in air	95.26	24	h	without temperature correction
PT depended rate constants:				
Rate constant in PT 11 for degradation during the cooling process for freshwater as cooling water (kdeg)	0.693 (DT50 = 1 h)	---	h^{-1}	Value from the CAR of PAA PT11, PT12 (FI, August 2016), measured DT50
Rate constant in PT 11 for degradation during the cooling process for seawater as cooling water (only use 11.1) ($kdeg_{SW}$)	20.8 (DT50 = 2 min)	--	h^{-1}	Value from the CAR of PAA PT11, PT12 (FI, August 2016)
Rate constant in the sewer system • for all PTs with indirect exposure of the environmental compartments via STP	4.38 (DT50 = 9.5 min)	3.65 (DT50 = 11.4 min)	h^{-1} (at 12°C)	#)
Rate constant in **PT 12** for: • kdeg1 (= degradation during paper making process) and • kdeg2 (= degradation during settling and during chemical/mechanical treatment)	kdeg1 = 0.525 (DT_{50} = 31.7 $h^{*)}$) kdeg2 = 199.626 (DT_{50} = 5 min)	kdeg1 = 11.215 (DT_{50} = 89 min) kdeg2 = 71.295 (DT_{50} = 14 min)	d^{-1}	*) value used at original test temperature

#) The amounts of peracetic acid and hydrogen peroxide that are actually emitted to the STP after one hour residence time in the sewer system (M_{t1}) was calculated assuming first order kinetic and using the following equation:

$$M_{t1} = M_{t0} * EXP^{(-k * t1)}$$

M_{t1} = total amount of substance present at t 1 [kg]
M_{t0} = total amount of substance at t 0 [kg] (= $Elocal_{water}$ in kg/d)
k = rate constant ($\ln 2/DT_{50}$)
t 1 = time [h] (= 1 h)

Following the Technical Agreements for Biocides (TAB) – ENV, February 2021; ENV-208 as well as the ENV WG-IV-2019 and WG-III-2020 (agreed documents of WGIV2019_ENV_6-3_Harmonisation of UA cases_PAA and WGIII2020_ENV_8-3a_Harmonisation of assessment for PAA) no groundwater assessment is needed for the rapidly reacting substances PAA and hydrogen peroxide.

Following the ENV WG-III-2020 (agreed document WGIII2020_ENV_8-3a_Harmonisation of assessment for PAA) the following distribution for peracetic acid and hydrogen peroxide in the STP was calculated by SimpleTreat 4.0 (Method 1).

Table 83: Calculated distribution in the STP

Compartment	Percentage [%]	
	PAA	H_2O_2
Air	0.0435	0.0002
Water	0.9903	0.6637
Sludge	0.0133	0.0145
Degraded in STP	98.95	99.32

For the a.s. peracetic acid and for the equilibrium substance evaluated like a SoC hydrogen peroxide a value below 0.1 % is estimated, respectively, for distribution into sewage sludge by SimpleTreat v. 4.0. Furthermore, due to the high reactivity of peracetic acid and hydrogen peroxide, and the high organic matter content of STP sludge, PAA and H_2O_2 are not expected to persist in relevant concentrations until the sludge is applied on agricultural land. Therefore, further environmental exposure via sludge application on agricultural land can be considered not relevant as it was done before in comparable national and union authorisations with PAA and H_2O_2. A quantitative assessment is not deemed necessary.

3.8.4.3 Foreseeable routes of entry into the environment on the basis of the use envisaged

The use of the products within the BPF results in exposure of the environment

- direct to aquatic compartments for PT 11 as well as indirect via STP/ industrial WWTP to freshwater/seawater and respective sediment for PT 11 and PT 12,
- indirect via deposition from atmosphere to the terrestrial compartment for PT 11,
- direct into the atmosphere by evaporation and drift from the cooling towers for PT 11.

Table 84: Identification of relevant receiving compartments based on exposure pathway*

	Surface water and sediment	Seawater and sediment	Wastewater (STP/WWTP)	Soil	Ground-water	Air
PT 11 - Scenario 11.1: Once-through cooling systems	Yes (direct)	Yes (direct)	No	Yes	not relevant	not relevant
PT 11 - Scenario 11.2: Large open recirculating cooling systems	Yes (direct)	not relevant	No	Yes	not relevant	not relevant
PT 11 - Scenario 11.3: Small open recirculating cooling systems	Yes (indirect)	not relevant	Yes	Yes	not relevant	not relevant
PT 12 - Scenario PT 12						
typical case	Yes (indirect)	No	Yes	not relevant	not relevant	not relevant
reasonable worst case	Yes (direct)	Yes (direct)	No	No	No	No

*"not relevant" means emissions are possible but for further assessment not relevant, No means no emissions

3.8.4.4 Local emission for relevant environmental compartments

Emission estimation PT 11: Preservatives for liquid-cooling and processing systems

The biocidal products of the BPF are used in various cooling water systems to reduce biofouling and its deleterious effects. The preservation of liquid cooling water in shock dosing regime is foreseen in the following technical systems:

- in once-through cooling systems (use 11.1), Meta SPC 1-3
- in large open recirculating cooling systems (use 11.2), Meta SPC 3 and
- in small open recirculating cooling systems (use 11.3), Meta SPC 1-3.

The ESD for PT 11 (EUBEES 2, 2003) supplies emission scenarios for all these uses and EUSES 2.1 background report, chapter III model calculations further supplements for the calculations.

Scenario 11.1: Once-through cooling systems

The application of the biocidal products takes place once a day per shock dosing direct into the cooling water stream with a highest target concentration for peracetic acid of 10 g PAA/m^3. According to the worst case ratio PAA/ H_2O_2 of 28.5 from Meta SPC 1 (see Table 81), the corresponding concentration of H_2O_2 results in 285 g H_2O_2/m^3. Usually, the water is pumped from a river, canal or lake, transported to the heat-exchange module and discharged after the flow as warmed-up water directly into surface or seawater. Therefore, also the path into the seawater has to be assessed.

Tier 1: The direct draining of the cooling water into the receiving water is evaluated. It is assumed that the cooling installation is located near the surface water/seawater, thus, no further degradation of peracetic acid or H_2O_2 during transport of the effluent water to surface water/seawater is taken into account. Complete mixing of the blowdown water in the adjacent surface water/seawater is assumed, whereas volatilisation, degradation and sedimentation are not considered in the local assessment.

Tier 2a: As the concentrations of PAA and H_2O_2 in the blowdown water in the tier 1 calculations resulting in unacceptable PEC/PNEC-ratios for direct release to surface water, a further treatment of the water is necessary. For this reason, PAA and H_2O_2 will be eliminated with an appropriate reducing agent as far as possible. Both substances, H_2O_2 and PAA, react quantitatively with various reducing agents. The treatment with sodium sulphite as reducing agent is described as Tier 2a. Before emission into the environment, H_2O_2 and PAA residues are captured by dosing of sodium sulphite (Na_2SO_3) into the discharged water stream. Sodium sulphite solution, which is commercially available, is dosed into the water cycle via a pump and is allowed to react there with the oxidative substances (PAA and H_2O_2). At the end of treatment with sodium sulphite a control measurement for the presence of residuals of H_2O_2 and PAA is necessary. This after-treatment procedure includes the following steps:

1) Measurement of the residual concentrations of PAA and H_2O_2 in the system.
2) Addition of sodium sulphite (Na_2SO_3)-solution:
   $Na_2SO_3 + H_2O_2 \Rightarrow Na_2SO_4 + H_2O$
   $Na_2SO_3 + CH_3COOOH \Rightarrow Na_2SO_4 + CH_3COOH$
3) After the addition of Na_2SO_3, a reaction time of at least 1 min should be given.
4) Before discharging the cooling water into the surface water/seawater, a control measurement of the residual amounts of H_2O_2 and PAA has to be carried out to verify the completeness of the biocide removal.

According to the applicant, the demonstration of the extent and completeness of the reaction of PAA and H_2O_2 with sodium sulphite (Na_2SO_3) as reducing agent is described as follows:

"The reducing agent will be dosed via pump into the cooling water cycle. After addition, both a.s. decompose rapidly and the reaction takes only a few minutes. As a proof of principle, the reduction of PAA and H_2O_2 was demonstrated in laboratory tests with deionized water and real life waste water samples from an Italian municipal sewage plant (Iuclid section 10.2; Report number: 2017-004). It could be demonstrated, that a quantitative reduction of PAA and H_2O_2 in effluent water (> 99.99%) was achieved after 35 seconds, which is below the response time of the amperometric sensor. In a second test, H_2O_2 was decomposed by the addition of catalase prior to testing. After the addition of sodium sulphite, the complete PAA decomposition took 40 seconds, which is also below the general response time of the used sensor. For a more realistic testing, treated wastewater from an Italian wastewater treatment plant was used. The quantitative reduction of a solution with a PAA content of 20 mg/L (H_2O_2: 30 mg/L) with sodium sulphite took ca. 15 seconds which demonstrated that the reaction is not affected by other substances in the wastewater. The reduction was ca. 99.95% for PAA (decrease from 18.4 mg/L to 0.01 mg/L) and 99.97% for H_2O_2 (decrease from 29.7 mg/L to 0.01 mg/L). In summary for all tests, the time needed for the complete reduction of PAA with sodium sulphite was shorter than the response time of the amperometric sensor (ca. 45 seconds). For this reason, the minimum response time of the sensor of 45 seconds can be considered as a worst case half-life for the reduction of PAA with 1.3 eq. sodium sulphite at room temperature. It is to be noted that the reaction time will presumably be significantly lower. **For the tier 2a refinement, an absolute substance elimination fraction of 99.95% for PAA and 99.97% for H_2O_2 is considered,** which was accordingly demonstrated in the laboratory tests. This is a realistic worst case assumption taking the fast reaction time into account."

German eCA accepted this proposed treatment as possibility for active substance reduction. Regarding the study, we were mindful that the information concerning the wastewater used in the last test was rather generalized, and its absence may hinder a comprehensive assessment of the reduction/degradation potential. Nevertheless, we perceive this omission as non-essential in this specific context. The evaluation should be understood rather as a standardized test, focusing on the quantification of the known redox reaction of peracetic acid with sodium sulphite over time, excluding also any influences from the wastewater, such as pH, DOC, ions, etc. This approach represents a worst-case scenario. The scientific validity of using sodium sulphite for peracetic acid degradation is supported by its redox properties, wherein sodium sulphite acts as a reducing agent by transferring electrons to the peracetic acid, a strong oxidizing agent. This electron transfer process leads to the reduction of peracetic acid into less reactive or harmless substances, such as acetic acid.
Hence, the decision to establish the minimum response time of the sensor at 45 seconds is highly conservative and incorporates an adequate safety margin, even though it is plausible that under more realistic conditions (e.g., wastewater conditions), this reduction could occur at a quicker rate. Therefore, we maintain the validity of the study and accept the proposed treatment as a potential measure for active substance reduction. This study should only be applicable to this specific biocidal product.
Sodium sulphite is also used as preservatives and antioxidants for food and its reducing properties prevent dried fruit from discoloring and preserved meats. Additionally, the ESD PT 11 mentions sodium sulphite as an oxygen scavenger used for cooling systems.
The REACH registration dossier mentions following information for sodium sulphite (CAS-number 7757-83-7)[8]:
Hydrolysis is not expected for sodium sulphite due to chemical properties. Photodegradation in water is not relevant for sodium sulphite because it dissociates quickly into ions (sodium, potassium and sulphite ions), is not susceptible to photolysis and decomposes in water. The substance is an inorganic compound and is not subject to biodegradation. Bioaccumulation is not expected because of the resulting strong anionic nature of the substance, as well as its rapid oxidative transformation to sulphates under physiological and environmental circumstances. A low log Kow underlines this statement. Relevant adsorption onto soils, sediments or suspended matter is not to be expected because of the anionic nature, chemical instability in the environment and rapid oxidation.

