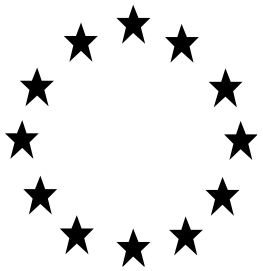
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Formaldehyde

Product-type 03
(Veterinary hygiene)

November 2019

Germany

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1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of the active substance formaldehyde as product-type 03(veterinary hygiene), carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

Formaldehyde (CAS no. 50-00-0) was notified as an existing active substance, by Ewabo Chemikalien GmbH & Co. KG, Lysoform Dr. Hans Rosemann GmbH and Synthite Ltd. as well as Interhygiene GmbH, hereafter referred to as the applicant, in product-type **03**.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[1] lays down the detailed rules for the evaluation of dossiers and for the decision-making process.

In accordance with the provisions of Article 7(1) of that Regulation, Germany was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for formaldehyde as an active substance in Product Type 03 was 31st July 2007, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 26th of June 2009, Germany competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 15th of December 2009.

On 29th of July 2013, the Rapporteur Member State submitted to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report.

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

1.2. Purpose of the assessment report

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of formaldehyde for product-type 03, and, should it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

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

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

[1] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Formaldehyde is a colourless gas with a melting point of -92°C which boils at -19,5°C (p = 1013 hPa). The vapour pressure of formaldehyde is 5490 hPa at 27°C, above aqueous solutions, the partial pressure (1% aqueous solution: 13 Pa; 25 °C) of formaldehyde is relatively low. Although formaldehyde is well soluble in water (up to 55%) and has a low volatilization potential from water. It is also soluble in alcohol and ether.

Furthermore, the Henry Law constant is 0.034 Pa m³/mol at 25°C and formaldehyde has a low logPow of 0.35.

The active substance is a colourless formaldehyde solution in water (25-55% formaldehyde. 0-7% methanol; dry weight: > 87.5% formaldehyde, < 12.5% Methanol, Task Force and 37.0 – 37.5% formaldehyde, 0.5 – 1.5% Methanol, Interhygiene GmbH) with an irritating, pungent odour. For formalin a melting point of -15°C and a boiling point of 96°C could be found in the literature. For higher concentrated formaldehyde solutions the determination of the melting point is not possible, because formaldehyde polymerises at lower temperatures.

In aqueous solution formaldehyde exists as methylene glycol (HOCH2OH) and its oligomers, namely the low molecular mass poly(oxymethylene) glycols with the following structure HO(CH2O)nH (n = 1-8). Monomeric, physically dissolved formaldehyde is only present in low concentrations of up to 0.1 wt%. The density of the active substance (50% formaldehyde. 7% methanol) is 1.1346 g/cm³ at 25°C and it is completely soluble in water and in all proportions soluble in toluene, ether, chloroform and ethylacetate. The vapour pressure of formalin is 187 Pa at 20°C, which is comparable with the vapour pressure of water.

A method for determining formaldehyde in aqueous solutions for industrial use is described in the international standard ISO 2227. The method as described is applicable to formaldehyde solutions with formaldehyde contents between 25% and 45%, but the field of application may be extended by modifying the mass of the test portion. The principle of the method is the reaction of formaldehyde with sodium sulphite, and acidimetric titration of the liberated sodium hydroxide using thymolphthalein as indicator.

Additionally derivatisation methods with following GC or HPLC detection are applicable for the determination of formaldehyde solutions

Acceptable primary methods are available for the determination of formaldehyde in air, drinking and surface water. Acceptable confirmatory methods were also presented for these matrices. An acceptable primary analytical method was presented for the determination of formaldehyde in soil. No relevant residues in food of plant and animal origin are expected to occur. Analytical methods for food of plant origin are not necessary.

Sufficiently validated analytical methods for monitoring of formaldehyde in food and feed of animal origin are required if relevant residues are not excluded. An acceptable primary method was presented for the determination of formaldehyde in meat.

Formaldehyde is classified as toxic. Therefore analytical methods for the determination of formaldehyde in body fluids and tissues are required. It is concluded from the study of Shara (1992) and from expert judgment that an exposure of formaldehyde has no influence on the formaldehyde concentration in body fluids or tissues. Thus, analytical methods in body fluids and tissues are not suitable for monitoring purposes. Nevertheless an analytical method (primary and confirmatory method) for the determination of formaldehyde in body fluids (urine) was provided. An additional method for the quantification of formaldehyde in water-based latex

paints is provided. It could be useful for several formaldehyde releasers and for measurements in products.