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[8] https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15131/5/2/3

According to information from the REACH registration dossier concerning the aquatic toxicology of sodium sulphite, it is indicated that the toxicity of sodium sulphite is orders of magnitude lower than the toxicity of PAA and H_2O_2.

As indicated by publicly available information, sodium sulphite is commonly used in surface water body and groundwater decontamination, as well as for removal of chlorine from process water and as corrosion inhibitor in water purification.

The REACH registration dossier for sodium sulphate (CAS-number 7757-82-6)[9] stated that studies concerning abiotic degradation, fate and behaviour in environment are scientifically not necessary. Sodium sulphate is generally regarded as non-toxic and is used in food industry as firming agent, acidity regulator and carrier substance. Sodium sulphate are approved in the EU as a food additive number E514 without maximum quantity restriction for foodstuffs. Additionally, it is used as a homeopathic medicine.

Due to the information cited above the eCA concluded that sodium sulphite and sodium sulphate are of minor relevance for the environmental exposure assessment.

Tier 2b: The concentrations of PAA and H_2O_2 discharged through the cooling towers and subsequently deposited to the soil result in unacceptable PEC/PNEC-ratios for soil in the Tier 1 calculations. Therefore, drift eliminators are used as risk mitigation measure to prevent the water droplets and mist from escaping the cooling tower. According to the Note “Environmental assessment of biocides in PT11 cooling water systems” endorsed at TM IV 2013, a drift reduction of factor 100 can be obtained by applying drift eliminators in cooling towers.

Figure 1 shows the schematic illustration of both mitigation measures as provided by the applicant, dosage points for sodium sulphite and the position of drift eliminators are marked with blue arrows.

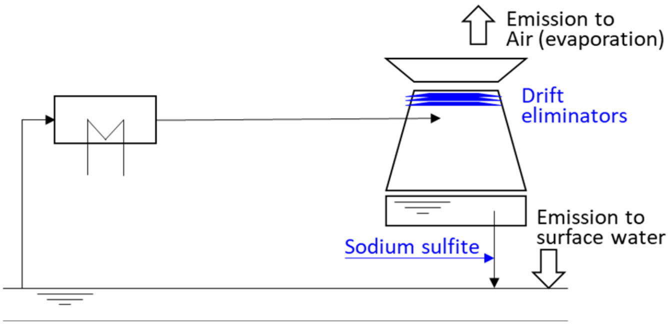

Figure 1: Preservation of cooling water in once-through cooling systems (use 11.1).

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[9] https://www.echa.europa.eu/web/guest/registration-dossier/-/registered-dossier/13138

The emission estimations are carried out according to ESD PT 11, EUSES 2.1 background report, chapter III model calculations and ECHA-Guidance (2017) BPR, Vol. IV, ENV - Part B+C. The necessary input parameters and the resulting output values are summarised in the following Table 85.

Table 85: Input and output values for local emissions of the scenario for once-through cooling systems, use 11.1

Parameters/variables	**Symbol**	**Value**		**Unit**	**Origin/Remarks**
		PAA	**H_2O_2**		
Input parameters for calculating the local emission for Scenario: Once-through cooling systems, use 11.1					
Nominal target concentration in cooling water (shock dosing)	Cproc	10	285	[g/m³]	S
Water volume in the system	Vsyst	6000		[m³]	D
Blowdown flow rate	Qbld	24000		[m³/h]	D
Recirculating cooling water flow rate	Qcirc	24000		[m³/h]	D
Dosing interval	Tint	24		[h]	S
Duration of dosing	tdose	0.25		[h]	S
Fraction evaporated + drift	Fevap_drift	0.01		[-]	D
Fraction deposited to soil	Fdepos	0.00025		[-]	D
Degradation rate constant freshwater	kdeg*	0.693	0	[h^{-1}]	peracetic acid kdeg* resulting from DT50 = 1 h
Degradation rate constant seawater	$kdeg_{sw}$	20.8	0	[h^{-1}]	peracetic acid $kdeg_{sw}$ resulting from DT50 = 2 min, value as used in the CAR and by the applicant
Soil surface where deposition occurs	AREAdepos	75000		[m²]	D
Number of cooling towers per site	N	2		[-]	D
Hydraulic retention time	HRT	14.85		[min]	O
Tier 2a: Fraction eliminated due to reduction with sodium sulphite	Felim	0.9995	0.9997	[-]	Tier 2a: treatment with reducing agent Na_2SO_3
Output: Once-through cooling systems: cooling water = freshwater, for PAA: DT50=1 h, kdeg=0.693 h^{-1}					
Release to water					
Concentration of a.i. in blowdown water	$Cbld_{fw}$	8.424	285	[mg/L]	
Tier 2a: Concentration of a.i. in blowdown water after treatment with reducing agent Na_2SO_3	$Cbld2_{fw}$	4.212E-03	8.55E-02	[mg/L]	Tier 2a: treatment with reducing agent Na_2SO_3
Release to air and soil					

Release to air = Elocal.air_event	RELEASEair$_{fw}$ Elocal.air_event	1.011	34.2	[kg/d]	
Tier 2b: Release to air by using of drift eliminators	RELEASEair2$_{sw}$	1.011E-02	0.342	[kg/d]	Tier 2b: Use of drift eliminators in the cooling towers
Dose of a.i. deposited to soil	DOSEpres$_{fw}$	3.369E-07	1.14 E-05	[kg/(m^2·d)]	
Tier 2b: Dose of a.i. deposited to soil by using of drift eliminators	DOSEpres2$_{fw}$	3.369E-09	1.14 E-07	[kg/(m^2·d)]	Tier 2b: Use of drift eliminators in the cooling towers
Output: Once-through cooling systems: cooling water = seawater, for PAA: DT50=2 min, kdeg$_{SW}$=20.8 h^{-1}					
Release to water					
Concentration of a.i. in blowdown water	Cbld$_{sw}$	0.058	285	[mg/L]	
Tier 2a: Concentration of a.i. in blowdown water after treatment with reducing agent Na_2SO_3	Cbld2$_{sw}$	2.904 E-05	8.55E-02	[mg/L]	Tier 2a: treatment with reducing agent Na_2SO_3
Release to air and soil					
Release to air	RELEASEair$_{sw}$	6.97E-03	34.2	[kg/d]	
Tier 2b: Release to air by using of drift eliminators	RELEASEair2$_{sw}$	6.97E-05	0.342	[kg/d]	Tier 2b: Use of drift eliminators in the cooling towers
Dose of a.i. deposited to soil	DOSEpres$_{sw}$	2.323E-09	1.14 E-05	[kg/(m^2·d)]	
Tier 2b: Dose of a.i. deposited to soil by using of drift eliminators	DOSEpres2$_{sw}$	2.323E-11	1.14 E-07	[kg/(m^2·d)]	Tier 2b: Use of drift eliminators in the cooling towers

* The applicant used the spontaneous abiotic decomposition in seawater (DT50 = 2 min, kdeg$_{SW}$ = 20.8 h^{-1}). Since the cooling water in the system could be surface water or seawater, eCA DE decided not to use this best value but rather to use the value DT50=1h (measured DT50-value, see CAR PAA, PT11, 12, (FI 2016), DocIIB, table 8.3-1) as a realistic worst case for degradation of PAA in surface water within the cooling process. Both approaches are presented in the PAR.

The concentration of the substance in blowdown water corresponds with the local emission concentration to water/seawater since direct discharge to surface and/or seawater occurs. Only the dilution in the receiving waters has to be considered for the calculation of the aquatic risk quotient.

As described in chapter 3.8.2.2 the risk assessment for freshwater/seawater is considered to cover the risks for sediment. Therefore, no emission values for the sediment have been derived.

Scenario 11.2: Large open recirculating liquid cooling systems

The application of the biocidal products takes place once a day per shock dosing direct into the cooling water stream with a highest target concentration for peracetic acid of 10 g PAA/m^3. According to the worst case ratio PAA/H_2O_2 of 1.55 from Meta SPC 3 (see Table 81) the corresponding concentration of H_2O_2 results in 15.5 g H_2O_2/m^3.

The exposure assessment for the use in large open-recirculating cooling systems typically considers direct discharge to surface water/seawater, where it is further diluted. Other processes will not be considered (see also description for scenario 11.1). In reality, the discharged water may be treated in various ways, mainly depending on the volume of blowdown water, the involvement of other industries and the underlying national legislations. Industrial cooling towers may discharge blowdown water to an on-site wastewater treatment plant.

For the products of the BPF, the applicant foresees only direct discharge to surface water/seawater and therefore only considers this in the exposure assessment for the large system. As for the once-through cooling systems, large open-recirculating cooling systems require treatment with a reducing agent (Tier 2a) and the use of drift eliminators (Tier 2b), as the PEC/PNEC ratios for surface water/seawater and soil are unacceptable in Tier 1. The respective approach is described in the previous section concerning Scenario 11.1. Figure 2 shows the schematic illustration of both mitigation measures as provided by the applicant, dosage points for sodium sulphite and the position of drift eliminators are marked with blue arrows.

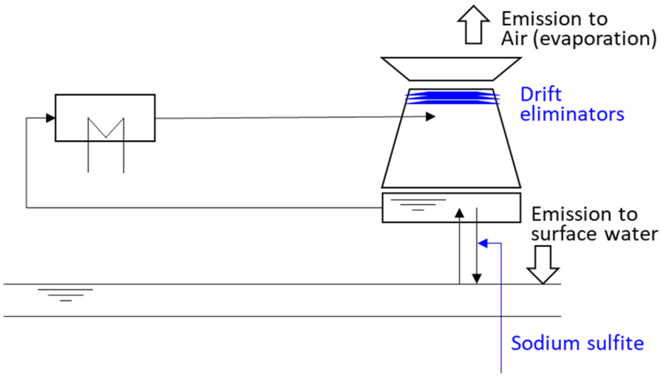

Figure 2: Preservation of cooling water in open recirculating cooling systems (large and small uses 11.2 and 11.3).

The emission estimations are carried out according to ESD PT 11, EUSES 2.1 background report, chapter III model calculations and ECHA-Guidance (2017) BPR, Vol. IV, ENV - Part B+C. The necessary input parameters and the resulting output values are summarised in the following Table 86.

Table 86: Input parameters and output values for local emissions of the scenario for large open recirculating liquid cooling systems, use 11.2

Parameters/variables	**Symbol**	**Value**		**Unit**	**Origin/Remarks**
		PAA	**H_2O_2**		
Input parameters for calculating the local emission for Scenario: **Large open recirculating liquid cooling systems, use 11.2**					
Nominal target concentration in cooling water (shock dosing)	Cproc	10	15.5	$[g/m^3]$	S
Water volume in the system	Vsyst	3000		$[m^3]$	D
Blowdown flow rate	Qbld	125		$[m^3/h]$	D
Recirculating cooling water flow rate	Qcirc	9000		$[m^3/h]$	D
Dosing interval	Tint	24		[h]	S
Duration of dosing	tdose	0.25		[h]	S
Fraction evaporated+drift	Fevap_drift	0.01		[-]	D
Fraction deposited to soil	Fdepos	0.00025		[-]	D
Degradation rate constant	kdeg*	0.693	0	$[h^{-1}]$	peracetic acid kdeg* resulting from DT50 = 1 h
Hydraulic retention time	HRT	0.581		[d]	S/O
Soil surface where deposition occurs	AREAdepos	75000		$[m^2]$	D
Number of cooling towers per site	N	2		[-]	D
Tier 2a: Fraction eliminated due to reduction with sodium sulphite	Felim	0.9995	0.9997	[%]	Tier 2a: treatment with reducing agent Na_2SO_3
Output					
Dissipation rate constant for whole system	Ksyst	0.765	0.072	$[h^{-1}]$	EUSES-Equation 311
Release to water					
Concentration of a. i. in blowdown water:	Cbld	1.071 E-07	2.776	[mg/L]	
Max. release after infinite time	RELEASEmax	3.269	54.07	[kg/d]	
Average concentration in blowdown water	Cbld_ave	0.545	9.012	[mg/L]	Cbld-ave is the concentration of the a.s./SoC averaged over 24 h after one shock dose. $\mathrm{Cbld\_ave} := \frac{\mathrm{RELEASE}_{\mathrm{max}}}{(\mathrm{N}\cdot\mathrm{Qbld}\cdot 1\mathrm{d})}$
Tier 2a: Average concentration in blowdown water	Cbld_ave2	2.725 E-04	2.703 E-03	[mg/L]	Cbld_ave2= Cbld_ave – (Cbld_ave x Felim)
Release to air and soil					
Release to air = Elocal.air_event	Elocal.air_event	39.32	66.96	[kg/d]	

Tier 2b: Release to air	RELEASEair2	0.393	0.67	[kg/d]	Use of drift eliminators
Dose of a.i. deposited to soil	DOSEpres	1.311 E-05	2.232 E-05	[kg/m^2·d]	
Tier 2b: Dose of a.i. deposited to soil	DOSEpres2	1.311 E-07	2.232 E-07	[kg/m^2·d]	Use of drift eliminators

* The applicant as well as the eCA used for the large open recirculating liquid cooling systems the value of DT50=1h (measured DT50-value, see CAR PAA, PT11, 12, (FI 2016), DocIIB, table 8.3-1) as realistic worst case for degradation of PAA in water within the cooling process.

The average concentration of the substance in blowdown water corresponds with the local emission concentration to water since direct discharge to surface and/or seawater occurs. Only the dilution in the receiving waters has to be considered for the calculation of the aquatic risk quotient.

As described in chapter 3.8.2.2 the risk assessment for freshwater/seawater is considered to cover the risks for sediment. Therefore, no emission values for the sediment have been derived.

Scenario 11.3: Small open recirculating liquid cooling systems

The application of the biocidal products takes places once a day per shock dosing direct into the cooling water stream with a highest target concentration for peracetic acid of 10 g PAA/m^3. According to the worst case ratio PAA/H_2O_2 of 28.5 from Meta SPC 1 (see Table 81) the corresponding concentration of H_2O_2 results in 285 g H_2O_2/m^3.

The blowdown water of a small system could be directly discharged to surface water but, usually, the released water is directed into a sewage treatment plant. The applicant only foresees the route via the sewage treatment plant, therefore, only the indirect discharge into the surface water is assessed here in the PAR. According to the harmonised decisions on ENV WG-III-2020 and the CAR of PAA for the indirect pathway, degradation of PAA and H_2O_2 in raw sewage is likely to occur. Half-live times were derived for PAA with < 9.5 min (12°C) and for H_2O_2 with 11.4 min (12°C) by a sewer residence time of 1 hour.

For the PEC-calculations for STP and surface water a partition coefficient solid-water in suspended matter of 0.937 L/kg is used for PAA and of 0.16 L/kg for H_2O_2. For the fractions to water and sludge see chapter 3.8.4.2, Table 83 distribution in the STP.

The emission estimations are carried out according to ESD PT 11, EUSES 2.1 background report, chapter III model calculations and ECHA-Guidance (2017) BPR, Vol. IV, ENV - Part B+C. The necessary input parameters and the resulting output values are summarised in the following Table 87.

Table 87: Input parameters and output values for local emissions of the scenario for small open recirculating liquid cooling systems, use 11.3, and resulting local PEC-values

Parameters/variables	Symbol	Value		Unit	Origin/Remarks
		PAA	H_2O_2		
Input parameters for calculating the local emission for Scenario: **Small open recirculating liquid cooling systems, use 11.3**					
Nominal target concentration in cooling water (shock dosing)	Cproc	10	285	[g/m³]	S
Water volume in the system	Vsyst	300		[m³]	D
Blowdown flow rate	Qbld	2		[m³/h]	D
Recirculating cooling water flow rate	Qcirc	100		[m³/h]	D
Dosing interval	Tint	24		[h]	S
Duration of dosing	tdose	0.25		[h]	S
Fraction evaporated+drift	Fevap_drift	0.01		[-]	D
Fraction deposited to soil	Fdepos	0.00025		[-]	D
Degradation rate constant	kdeg*	0.693	0	[h^{-1}]	peracetic acid kdeg* resulting from DT50 = 1 h
Soil surface where deposition occurs	AREAdepos	75000		[m^2]	D
Number of cooling towers	N	1		[-]	D
Degradation rate constant in sewer system before reaching the STP	ksewer	4.378	3.65	[h^{-1}]	PAA: DT50sewer = 9.5 min H_2O_2: DT50sewer = 11.4 min Tsewer = 1 h (harmonised on WGIII2020_ENV_8-3a)
Output					
Hydraulic retention time	HRT	100	100	[h]	EUSES-Equation 310
Dissipation rate constant for whole system	Ksyst	0.703	0.01	[h^{-1}]	EUSES-Equation 311
Concentration of a. i. in blowdown water after dosing:	$Cbld_T$	9.171	284.6	[mg/L]	EUSES-Equation 314
Release to water after dosing	RELEASEshockT	4.585E-03	0.142	[kg]	
Release after sewer considering degradation in sewer	RELEASEafter_sewerT	5.756 E-05	3.706 E-03	[kg]	RELEASEafter_sewerT = RELEASEshockT · $e^{-(ksewer \cdot tsewer)}$
Emission into STP after sewer	Elocal.water_after_sewerT	5.526E-03	0.356	[kg/d]	EUSES-Equation 321
Indirect release to water (pathway via STP)					
STP influent concentration	$Clocal_{inf}$	2.763 E-03	0.178	[mg/L]	
STP effluent concentration	$Clocal_{eff}$	2.763 E-05	1.181 E-03	[mg/L]	
Conc. in the STP for evaluation of inhibition to microorganisms	**PEC_{STP}**	**2.763 E-05**	**1.181 E-03**	**[mg/L]**	

local concentration in surface water = PEClocal_water	Clocal_water = **PEClocal_water**	**2.763 E-06**	**1.181 E-04**	**[mg/L]**	
Release to air and soil					
Release to air = Elocal.air_event	RELEASEair	0.22	6.84	[kg/d]	EUSES-Equation 340, respective 338
Release to air, Tier 2b	RELEASEair2	2.2 E-03	0.068	[kg/d]	Use of drift eliminators
Dose of a.s. deposited to soil	DOSEpres	7.336 E-08	2.28 E-06	[kg/m^2·d]	EUSES-Equation 341, respective 339
Dose of a.i. deposited to soil, Tier 2b	DOSEpres	7.336 E-10	2.28 E-08	[kg/m^2·d]	Use of drift eliminators

* The applicant as well as the eCA used for the small open recirculating liquid cooling systems the value of DT50=1h (measured DT50-value, see CAR PAA, PT11, 12, (FI 2016), DocIIB, table 8.3-1) as realistic worst case for degradation of PAA in water within the cooling process.

For the small system, only the indirect pathway via sewage treatment plant into the surface water is considered. Since seawater as receiving compartment is rather unlikely. Moreover, there are no PNECs for seawater and the assessment is performed by a generic derivation by a factor of 10 from PNECwater to PNECseawater, and PECseawater is also derived by a factor of 10 from PECwater, the resulting risk quotient for seawater is the same as for PNECwater. The exposure estimation is made according to equations 35 ff., ECHA-Guidance (2017) BPR, Vol. IV, ENV – Part B+C.

As described in chapter 3.8.2.2 the risk assessment for freshwater is considered to cover the risks for sediment. Therefore, no emission values for the sediment have been derived.

Furthermore, see explanations in chapter 3.8.4.2, environmental exposure via sludge application on agricultural land can be assumed as not relevant. In contrast, the release to soil by deposition of the substances from air has to be considered.

Emission estimation – PT 12: Slimicides – Slimicide in the pulp and paper industry

For the use of slimicides in paper production processes the ESD for PT 12 (EUBEES, 2003) provides emission scenarios for continuous or shock dosing regimes, but only continuous dosing is supported by the applicant. The Technical Agreements for Biocides (TAB) – ENV, February 2021 provides revised formulas for the ESD PT 12 in entry ENV-203 concerning the hydraulic retention times. Doc II-B of the peracetic acid CAR for PT11 & PT12 (2016, CA FI) differentiates three cases, partly in compliance with the ESD:

- **Case A:** **Typical case** (in compliance with the ESD)
  - only hydrolytic degradation during paper making process and primary settling is assumed
  - discharge via industrial WWTP (capacity of 5000 m³/d)

- **Case B1:** **Typical case** (not in compliance with the ESD regarding degradation)
  - consideration of a refined degradation during primary settling

    - discharge via industrial WWTP (capacity of 5000 m³/d)

- **Case B2: reasonable worst case** (in compliance with the ESD)
    - refined degradation during primary settling is assumed
    - further degradation during an on-site chemical and mechanical treatment is assumed
    - direct emission to surface water

According to ESD for PT 12 there is a strong link between the choice of the scenario case (reasonable worst case or typical case) and the values of the parameter APPL (Treatment of long and short circulation part) and CONN (Connection to pulp mill). Therefore, regarding the scenario case arbitrary combinations of the values for APPL and CONN for the environmental emission estimation in PT 12 are not foreseen.