2.1.2. Intended Uses and Efficacy

Formaldehyde has been evaluated for its use by professionals as a disinfectant in veterinary hygiene in animal houses, hatcheries, vehicles and for animals' feet.

The studies performed are sufficient at the approval stage. In the frame of product authorisation, further tests in the field of use have to be provided. Tests performed with the active substance show that formaldehyde has a bactericide and fungicide activity at a concentration of ≥ 0.5% within short term contact time (60min) and at concentration of 0.05% within long term contact time (24h). Further tests using formaldehyde show a sufficient disinfecting efficacy against viruses at concentrations between ≥ 0.064 and ≥ 0.92 after 120 min exposure. The proposed application rates of 0.05% - 12% of formaldehyde seem reasonable if formulated to a product.

Since the disinfecting action of formaldehyde is well established the data submitted was considered sufficient for the evaluation of the efficacy of the active substance at the approval stage even though several shortcomings were identified in the studies: The information provided is only sufficient to show a basic efficacy of formaldehyde. This is accepted in the frame of Annex-I-inclusion. Within the frame of product authorisation, essentially more information has to be provided: To support the claim bactericidal, fungicidal, virucidal and sporicidal further laboratory tests would be necessary. Additionally, further tests in the field of use have to be provided.

Mode of action:

Formaldehyde interacts with protein, DNA and RNA in vitro. The interaction with protein results from a combination with the primary amide and the amino groups. It reacts with carboxyl, sulfhydryl and hydroxyl groups. Furthermore, formaldehyde reacts with nucleic acid (e.g. DNA of bacteriophages or viruses). It inhibits viral DNA synthesis by forming DNA cross-links (e.g. in SV40) and can modify viral proteins (e.g. HBsAg and HBcAg of HBV). It penetrates bacterial spores and fungal conidia, acts sporostatic and inhibits germination.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

Classification and Labelling of Formaldehyde

Table 2-1 Proposed classification of formaldehyde based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Acute Tox. 4 Acute Tox. 3 Acute Tox. 2 Skin Corr. 1B Skin Sens. 1A Muta. 2 Carc. 1B	Acute oral toxicity category 4 Acute dermal toxicity category 3 Acute inhalation toxicity category 2 Skin corrosion/irritation category 1B Skin sensitisation category 1A Mutagenicity category 2 Carcinogenicity category 1B
Hazard statements	H302 H311 H330 H314 H317 H341 H350	Harmful if swallowed Toxic in contact with skin Fatal if inhaled Causes severe skin burns and eye damage May cause an allergic skin reaction Suspected of causing genetic defects May cause cancer

Table 2-2 Proposed labelling of formaldehyde based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	 GHS05  GHS06  GHS08	
Signal Word	Danger	Danger
Hazard statements	H302 H311 H330 H314 H317 H341 H350i	Harmful if swallowed Toxic in contact with skin Fatal if inhaled Causes severe skin burns and eye damage May cause an allergic skin reaction Suspected of causing genetic defects May cause cancer
Suppl. Hazard statements	EUH071	Corrosive to the respiratory tract
Precautionary statements		

Table 2-3 Current harmonised classification of formaldehyde according to Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* Skin Corr. 1B Skin Sens. 1 Muta. 2 Carc. 1B	Acute oral toxicity category 3 Acute dermal toxicity category 3 Acute inhalation toxicity category 3 Skin corrosion/irritation category 1B Skin sensitisation category 1A Mutagenicity category 2 Carcinogenicity category 1B
Hazard statements	H301 H311 H331 H314 H317 H341 H350	Toxic if swallowed Toxic in contact with skin Toxic if inhaled Causes severe skin burns and eye damage May cause an allergic skin reaction Suspected of causing genetic defects May cause cancer

*minimum classification

Summary and Conclusion:

The submitted data on acute toxicity require classification of formaldehyde in Acute oral toxicity Category 4 (“Harmful if swallowed”, H302), based on an oral LD50 value of 640 mg/kg bw in rats; Acute dermal toxicity Category 3 (“Toxic in contact with skin”, H311), based on a dermal LD50 of 270 mg/kg bw in rabbits; and Acute inhalation toxicity (gases) Category 2 (“Fatal if inhaled”, H330), based on LC50 values of 1 mg/L x 0.5 h and 0.6 mg/L x 4 h in rats. Acc. to Regulation 1272/2008/EC, labelling as EUH071 “Corrosive to the respiratory tract” in addition to

classification for inhalation toxicity is foreseen if the mechanism of toxicity is corrosivity. Considering that formaldehyde is a corrosive substance, additional labelling with EUH071 was regarded as appropriate.