Considering Case B2, the treated water is discharged into surface water with a certain dilution factor. According to ENV-128 of the Technical Agreements for Biocides (TAB) – ENV, February 2021 the document “Note: Environmental assessment of biocides in PT11 cooling water systems” (endorsed at TM IV 2013) is also applicable to derive dilution factors for PT 12. For the current calculations two dilution factors were used: since it can be assumed that paper plants are typically located adjacent to rivers with large flow rates a dilution factor of 1000 and as worst case to rivers with small flow rates a dilution factor of 10.

Note: At renewal stage it is required that the exposure assessment should be done according to all available and agreed decisions in PT 12 which are reached in the meantime.

Scenario PT 12: Slimicide in the in the pulp and paper industry – continuous dosing

Table 88: Input and output values for local emissions of scenario PT 12 and resulting local PEC-values

Parameters/variables	Symbol	Value		Unit	Origin
		PAA	H_2O_2		
Input					
In-use concentration	C_{prod}	75	606	$[g/m^3]$	S (according SPC: 75 ppm PAA)
Treatment of both long and short circulation with slimicide	APPL	yes		[-]	Typical case → Case A and Case B1
Slimicide bearing fraction of the total wastewater flow coming from the short circulation of the wire part	F_{ww1}	0.6		[-]	
Connection to pulp mill	CONN	yes		[-]	
Fraction dilution of slimicide-free wastewater with wastewater from pulping	F_{ww2}	0.5		[-]	
Treatment of both long and short circulation with slimicide	APPL	no		[-]	Reasonable worst case → Case B2
Slimicide bearing fraction of the total wastewater flow coming from the short circulation of the wire part	F_{ww1}	1		[-]	
Connection to pulp mill	CONN	no		[-]	
Fraction dilution of slimicide-free wastewater with wastewater from pulping	F_{ww2}	0		[-]	
Total fraction of the slimicide lost in the dry end of the papermaking machine	$F_{total\ loss,paper}$	0.1		[-]	D
Effluent discharge of WWTP for paper plant	$EFFLUENT_{WWTP}$	5000		$[m^3/d]$	D
Half-life for degradation during paper production process	kdeg1	0.525	11.215	$[d^{-1}]$	agreed document WGIII2020_ENV_8-3a
Half-life for degradation during settling	kdeg2	199.626	71.295	$[d^{-1}]$	
Half-life for degradation during chemical/mechanical water treatment					

Hydraulic retention time for paper making process	Tpr	0.167		[d]	D
Hydraulic retention time for primary settling	Tps	0.167		[d]	D
Hydraulic retention time for chemical/mechanical treatment	Tcm	0.167		[d]	D
Dilution factor in receiving surface water (small flow rate river)	DIL_{SW_small}	10		[-]	TAB – ENV (Feb. 2021), ENV-128
Dilution factor in receiving surface water (large flow rate river)	DIL_{SW_large}	1000		[-]	TAB – ENV (Feb. 2021), ENV-128
Dilution factor at discharge into coastal waters	DIL_{CW}	100		[-]	D
Output					
Theoretical concentration (i.e. assuming no degradation) before wastewater treatment – Typical case	$C_{paper\_typical\ case}$	20.25	163.62	[g/m³]	O
Theoretical concentration (i.e. assuming no degradation) before wastewater treatment – Reasonable worst case	$C_{paper\_worst\ case}$	67.5	545.4	[g/m³]	O
Case A					
Concentration in influent to WWTP *(without degradation in primary settler)*	$Clocal_{infl\_WWTP\_A}$	16.99	3.86	[mg/L]	O
Local emission to wastewater (*without degradation*)	**$Elocal_{water}$**	**84.97**	**19.32**	[kg/d]	O
Case B1					
Concentration in influent to WWTP *(with degradation in primary settler)*	$Clocal_{infl\_WWTP\_B}$	6.17E-14	1.70E-04	[mg/L]	O
Local emission to wastewater (*with degradation*)	**$Elocal_{water\_deg}$**	**3.08E-13**	**8.48E-04**	[kg/d]	O
Case B2					
Concentration in influent to the primary settler	C_{infl_ps}	62.06	189.84	[mg/L]	O
Concentration in effluent of water treatment system *(after chemical/mechanical treatment, with degradation)*	$Clocal_{effl\_treat}$	6.86E-28	8.64E-9	[mg/L]	O

Local concentration in receiving surface water for small rivers	**PEClocal$_{sw\_small\_deg}$**	**6.86E-29**	**8.64E-10**	[mg/L]	O
Local concentration in receiving surface water for large rivers	**PEClocal$_{sw\_large\_deg}$**	**6.86E-31**	**8.64E-12**	[mg/L]	O
Local concentration in receiving coastal water	**PEClocal$_{cw\_deg}$**	**6.86E-30**	**8.64E-11**	[mg/L]	O

Model Calculations

General:

$$C_{paper} := C_{prod} \cdot F_{ww1} \left(1 - F_{ww2}\right) \cdot \left(1 - F_{total\_loss\_paper}\right)$$

Case A:

$$Clocal_{infl\_WWTP\_A} := C_{paper\_typical} \cdot \left[\left(1 - F_{ads\_settling}\right) \cdot \exp[-kdeg1(Tpr + Tps)]\right]$$

$$Elocal_{water} := \frac{Clocal_{infl\_WWTP\_A} \cdot EFFLUENT_{WWTP}}{1000}$$

Case B1:

$$Clocal_{infl\_WWTP\_B1} := C_{paper\_typical} \cdot \left[\left(1 - F_{ads\_settling}\right) \cdot (\exp(-kdeg1 \cdot Tpr) \cdot \exp(-kdeg2 \cdot Tps))\right]$$

$$Elocal_{water\_deg} := \frac{Clocal_{infl\_WWTP\_B1} \cdot EFFLUENT_{WWTP}}{1000}$$

Case B2:

$$C_{infl\_ps} := \frac{C_{paper\_worst}}{(1 + kdeg1 \cdot Tpr)}$$

$$Clocal_{effl\_treat} := C_{infl\_ps} \cdot \left(1 - F_{ads\_settling} - F_{ads\_cm}\right) \cdot \exp[-kdeg2 \cdot (Tps + Tcm)]$$

$$PEClocal_{sw\_small\_deg} := \frac{Clocal_{effl\_treat}}{DIL_{sw\_small}}$$

$$PEClocal_{sw\_large\_deg} := \frac{Clocal_{effl\_treat}}{DIL_{sw\_large}}$$

$$PEClocal_{cw\_deg} := \frac{Clocal_{effl\_treat}}{DIL_{cw}}$$

3.8.4.5 Calculated PEC values

Aquatic compartment

PT 11 Direct and indirect emissions to surface water/ seawater

Once-through cooling systems (use 11.1) and large open recirculating cooling systems (use 11.2) are emitting the blowdown water directly to either surface water or seawater. Discharge into a sewage treatment plant is unrealistic due to the high amounts of water released. Direct emission to surface water/seawater is also possible for small open recirculating cooling systems (use 11.3), but is unlikely and is not assessed in the PAR. Only for small open recirculating cooling systems the usual release pathway leads over a municipal sewage treatment plant. For this indirect pathway via STP the emission estimation and PEC-calculation are made according to equations 35 ff., ECHA-Guidance (2017) BPR, Vol. IV, ENV – Part B+C.

It is assumed that the cooling installation or the STP is located close to the surface water/seawater, so that no further degradation of the substances is taken into account when transporting the released cooling water to the surface water/seawater. After direct emission, complete mixing of the blowdown water with the adjacent water is assumed, whereas volatilisation, degradation and sedimentation are not considered in the local assessment. According to “Note: Environmental assessment of biocides in PT11 cooling water systems (TM IV, 2013)” (endorsed at TM IV 2013) several dilution factors for the systems were derived depending on the receiving river size (discharge):

- Once-through cooling systems: dilution factor 10 and 50
- large open recirculating cooling systems: dilution factor 10, 200 and 1000
- small open recirculating cooling systems: dilution factor 350 and 1000 by direct emission, but this pathway is not foreseen by the applicant and is not assessed here in the PAR.

For seawater the used dilution factor is 100 according to ECHA-Guidance (2017) BPR, Vol. IV, ENV – Part B+C, chapter 2.6.5.2.

In the absence of ecological data for sediment-dwelling organisms PNEC for sediment is calculated using equilibrium partitioning method from PNEC for water. As $PEC_{local\_sediment}$ is also derived by using equilibrium partitioning method from PEC_{local_water} the risk assessment for surface water and sediment will be equal. Thus, $PEC_{local\_sediment}$ according to equation 53, chapter 2.3.7.4, Guidance on the BPR, Vol. IV, Part B+C (2017) has not been summarised in the following table.

Table 89: Summary table on calculated PEC values for direct/indirect emissions to aquatic compartment

	a.s.	conc. in blowdown water	PEC_{water}	PEC_{water}	PEC_{water}	PEC_{water}	$PEC_{seawater}$	PEC_{STP}
		[mg/L]	[mg/L]	[mg/L]	[mg/L]	[mg/L]	[mg/L]	[mg/L]
Dilution factor			10	50	200	1000	100	
Once-through cooling systems*	PAA	8.424	0.842	0.168	--	--	0.084	--
	H_2O_2	285	28.5	5.7	--	--	2.85	--
Once-through cooling systems* Tier 2a	PAA	4.212 E-03	4.212E-04	8.424E-05	--	--	4.212E-05	--
	H_2O_2	8,55 E-02	8.55E-03	0.171E-03	--	--	8.55E-04	--
Once-through cooling systems**	PAA	0.058	5.8 E-03	1.16 E-03	--	--	5.8 E-04	--
	H_2O_2	285	28.5	5.7	--	--	2.85	--
Once-through cooling systems** Tier 2a	PAA	2.904 E-05	2.904 E-06	5.808 E-07	--	--	2.904 E-07	--
	H_2O_2	8,55 E-02	8.55E-03	0.171E-03	--	--	8.55E-04	--
large open recirculating systems	PAA	0.545	0.055	--	2.725E-03	5.45E-04	5.45E-03	--
	H_2O_2	9.012	0.901	--	4.506 E-02	9.012 E-03	9.012 E-02	--
large open recirculating systems Tier 2a	PAA	2.724E-04	2.724E-05	--	1.362E-06	2.724E-07	2.724E-06	--
	H_2O_2	2.703 E-03	2.703 E-04	--	1.352 E-05	2.703 E-06	2.703 E-05	--
Small open recirculating system via STP	PAA	9.171	2.736 E-06	--	--	--		2.736 E-05
	H_2O_2	284.6	1.181E-04	--	--	--		1.181E-03

*blowdown water = freshwater, representing the worst case
**blowdown water = seawater

PT 12 Indirect emissions to surface water (A and B1) and direct emissions (B2)

In the Typical Case (A and B1) the treated water is discharged to surface water via an industrial WWTP with a capacity of 5000 m^3/d. For this indirect pathway into the environment via industrial WWTP the respective PEC-calculations are made according to equations 35 ff., ECHA-Guidance (2017) BPR, Vol. IV, ENV – Part B+C.

As continuous release of waste water is assumed to the industrial WWTP, the effluent concentration is representative for the exposure of microorganisms in WWTP. Thus, PEC_{WWTP} (= $Clocal_{eff}$) is calculated according to equation 41, chapter 2.3.6.7, Guidance on the BPR, Vol. IV, Part B+C (2017). The estimation of the local PECs for the aquatic compartment includes PECs for surface water and sediment.

$PEC_{local\_surfacewater}$ has been calculated according to equation 51, chapter 2.3.8.3, Guidance on the BPR, Vol. IV, Part B+C (2017). As the PNEC values for sediment were calculated by the equilibrium partitioning method, the risk assessment results for surface water and sediment are equal. Thus, $PEC_{local\_sediment\_surfacewater}$ according to equation 53, chapter 2.3.7.4, Guidance on the BPR, Vol. IV, Part B+C (2017) has not been summarised in the following table.

For the reasonable worst case (Case B2) a direct pathway into the environment is foreseen. Only the worst case PECs of receiving surface water for small rivers are presented in the following table and used for the further environmental risk assessment.

$PEC_{local\_seawater}$ has been calculated according to chapter 3.8.4.4, Emission estimation – PT 12. As the PNEC values for seasediment were calculated by the equilibrium partitioning method, the risk assessment results for seawater and seasediment are equal. Thus, $PEC_{local\_seasediment\_seawater}$ according to equation 87, chapter 2.6.5.3, Guidance on the BPR, Vol. IV, Part B+C (2017) has not been summarised in the following table.

Table 90: Summary table on calculated PEC values for emissions to water

			PEC_{WWTP}	$PEC_{freshwater}$	$PEC_{seawater}$
			[mg/L]	**[mg/L]**	**[mg/L]**
Scenario PT 12 Typical case (Case A and B1) and Reasonable worst case (Case B2)	PAA	Case A	1.68E-01	1.68E-02	---
		Case B1	6.11E-16	6.11E-17	---
		Case B2	---	6.86E-29	6.86E-30
	H_2O_2	Case A	2.57E-02	2.57E-03	---
		Case B1	1.13E-06	1.13E-07	---
		Case B2	---	8.64E-10	8.64E-11

Terrestrial compartment

PT 11 Emissions into the terrestrial environment

For all three systems in PT11, direct emissions to soil may occur by deposition from air due to evaporation and drift of cooling water from the cooling towers.
In Tier 2b, the use of drift eliminators is envisaged as a refinement to reduce emissions to the ground. The use of drift eliminators is state of the art, leads to drift reduction and is acceptable, therefore. According to the Note “Environmental assessment of biocides in PT11 cooling water systems” endorsed at TM IV 2013, a drift reduction of factor 100 can be obtained by applying drift eliminators in cooling towers.
PEC-values are calculated according to Guidance on the BPR, Vol. IV, Part B+C (2017) and to the just mentioned note and summarised in Table 91.

Table 91: Summary table on calculated PEC values for indirect emissions to soil via deposition from air

		PECsoil
		[mg/kg ww]
Once-through cooling systems*	PAA	6.887 E-04
	H_2O_2	0.024

Once-through cooling systems with use of drift eliminators (Tier 2b)*	PAA	6.887 E-06
	H_2O_2	2.4 E-04
Once-through cooling systems**	PAA	4.749 E-06
	H_2O_2	0.024
Once-through cooling systems with use of drift eliminators (Tier 2b)**	PAA	4.749 E-08
	H_2O_2	2.4 E-04
large open recirculating systems	PAA	2.68 E-02
	H_2O_2	0.047
large open recirculating systems with use of drift eliminators (Tier 2b)	PAA	2.68 E-04
	H_2O_2	4.7 E-04
small open recirculating systems	PAA	1.5 E-04
	H_2O_2	4.803 E-03
small open recirculating systems with use of drift eliminators (Tier 2b)	PAA	1.5 E-06
	H_2O_2	4.803 E-05

*blowdown water = freshwater, representing the worst case
**blowdown water = seawater

For the small open recirculating cooling system indirect emission of soil via sewer sludge may occur but according to the explanations in chapter 3.8.4.2 no local PECs for the terrestrial compartment over this pathway (includes PECs for soil and groundwater) were estimated.

PT 12 Emissions to the terrestrial compartment

Indirect emission to soil via sewage sludge may occur but according to the explanations in chapter 3.8.4.2 no local PECs for the terrestrial compartment over this pathway (includes PECs for soil and groundwater) were estimated.

Groundwater

PT 11 and PT 12 Emissions to groundwater

As described in chapter 3.8.4.2 no groundwater assessment is necessary for peracetic acid and hydrogen peroxide and thus, no data are presented here.

Atmosphere

PT 11

For uses in PT 11 emissions to air of PAA and H_2O_2 occur by evaporation and drift of cooling water from the cooling towers.

According to CAR DocII-B of H_2O_2 (PT 11 & 12, Oct 2017, p. 34) traces of hydrogen peroxide may be present in water droplets formed in cooling towers, even if hydrogen peroxide is decomposed under the elevated temperatures and on the large internal surfaces of cooling towers, during the passage of water droplets through the tower. Evaporation of water remains at the same level, independent of the fact that hydrogen peroxide will not evaporate.

In addition, drift eliminators are used to further increase the internal surface area of the cooling towers and disrupt the airflow. This results in increased separation of water droplets and thus reduces the amount of water droplets and mist discharged from the cooling towers. This can further reduce the impact of PAA and H_2O_2 on the surrounding environment.

Moreover, due to the low measured Henry's Law constant of both substances air is not considered as an environmental compartment of concern.
For the sake of completeness, the calculated PECair-values are given in Table 92.

Table 92: Summary table on calculated PEC values for emissions into air

		PECair
		[mg/m^3]
Once-through cooling systems*	PAA	1.694E-04
	H_2O_2	5.731E-03
Once-through cooling systems with use of drift eliminators (Tier 2b)*	PAA	1.694E-06
	H_2O_2	5.731E-05
Once-through cooling systems**	PAA	1.168 E-06
	H_2O_2	5.731E-03
Once-through cooling systems with use of drift eliminators (Tier 2b)**	PAA	1.168 E-08
	H_2O_2	5.731E-05
large open recirculating systems	PAA	6.589 E-03
	H_2O_2	0.011
large open recirculating systems with use of drift eliminators (Tier 2b)	PAA	6.589 E-05
	H_2O_2	1.1 E-04
small open recirculating systems	PAA	3.686 E-05
	H_2O_2	1.146 E-03
small open recirculating systems with use of drift eliminators (Tier 2b)	PAA	3.686 E-07
	H_2O_2	1.146 E-05

*blowdown water = freshwater, representing the worst case
**blowdown water = seawater

Peracetic acid and hydrogen peroxide might reach the air compartment also by volatilisation from the sewage treatment plant. However, it is not necessary to consider their distribution in the air from STP because the fraction of volatilisation is less than 0.1 % (see chapter 3.8.4.2).

PT 12

Direct release to the atmosphere from the paper mill is not considered relevant according to ESD PT 12.

3.8.4.6 Non-compartment specific effects

- **Primary poisoning**

Not relevant.

- **Secondary poisoning**

Due to the hydrophilicity, negligible bioconcentration potential and rapid dissipation behaviour of the active substance peracetic acid and the equilibrium substance evaluated as SoC hydrogen peroxid, the risk of secondary poisoning is considered negligible in the aquatic and terrestrial compartment.

3.8.4.7 Aggregated exposure (combined for relevant emission sources)

An agreed guidance document for aggregated exposure assessment is not available, yet. Therefore, such an assessment was not conducted.

3.8.5 Risk characterisation

3.8.5.1 Aquatic compartment

- **Surface water/ seawater**

The PEC/PNEC values for surface water and seawater for the active substance PAA and the equilibrium substance evaluated as SoC H_2O_2 are given in the table below, as well as the summation for mixture toxicity assessment.

There are no PNECs for seawater and the assessment is performed by a generic derivation by a factor of 10 from PNECwater to PNECseawater, and PECseawater is also derived by a factor of 10 from PECwater, the resulting risk quotient for seawater is the same than for PNECwater. For the sake of completeness the quotient is nevertheless included in the following table.

A separate risk assessment for sediment is not necessary, as adsorption potential of both substances is very low, PAA and H_2O_2 were shown to degrade rapidly and the risk assessment for surface water and seawater is considered to cover the risks for sediment, respectively.

PT 11

Table 93: Summary table on calculated PEC/PNEC values for aquatic compartment for preservatives for liquid-cooling and processing systems (PT 11 scenarios)

Summary table on calculated PEC/PNEC values			
Scenario	**PEC/PNEC$_{water}$**		
Direct emissions to water			
	PAA	**H_2O_2**	**PAA + H_2O_2**

Once-through cooling systems: cooling water = freshwater, for PAA: DT50=1 h, kdeg=0.693 h^{-1}			
Scenario 11.1. Once-through cooling systems - Shock dosing - Dilution factor 10 – Tier 1 - Freshwater	**12209**	**2262**	**14471**
Scenario 11.1. Once-through cooling systems - Shock dosing - Dilution factor 50 – Tier 1 - Freshwater	**2442**	**452.4**	**2894**
Scenario 11.1. Once-through cooling systems - Shock dosing - Dilution factor 100 – Tier 1 – Seawater	**12209**	**2262**	**14471**
Scenario 11.1. Once-through cooling systems - Shock dosing - Dilution factor 10 – Tier 2a - Freshwater	**6.104**	0.679	**6.783**
Scenario 11.1. Once-through cooling systems - Shock dosing - Dilution factor 50 – Tier 2a - Freshwater	**1.221**	0.136	**1.357**
Scenario 11.1. Once-through cooling systems - Shock dosing - Dilution factor 100 – Tier 2a – Seawater	**6.104**	0.679	**6.7837**
Once-through cooling systems: cooling water = seawater, for PAA: DT50=2 min, $kdeg_{SW}$=20.8 h^{-1}			
Scenario 11.1. Once-through cooling systems - Shock dosing - Dilution factor 10 – Tier 1 - Freshwater	**84.06**	**2262**	**2346**
Scenario 11.1. Once-through cooling systems - Shock dosing - Dilution factor 50 – Tier 1 - Freshwater	**16.81**	**452.4**	**469.2**
Scenario 11.1. Once-through cooling systems - Shock dosing - Dilution factor 100 – Tier 1 – Seawater	**84.06**	**2262**	**2346**
Scenario 11.1. Once-through cooling systems - Shock dosing - Dilution factor 10 – Tier 2a - Freshwater	0.042	0.679	0.721
Scenario 11.1. Once-through cooling systems - Shock dosing - Dilution factor 50 – Tier 2a - Freshwater	8.417 E-03	0.136	0.144
Scenario 11.1. Once-through cooling systems - Shock dosing - Dilution factor 100 – Tier 2a – Seawater	0.042	0.683	0.725
Large open recirculating cooling systems			
Scenario 11.2: Large open recirculating cooling systems - Shock dosing - Dilution factor 10 – Tier 1	**789.9**	**71.52**	**861.4**
Scenario 11.2: Large open recirculating cooling systems - Shock dosing - Dilution factor 200 – Tier 1	**39.49**	**3.58**	**43.07**
Scenario 11.2: Large open recirculating cooling systems - Shock dosing - Dilution factor 1000 – Tier 1	**7.9**	**0.715**	**8.614**
Scenario 11.2: Large open recirculating cooling systems - Dilution factor 100 – Tier 1 – Seawater	**789.9**	**71.52**	**861.4**
Scenario 11.2: Large open recirculating cooling systems - Shock dosing - Dilution factor 10 – Tier 2a	0.395	0.021	0.416
Scenario 11.2: Large open recirculating cooling systems - Shock dosing - Dilution factor 200 – Tier 2a	0.019	1.073 E-03	0.021
Scenario 11.2: Large open recirculating cooling systems - Shock dosing - Dilution factor 1000 – Tier 2a	3.948 E-03	2.145 E-04	4.162 E-03