Classification in Skin corrosion/irritation Category 1B ("Causes severe skin burns and eye damage", H314) and Skin sensitisation Category 1 ("May cause an allergic skin reaction", H317) is confirmed. However, based on EC3 values of 0.33- 0.96 % in various LLNAs, an induction rate of 100 % following intradermal injection at 0.25 % a.s. in the GPMT and a high frequency of occurrence in humans at relatively low exposure, formaldehyde should be subclassified into Skin Sens. Cat. 1A (strong sensitiser). Classification for respiratory sensitisation is not supported by current data. In principle, the database would require the following additional classification: Serious eye damage/eye irritation Category 1 ("Causes serious eye damage", H318) and Specific target organ toxicity – single exposure Category 3 ("May cause respiratory irritation", H335). However, both hazards are considered implicit when a substance is classified as corrosive, i.e. at C ≥ 25 %.

The harmonised classification acc. to Reg. (EC) 1272/2008 includes the following concentration limits: Skin Corr. 1B, H314: C ≥ 25%; Skin Irrit. 2, H315: 5% ≤ C < 25%; Eye Irrit. 2, H319: 5% ≤ C < 25%; and STOT SE 3, H335: C ≥ 5%. Additional labelling with EUH208 ("Contains formaldehyde. May produce an allergic reaction.") applies at C ≥ 0.02 % (w/w).

There is strong evidence for genotoxicity/mutagenicity induced by formaldehyde in non-mammalian and mammalian cells in vitro and in vivo, namely DNA crosslinks, SCE, micronucleoli formation as well as DNA adducts. Furthermore, there is supportive evidence for germ cell mutation from intra-peritoneal administered formaldehyde in male albino rats (Odeigah 1997) and male mice (SCE at 2, and 20 mg/kg x 5d; Tang; abstract). The Guidance to Reg (EC) No. 1272/2008 further notes: "classification as a Category 2 mutagen would generally apply if only intraperitoneal in vivo tests show mutagenicity/genotoxicity and the negative test results from the in vivo tests using other routes of application are plausible". Therefore, classification of formaldehyde in Mutagenicity Category 2 ("Suspected of causing genetic defects", H341) is confirmed.

A relationship between exposure to formaldehyde and haematopoetic malignancies, especially myeloid leukaemia, was indicated in epidemiological studies. Meta-analysis supported the association when taking into account the level of exposure to formaldehyde, in line with reports on lymphatic cell genotoxicity and bone marrow toxicity in highly exposed humans. Experimental evidence for a causal relation between an increased incidence of respiratory tract cancer following repeated formaldehyde inhalation is available from studies in more than one animal species, supported by mechanistic investigations. Therefore, classification of formaldehyde in Carcinogenicity Category 1B ("May cause cancer", H350) according to the criteria laid down in Regulation (EC) No 1272/2008 is confirmed.

Finally, methanol is present in the a.s. as impurity at concentrations of 0 - 7 % w/w. Currently, methanol is classified in Acute Toxicity Category 3 and Specific Target Organ Toxicity – Single Exposure (STOT SE): Category 1 with specific concentration limits of C ≥ 10% for STOT SE 1 (H370) and 3% ≤ C < 10% for STOT SE 2 (H371). At impurity levels above 3 % (i.e. in the range of 3-7 %), this would in principle trigger additional classification of the a.s. for STOT SE 2. However, as the concentration at which the impurity occurs is variable and classification for the a.s. formaldehyde is more severe and sufficiently protective, additional classification and labelling is not proposed.