Scenario 11.2: Large open recirculating cooling systems - Dilution factor 100 – Tier 2a – Seawater	0.395	0.210	0.416
Indirect emissions to water via STP (small open recirculating cooling systems)			
Scenario 11.3: Small open recirculating cooling systems - Shock dosing - path over the STP	3.965E-02	9.373E-03	0.049

Bold numbers indicate an unacceptable risk to the compartment

PT 12

According to chapter 3.8.4.5 for the scenario PT 12 - reasonable worst case (Case B2), only the lowest dilution (DIL=10, representing the worst case) has been used for the environmental risk assessment for the compartment freshwater.

Table 94: Summary table on calculated PEC/PNEC values for freshwater in scenario PT 12

		$PEC/PNEC_{fresh\text{-}water}$ PAA	**$PEC/PNEC_{fresh\text{-}water}$ H_2O_2**	**Σ $PEC/PNEC_{fresh\text{-}water}$**
Typical case (Case A and B1) and Reasonable worst case (Case B2)	Case A	**243.91**	0.20	**244.12**
	Case B1	<0.01	<0.01	<0.01
	Case B2	<0.01	<0.01	<0.01

Bold numbers indicate an unacceptable risk to the compartment

Only relevant case B2 is presented in the following table concerning the environmental risk assessment for the compartment seawater.

Table 95: Summary table on calculated PEC/PNEC values for seawater in scenario PT 12

		$PEC/PNEC_{seawater}$ PAA	**$PEC/PNEC_{seawater}$ H_2O_2**	**Σ $PEC/PNEC_{seawater}$**
Reasonable worst case (Case B2)	Case B2	<0.01	<0.01	<0.01

Conclusion

PT 11

Tier 1: For direct emissions to surface water or seawater unacceptable risks result from both scenarios assessed (scenario 11.1 once-through cooling system and 11.2 large open recirculating cooling system).

No unacceptable risk results from indirect emissions via STP as a realistic pathway for the small open recirculating cooling system.

Tier 2a: Taking the result of Tier 1 into account, a treatment with the reducing agent sodium sulphite is necessary for use 11.1 and 11.2 before the blowdown water is released.

For the **large open recirculating cooling system**, this treatment leads to no unacceptable risks at all relevant dilutions for both surface water and seawater.

For **once-through cooling systems**, the results are presented for plant operating with freshwater as well as with seawater. The applicant has only provided an assessment for operation with seawater, as it was also done in the CAR. Germany cannot agree with this one-sided view, as the majority of cooling plants are not operated at the sea, but on large rivers. Therefore, in our view, the half-life of freshwater should be applied additionally.

When operating with freshwater, no acceptable risk could be achieved.

When operating with seawater, no unacceptable risk is achieved at all relevant dilutions.

PT 12

No unacceptable risks were identified for the aquatic compartment (surface water) for the assessed scenario PT 12 (Case B1 and B2, respectively) regarding the use of biocidal products from the BPF. Case A leads to unacceptable risk for the compartment (surface water) for PAA. However, according to Doc II-B of the peracetic acid CAR for PT11 & PT12 (2016, CA FI) Case A is an unrealistic worst-case approach since both peracetic acid and hydrogen peroxide degrade rapidly by reaction with organic substances present abundantly in the water circuits of paper mills. Therefore, this Case A is considered neither realistic nor typical for the assessment of peracetic acid and hydrogen peroxide because only hydrolytic degradation of peracetic acid is taken into consideration. Since no unacceptable risks are identified for Case B1 and B2, where the reactivity of peracetic acid and hydrogen peroxide, i.e. their total degradation in paper mills is taken into account, the scenario PT 12 use is acceptable regarding the aquatic compartment (surface water).

No unacceptable risks were identified for the aquatic compartment (seawater) for the assessed scenario PT 12 regarding the use of biocidal products from the BPF.

- **STP/WWTP**

PT 11

Table 96: Summary table on calculated PEC/PNEC values for STP in PT 11

	PEC/PNEC$_{STP}$ PAA	PEC/PNEC$_{STP}$ H_2O_2	Σ PEC/PNEC$_{STP}$
PT 11 – Scenario 11.3 (small open recirculating cooling system – shock dosing)	5.365E-04	2.534 E-04	7.899 E-04

PT 12

Only relevant cases A and B1 are presented in the following table.

Table 97: Summary table on calculated PEC/PNEC values for industrial WWTP in scenario PT 12

		$PEC/PNEC_{WWTP}$ PAA	$PEC/PNEC_{WWTP}$ H_2O_2	Σ $PEC/PNEC_{WWTP}$
Typical case (Case A and B1)	Case A	**3.30**	0.01	**3.31**
	Case B1	<0.01	<0.01	<0.01

Bold numbers indicate an unacceptable risk to the compartment

Conclusion

PT 11

No unacceptable risks were identified for the STP for the assessed scenario in PT 11 small open recirculating cooling systems.

PT 12

No unacceptable risks were identified concerning Case B1 for the industrial WWTP for the assessed scenario PT 12 regarding the use of biocidal products from the BPF.

In Case A (without consideration of a refined degradation during primary settling) unacceptable risks were identified for the industrial WWTP. However, according to Doc II-B of the peracetic acid CAR for PT11 & PT12 (2016, CA FI) Case A is an unrealistic worst case since both peracetic acid and hydrogen peroxide degrade rapidly by reaction with organic substances present abundantly in the water circuits of paper mills. Therefore, Case A is considered neither realistic nor typical for the assessment of peracetic acid and hydrogen peroxide because only hydrolytic degradation of peracetic acid is taken into account. Since no unacceptable risks are identified for Case B1 where the reactivity of peracetic acid and hydrogen peroxide, i.e. their total degradation in paper mills is taken into account, the scenario PT 12 use is acceptable regarding the industrial WWTP.

3.8.5.2 Terrestrial compartment

- **Soil**

PT 11

Direct emissions to soil are not expected for all PT11 scenarios.

For the small open recirculating cooling systems indirect emission of soil via sewer sludge may occur. However, a risk assessment for this pathway was not considered necessary for both substances due to their distribution in sewage sludge below 0.1 % (see chapter 3.8.4.2).

Indirect emissions via the atmosphere by deposition of peracetic acid and hydrogen peroxide from air to soil may occur for all three systems in PT11. The relevant scenarios are presented in the following table. Hydrogen peroxide determines the PEC/PNEC ratio in soil because no degradation is considered.

Table 98: Summary table on calculated PEC/PNEC values for soil

	$PEC/PNEC_{Soil}$ PAA	$PEC/PNEC_{Soil}$ H_2O_2	Σ $PEC/PNEC_{Soil}$
PT 11- Use 11.1 Once-through cooling systems (shock dosing), Tier 1*	2.44 E-03	**13.33**	**13.34**
PT 11- Use 11.1 Once-through cooling systems (shock dosing), Tier 2b*[#]	2.44 E-05	0.133	0.133
PT 11- Use 11.1 Once-through cooling systems (shock dosing), Tier 1**	1.684 E-05	**13.33**	**13.33**

	$PEC/PNEC_{Soil}$ PAA	**$PEC/PNEC_{Soil}$ H_2O_2**	**Σ $PEC/PNEC_{Soil}$**
PT 11- Use 11.1 Once-through cooling systems (shock dosing), Tier 2b**[#]	1.684 E-07	0.133	0.133
PT 11- Use 11.2 Large open recirculatiing cooling systems (shock dosing), Tier 1	0.095	**26.11**	**26.21**
PT 11- Use 11.2 Large open recirculating cooling systems (shock dosing), Tier 2b[#]	9.504 E-04	0.261	0.262
PT 11- Use 11.3 Small open recirculating cooling systems (shock dosing), direct discharge, Tier 1	5.318 E-04	**2.668**	**2.669**
PT 11- Use 11.3 Small open recirculating cooling systems (shock dosing), direct discharge, Tier 2b[#]	5.318 E-06	0.027	0.027

[*] blowdown water = freshwater, representing the worst case
** blowdown water = seawater
[#] Tier 2b refers to the use of drift eliminators.

PT 12

No direct emissions to soil are expected and no indirect emissions to soil are expected via the atmosphere as explained in chapter 3.8.2.4.

Conclusion

PT 11

For the a.s. peracetic acid no unacceptable risks for soil are identified for all scenarios independently from Tier 1 or Tier 2b.

For the equilibrium substance evaluated like a SoC hydrogen peroxide, unacceptable risks to soil are identified for all Tier 1 scenarios.

The use of drift eliminators that reduce drift with at least 99% sufficiently reduces releases via evaporation and drift (Tier 2b), such that no unacceptable risks are identified for all three scenarios assessed.

PT 12

As neither direct nor indirect emissions via the atmosphere to soil are expected as explained in chapter 3.8.2.4, no unacceptable risks for soil are identified.

- ## Groundwater

Following the Technical Agreements for Biocides (TAB) – ENV, February 2021; ENV-208 as well as the ENV WG-IV-2019 and WG-III-2020 (agreed documents of WGIV2019_ENV_6-3_Harmonisation of UA cases_PAA and WGIII2020_ENV_8-3a_Harmonisation of assessment for PAA) no groundwater assessment is needed for the rapidly reacting substances PAA and H_2O_2.

3.8.5.3 Atmosphere

In PT 11 direct local emissions to air from cooling towers are assumed to be 1 % of the blowdown water rate without taking into account substance-specific properties. However, during the passage of water droplets through the tower under the elevated temperatures and on the large internal surfaces of cooling towers, PAA and H_2O_2 most probably decomposes for example when reacting with organic substances. Thus, emission from PAA and H_2O_2 that actually enter the outside air via wind throw from cooling towers would be probably much lower than calculated according to the default assumptions of the emissions scenarios when the substance specific-properties would be taken into account.

Indirectly, PAA and H_2O_2 might reach the air compartment by volatilisation from the sewage treatment plant regarding small open recirculating systems connected to STP in PT 11. Due to the very small amounts of PAA and H_2O_2 distributed into the atmosphere at the STP, this pathway is not considered relevant.

No relevant emissions from the scenario cases or industrial WWTP in PT 12 take place.

Conclusion

No unacceptable risk is expected for the air compartment using the BPF.

3.8.5.4 Non-compartment specific

- **Primary poisoning**

Not relevant.

- **Secondary poisoning**

3.8.5.5 Due to the hydrophilicity, negligible bioconcentration potential and rapid dissipation behaviour of the active substance and the SoC, the risk of

secondary poisoning is considered negligible in the aquatic and terrestrial compartment.Summary of environmental risk assessment

A separate risk assessment for sediment is not necessary, since the PNEC values for sediment were calculated by the equilibrium partitioning method. Therefore, the risk assessment results for surface water/seawater and sediment are equal. The summary of PEC/PNEC values for mixture toxicity are presented in the following table.

PT11

Table 99: Summary table on calculated PEC/PNEC values for mixture toxicity

		PEC/ PNEC$_{STP}$	PEC/ PNEC$_{surfacewater}$	PEC/ PNEC$_{seawater}$	PEC/ PNEC$_{soil}$
Scen. 11.1: Once-through cooling system, cooling water = freshwater, for PAA: DT50=1 h, kdeg=0.693 h^{-1}					
Dilution factor 10 – Freshwater	Tier 1 Tier 2a[1] Tier 2b[2]	-	**14471** **6.78**		**13.34** 0.133
Dilution factor 50 – Freshwater	Tier 1 Tier 2a Tier 2b	-	**2894** **1.36**		**13.34** 0.133
Dilution factor 100 – Seawater	Tier 1 Tier 2a Tier 2b	-		**14471** **6.78**	**13.34** 0.133
Scen. 11.1: Once-through cooling system, cooling water = seawater, for PAA: DT50=2 min, kdeg=20.8 h^{-1}					
Dilution factor 10 – Freshwater	Tier 1 Tier 2a Tier 2b	-	**2346** 0.72		**13.33** 0.133
Dilution factor 50 – Freshwater	Tier 1 Tier 2a Tier 2b	-	**469.2** 0.144		**13.33** 0.133
Dilution factor 100 – Seawater	Tier 1 Tier 2a Tier 2b	-		**2346** 0.72	**13.33** 0.133
Scen. 11.2: Large open recirculating cooling systems					
Dilution factor 10 – Freshwater	Tier 1 Tier 2a Tier 2b	-	**861.4**0.416		**26.21** 0.262
Dilution factor 200 – Freshwater	Tier 1 Tier 2a Tier 2b	-	**43.07** 0.021		**26.21** 0.262
Dilution factor 1000 – Freshwater	Tier 1 Tier 2a Tier 2b	-	**8.614**4.162 E-03		**26.21** 0.262
Dilution factor 100 – Seawater	Tier 1 Tier 2a Tier 2b	-		**861.4**0.416	**26.21** 0.262
Scen 11.3: Small open recirculating cooling systems					
via STP	Tier 1 Tier 2b	7.9 E-04	0.049	0.049	**2.669** 0.027

[1] use of sodium sulphite in the released water stream to reduce PAA and H_2O_2

[2] use of drift eliminators in the cooling towers to reduce the discharge via the air path

PT 12

Table 100: Summary table on calculated PEC/PNEC values for mixture toxicity for scenario PT 12

		PEC/PNEC$_{WWTP}$	PEC/PNEC$_{freshwater}$	PEC/PNEC$_{seawater}$
Typical case (Case A and B1) and	Case A	**3.31**	**244.12**	**244.12**

		$\text{PEC/PNEC}_{\text{WWTP}}$	**$\text{PEC/PNEC}_{\text{freshwater}}$**	**$\text{PEC/PNEC}_{\text{seawater}}$**
Reasonable worst case (Case B2)	Case B1	<0.01	<0.01	<0.01
	Case B2	---	<0.01	<0.01

<u>Conclusion</u>

<u>PT 11</u>

For the **Once-through cooling system (Scenario 11.1)**, unacceptable risks to water bodies are identified when freshwater is used as cooling water. There are no unacceptable risks identified if seawater is used as cooling water and if the discharge water is treated with a reducing agent, in this case sodium sulphite, is carried out as a risk mitigation measure. No unacceptable risks are identified for soil regardless of whether freshwater or seawater is used as cooling water if drift eliminators that reduce drift with at least 99% are installed in the cooling towers as risk mitigation measure.

For the **large open recirculating cooling system (Scenario 11.2),** no unacceptable risks to water bodies are identified if treatment of the discharge water with a reducing agent, in this case sodium sulphite, is carried out as a risk mitigation measure. Also for soil, no unacceptable risks are identified when drift eliminators that reduce drift with at least 99% are used in the cooling towers.

For the **small open recirculating cooling system (Scenario 11.3),** no unacceptable risks are identified for the sewage treatment plant and surface water/seawater. There are also no unacceptable risks identified for the soil when drift eliminators that reduce drift with at least 99% are used in the cooling towers.

<u>PT 12</u>

In general, no unacceptable risks were identified for all environmental compartments for the assessed scenario PT 12 (Case B1 and B2) regarding the use of biocidal products from the BPF.

The identified unacceptable risk for surface water for Case A in scenario PT 12 is not considered as realistic because according to Doc II-B of the peracetic acid CAR for PT11 & PT12 (2016, CA FI) Case A is an unrealistic worst case.

3.8.5.6 PBT assessment

According to the active substance ARs of peracetic acid (FI, 2016) and of hydrogen peroxide (FI, 2015) PAA and H_2O_2 do not fulfil any of the PBT criteria, nor the POP criteria.

3.8.5.7 Endocrine disrupting properties

The full composition of the product is listed in the Confidential annex.

Co-formulants:

There are no indications that a non-active substance of the BPF may have endocrine disrupting properties on environmental non-target organisms. Details can be found in the Confidential annex.

Active substance:

According to the CAR for Peracetic acid (eCA: Finland, August 2016), the active substance is not considered having endocrine disrupting properties. However, a comprehensive ED-assessment for the active substance according to Regulation (EU) 2017/2100 and the EFSA/ECHA Guidance on endocrine disruptors will need to be performed at the renewal stage.

3.8.5.8 Summary of risk characterisation

Overall conclusion on the risk assessment for the environment of the product
PT 11 For the **Once-through cooling system (Scenario 11.1)**, unacceptable risks to the aquatic environment are identified when freshwater is used as cooling water. Even the use of a reducing agent does not eliminate the unacceptable risk. No unacceptable risks are identified, if seawater is used as cooling water and if treatment of the discharge water with a reducing agent is carried out as a risk mitigation measure. For the soil compartment, no unacceptable risks are identified in both cases (freshwater or seawater as cooling water) if drift eliminators that reduce drift with at least 99% are installed in the coolings towers as risk mitigation measures. For the **large open recirculating cooling system (Scenario 11.2),** the expected risks to the environment from the use of the BPF products are considered acceptable for all relevant environmental compartments provided that, as risk mitigation measures, drift eliminators that reduce drift with at least 99% are used in the cooling towers and that the discharge water is treated with a reducing agent. For the **small open recirculating cooling system (Scenario 11.3),** the expected risks to the environment from the use of the BPF products are considered acceptable for all relevant environmental compartments provided that, as risk mitigation measures, the cooling water is discharged via a sewage treatment plant and drift eliminators that reduce drift with at least 99% are used in the cooling towers. **PT 12** The expected risks to the environment from the use of the BPF products are considered acceptable for the assessed scenario in PT 12 (Case B1 and B2) and for all relevant environmental compartments.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

No candidate for substitution was identified, hence a comparative assessment is not necessary.

4 Annexes

4.1 List of studies for the biocidal product family

Table 101

No	Data set according to Annex III Regulation (EU) No 528/2012 / IUCLID Section	Title	Author(s)	Year	Owner company
1	3.1 Appearance (at 20°C and 101.3 kPa)	Product Appearance of peracetic acid containing biocidal products of the PERACLEAN® and DEGACLEAN® group *No report number provided*	Anonymous	2018	Evonik Resource Efficiency GmbH
2	3.2 Acidity, alkalinity	Determination of the apparent acidity of peracetic acid containing biocidal products of the PERACLEAN® and DEGACLEAN® group *No report number provided*	Anonymous	2019	Evonik Resource Efficiency GmbH
3	3.2 Acidity, alkalinity	Determination of the pH-value of peracetic acid containing biocidal products of the PERACLEAN® and DEGACLEAN® group *No report number provided*	Anonymous	2018	Evonik Resource Efficiency GmbH
4	3.3 Relative density (liquids) and bulk, tap density (solids)	Determination of the density of peracetic acid containing biocidal products of the PERACLEAN® and DEGACLEAN® group *No report number provided*	Anonymous	2018	Evonik Resource Efficiency GmbH
5	3.4.1 Storage stability tests	Accelerated storage test of peracetic acid containing biocidal products of the PERACLEAN® group *No report number provided*	Anonymous	2019	Evonik Resource Efficiency GmbH

6	3.4.1 Storage stability tests	Storage test of peracetic acid containing biocidal products of the PERACLEAN®group with steal coupon *No report number provided*	Anonymous	2017	Evonik Resource Efficiency GmbH
7	3.4.1 Storage stability tests	Long term storage test of peracetic acid containing biocidal products of the DEGACLEAN® and PERACLEAN® group *No report number provided*	Anonymous	2019	Evonik Resource Efficiency GmbH
8	3.5 Technical characteristics of the biocidal product	Persistent foaming test of peracetic acid containing biocidal products of the PERACLEAN® and DEGACLEAN® group *No report number provided*	Anonymous	2018	Evonik Resource Efficiency GmbH
9	3.5 Technical characteristics of the biocidal product	Dilution stability test of peracetic acid containing biocidal products of the PERACLEAN® and DEGACLEAN® group *No report number provided*	Anonymous	2018	Evonik Resource Efficiency GmbH
10	3.5 Technical characteristics of the biocidal product	Dilution stability test of peracetic acid containing biocidal products of the PERACLEAN® and CLARMARIN® group Report number: 2017BR09	Evonik Resource Efficiency GmbH	2017	Evonik Resource Efficiency GmbH
11	3.8 Surface tension	Determination of surface tension of aqueous solutions using the pendant drop method *No report number provided*	Krüss GmbH	2017	
12	3.8 Surface tension	Test Report No. A170003713; AG17-1030 Pos. 2: Surface Tension Report number: A170003713	Evonik Resource Efficiency GmbH	2017	Evonik Resource Efficiency GmbH
13	3.9 Viscosity	AG17-1030, Pos. 1: Kinematic viscosity Report number: A170007171	Anonymous	2020	Evonik Resource Efficiency GmbH
14	3.9 Viscosity	AG17-1030 Pos. 1: Kinematic viscosity Report number: A170003712	Anonymous	2020	Evonik Resource Efficiency GmbH
15	4.2 Flammability	Determination of the flash point (test method: Pensky-Martens, EN ISO 2719) of “PERACLEAN® 2” Report number: A170009121	Anonymous	2017	Evonik Resource Efficiency GmbH

16	4.2 Flammability	Determination of the flash point (test method: Pensky-Martens, EN ISO 2719) of "PERACLEAN® 5" Report number: A170009211	Anonymous	2017	Evonik Resource Efficiency GmbH
17	4.2 Flammability	Determination of physico-chemical properties Flash Point Report number: CSL-17-1264-01	Anonymous	2017	
18	4.4 Oxidising properties	"PERACLEAN® 2" Test on oxidizing properties (according to the UN "Transport of Dangerous Goods") Report number: A170004202	Anonymous	2017	Evonik Resource Efficiency GmbH
19	4.4 Oxidising properties	"PERACLEAN® 5" Test on oxidizing properties (according to the UN "Transport of Dangerous Goods") Report number: A170004209	Anonymous	2017	Evonik Resource Efficiency GmbH
20	4.8 Self-reactive substances and mixtures	SPZ-Report No. 44c-17 Sample: "PERACLEAN® 2" UN H.4 SADT test at 75 °C (According to the UN "Transport of Dangerous Goods, Manual of Tests&Criteria", Rev.6, 2015 Report number: A170009213	Anonymous	2017	Evonik Resource Efficiency GmbH
21	4.8 Self-reactive substances and mixtures	SPZ-Report No. 46c-17 Sample: "PERACLEAN® 5" UN H.4 SADT test at 75 °C (According to the UN "Transport of Dangerous Goods, Manual of Tests&Criteria", Rev.6, 2015 Report number: A170009215	Anonymous	2017	Evonik Resource Efficiency GmbH
22	4.8 Self-reactive substances and mixtures	Determination of the SADT of the peracetic acid containing sample "Peraclean® 2 WT" Report number: SPZ20-019	Anonymous	2020	Evonik Resource Efficiency GmbH
23	4.8 Self-reactive substances and mixtures	Determination of the SADT of the peracetic acid containing sample "Peraclean® 5" Report number: SPZ20-021	Anonymous	2020	Evonik Resource Efficiency GmbH
24	4.8 Self-reactive substances and mixtures	Determination of the SADT of the peracetic acid containing sample "Peraclean® 17" Report number: SPZ20-024	Anonymous	2020	Evonik Resource Efficiency GmbH
25	4.15 Organic peroxides	Determination of safety data according to transport regulation for one liquid formulation (PERACLEAN® 5) Report number: SPZ21-061 Rev. 01	Anonymous	2022	Evonik Operations GmbH

26	4.15 Organic peroxides	Test of the sample “PERACLEAN® 17” according to the UN classification procedures for organic peroxides Report number: A170011401	Anonymous	2017	Evonik Resource Efficiency GmbH
27	4.15 Organic peroxides	Determination of safety data according to transport regulation for one liquid formulation (PERACLEAN® 15) Report number: SPZ21-090 Rev.01	Anonymous	2022	Evonik Operations GmbH,
28	4.16 Corrosive to metals	Oxypure BIO 15% Test for corrosion to metals Report number: BC-37/16	Anonymous	2016	PeroxyChem Spain, s.l.u.
29	4.16 Corrosive to metals	Oxypure BIO 5% Test for corrosion to metals Report number: BC-73/16	Anonymous	2016	PeroxyChem Spain, s.l.u.
30	4.16 Corrosive to metals	OxyPure 1.5TE Test for corrosion to metals Report number: BC-63/17	Anonymous	2017	Bibliographic source: Not applicable PeroxyChem Spain s.l.u.
31	5 Methods of detection and identification	Validation of the Determination of Peracetic Acid and Hydrogen Peroxide Content in biocidal Peracetic Acid Products. Version for the PT11-PT12 application. *No report number provided*	Evonik Resource Efficiency GmbH	2019	Evonik Resource Efficiency GmbH
32	5 Methods of detection and identification	Peracetic acid 15%: Method validation for Acetic Acid Report number: 161104AC / CMV17511	Noack Laboratorien GmbH	2017	Evonik Resource Efficiency GmbH (as member of the Peracetic Acid Registration Group PAR)
33	5 Methods of detection and identification	AL 220 method validation report: Quantification of dipicolinic acid by HPLC Report number: AL 220	HYPRED SA	2016	Evonik Resource Efficiency GmbH
34	5 Methods of detection and identification	Method validation of the Determination of the Stabilizer Hydroxyethane-1,1-Diphosphonic Acid (HEDP) in Peracetic Acid Solutions Report number: 23MV17001.E2	Henkel AG & Co. KGaA	2017	Evonik Resource Efficiency GmbH (as member of the Peracetic Acid Registration Group PAR)
35	6.7 Efficacy data to support these claims	Evaluation of Microbiocides Used in Cooling Water Systems Report number: J000800	Anonymous	2018	Evonik Resource Efficiency GmbH, Hanau, Germany

36	6.7 Efficacy data to support these claims	Quantitative suspension test for the evaluation of bactericidal activity against Legionella of PERACLEAN 15 BULK in aqueous systems according to DIN EN 13623:2010 (Phase 2, step 1) Report number: L17/0802.1	Anonymous	2018	Evonik Resource Efficiency GmbH, Hanau, Germany
37	6.7 Efficacy data to support these claims	Evaluation of PERACLEAN® 15 BULK for use in cooling water systems according to ASTM E645-13 (1) Report number: L20/0014.4	Anonymous	2020	Bibliographic source: upublished report Evonik Operations GmbH
38	6.7 Efficacy data to support these claims	Evaluation of PERACLEAN® 15 BULK for use in cooling water systems according to ASTM E645-13 (2) Report number: L20/0014.5	Anonymous	2020	Bibliographic source: unpublished report Evonik Operations GmbH
39	6.7 Efficacy data to support these claims	Evaluation of Microbiocides Used in Cooling Water Systems – Adapted method for Algae Report number: J002126-5	Anonymous	2020	Evonik Operations GmbH
40	6.7 Efficacy data to support these claims	Evaluation of PERACLEAN® 15 BULK for use in cooling water systems according to ASTM E645-13 (3) Report number: L20/0014.7	Anonymous	2020	Bibliographic source: upublished report Evonik Operations GmbH
41	6.7 Efficacy data to support these claims	Evaluation of Microbiocides Used in Cooling Water Systems Report number: J000799	Anonymous	2018	Evonik Resource Efficiency GmbH, Hanau, Germany
42	6.7 Efficacy data to support these claims	Evaluation of PERACLEAN® 15 BULK for use in cooling water systems according to ASTM E645-13 (4) Report number: L20/0014.8	Anonymous	2020	Bibliographic source: upublished report Evonik Operations GmbH
43	6.7 Efficacy data to support these claims	Standard test method for Efficacy of Slimicides for the Paper Industry - Bacterial and Fungal Slime (1) Report number: J002126-1	Anonymous	2020	Evonik Operations GmbH
44	6.7 Efficacy data to support these claims	Standard test method for Efficacy of Slimicides for the Paper Industry - Bacterial and Fungal Slime (2) Report number: J002126-2	Anonymous	2020	Evonik Operations GmbH
45	6.7 Efficacy data to support these claims	Standard test method for Efficacy of Slimicides for the Paper Industry - Bacterial and Fungal Slime (3) Report number: J002126-3	Anonymous	2020	Evonik Operations GmbH

46	6.7 Efficacy data to support these claims	Standard test method for Efficacy of Slimicides for the Paper Industry - Bacterial and Fungal Slime (4) Report number: J002126-4	Anonymous	2020	Evonik Operations GmbH
47	6.7 Efficacy data to support these claims	Standard test method for Efficacy of Slimicides for the Paper Industry - Bacterial and Fungal Slime Report number: J000896-1	Anonymous	2018	Evonik Resource Efficiency GmbH, Hanau, Germany
48	6.7 Efficacy data to support these claims	Quantitative suspension test for the evaluation of bactericidal activity according to EN 1040 Report number: 170601-0021-005	Anonymous	2018	Evonik Resource Efficiency GmbH, Hanau, Germany
49	6.7 Efficacy data to support these claims	Quantitative suspension test for the evaluation of fungicidal activity according to EN 1275 Report number: 170601-0021-006	Anonymous	2018	Evonik Resource Efficiency GmbH, Hanau, Germany
50	6.7 Efficacy data to support these claims	Bespoke pulp validation study Report number: J000813	Anonymous	2018	Evonik Resource Efficiency GmbH, Hanau, Germany
51	8.10 Other test(s) related to the exposure to humans	Documentation of the threshold limit values and biological exposure indices (Nitric Acid) *No report number provided*	American Conference of Governmental Industrial Hygienists (ACGIH)	1996	Bibliographic source: 6th ed. ACGIH, pp. 1088-1092. Cincinnati, USA
52	8.10 Other test(s) related to the exposure to humans	EUR 16668 — Occupational exposure limits Criteria document for nitric acid *No report number provided*	Danish Toxicology Centre on behalf of the European Commission	1996	Bibliographic source: Luxembourg, Office for Official Publications of the European Communities, 1996, VII, 44 pp. ISBN 92-827-6781-7
53	8.10 Other test(s) related to the exposure to humans	Recommendation from the Scientific Committee for Occupational Exposure Limits for nitric acid *No report number provided*	Committee for Occupational Exposure Limits	2001	Bibliographic source: Recommendation from the Scientific Committee for Occupational Exposure Limits for nitric acid, SCOEL/SUM/61, June 2001

54	8.10 Other test(s) related to the exposure to humans	Effects of breathing nitrate aerosols in high concentrations for 10 minutes on pulmonary function of normal and asthmatic adults, and preliminary results in normals exposed to nitric acid fumes *No report number provided*	Anonymous	1981	Bibliographic source: American Thoracic Society, Annual Meeting supplement, Vol 123, No 4, April 1981
55	10.2 Further studies on fate and behaviour in the environment	Reduction of PAA with sodium sulfite Report number: 2017-004	Anonymous	2017	Evonik Resource Efficiency GmbH, Hanau, Germany

4.2 List of studies for the active substance(s)

The applicant provided a letter of access to the dossier assessed for the approval of the active substance peracetic acid for use in product-type 11 and 12. Please, refer to the corresponding Assessment Report for a reference list.

4.3 *Output tables from human health exposure assessment tools*

4.3.1 Safety for professional users

Calculation of exposure

HH output tables

Calculation of activity coefficients with AIOMFAC

Sc 1 - Concentrate worst-case.pdf

Sc 2 - Application liquid - worst-case fo

Sc 3 - Application liquid - worst-case fo

Sc 4 - Concentrate meta-SCP 3, 1 to 100

Sc 4 - Concentrate meta-SPC 2, 1 to 100