Task Force:

Classification and Labelling of the biocidal product ("Dummy Product")

Table 2-4 Proposed classification of the biocidal product based on Regulation (EC) No 1272/2008

	Hazard classes, hazard categories, hazard statements	Wording
Classification	Acute Tox. 4, H302 Acute Tox. 3, H311 Acute Tox. 2, H330 Skin Corr. 1B, H314 STOT-SE 3, H335 Skin Sens. 1, H317 Muta. 2, H341 Carc. 1A*, H350i	Harmful if swallowed Toxic in contact with skin Fatal if inhaled Causes severe skin burns and eye damage May cause respiratory irritation May cause an allergic skin reaction Suspected of causing genetic defects May cause cancer by inhalation

Remark:

No environmental classification is proposed.

Table 2-5 Proposed labelling of the biocidal product based on Regulation (EC) No 1272/2008

	Labelling	Wording
Hazard pictograms, signal words, hazard statements precautionary statements		Danger
	H302 H311 H330 H314 H335 H317 H341 H350i	Harmful if swallowed Toxic in contact with skin Fatal if inhaled Causes severe skin burns and eye damage May cause respiratory irritation May cause an allergic skin reaction Suspected of causing genetic defects May cause cancer by inhalation
	P271 P281 P301 + P330 + P331 P303 + P361 + P353 P305 + P351 + P338 P308 + P313 P403 + P233 P405	Use only outdoors or in a well-ventilated area. Use personal protective equipment as required. IF SWALLOWED: rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. IF IN EYES: Rinse cautiously with water for several minuts. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Get medical advice/attention. Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Summary & Conclusion:

The proposed classification and labelling of the biocidal product is inherited from the active substance.

Interhygiene GmbH:

The proposed classification of the biocidal product is based on toxicity information of its components. However, it might be expected that formaldehyde and ethylen glycol react; in this case the estimation of toxicity of the mixture by the toxicity of its compounds will not be valid. Therefore the applicant was asked whether a reaction takes place or not. The applicant argued that this was not the case; however, the evidence supplied relies on concentration measurements which have a relative error of 20-30 percent. Therefore it is still not clear whether toxicologically relevant compounds other than the constituents develop in the mixture. Further clarification, for instance by NMR, may be postponed to the national authorisation stage.

Table 2-6 Proposed classification of the biocidal product 0901001 based on Regulation (EC) No 1272/2008

	Hazard classes, hazard categories, hazard statements	Wording
Classification	Acute Tox. 4 (oral) – H302 Acute Tox. 4 (dermal) – H312 Acute Tox. 2 (inhal.) – H330 Skin Irrit. 2 – H315 Eye Dam. 1 – H318 STOT-SE 3 (RTI) – H335 Skin Sens. 1 – H317 Muta. 2 – H341 Carc. 1B– H350i	Harmful if swallowed. Harmful in contact with skin. Fatal if inhaled. Causes skin irritation. Causes serious eye damage. May cause respiratory irritation. May cause an allergic skin reaction. Suspected of causing genetic defects. May cause cancer by inhalation.

Table 2-7 Proposed labelling of the biocidal product 0901001 based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	 GHS05  GHS06  GHS08	
Signal Word	Danger	Danger

Hazard statements	H302	Harmful if swallowed.
	H312	Harmful in contact with skin.
	H330	Fatal if inhaled.
	H315	Causes skin irritation.
	H318	Causes serious eye damage.
	H335	May cause respiratory irritation.
	H317	May cause an allergic skin reaction.
	H341	Suspected of causing genetic defects.
	H350i	May cause cancer by inhalation.
Precautionary statements	P201	Obtain special instructions before use
	P260	Do not breathe dust/fume/gas/mist/vapours/ spray.
	P280	Wear protective gloves / protective clothing / eye protection / face protection.
	P284	Wear respiratory protection.
	P304+340+310	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	308+313	IF exposed or concerned: Get medical advice/attention.
	403+233	Store in a well-ventilated place. Keep container tightly closed.
	P501	Dispose of contents/container in accordance with national/international regulations.

Summary & Conclusion:

No environmental classification is proposed for the active substance as well as the biocidal product for both applicants.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Formaldehyde is of high chemical reactivity, causing local irritation or corrosion at exposed epithelia. There is no convincing evidence for skin sensitisation by the a.s.. Formation of DNA-protein links is thought to lead to clastogenic effects. At concentrations causing cytotoxicity in the respiratory tract with induction of regenerative cell proliferation, formation of nasopharyngeal cancer has been established in rats.

2.2.1.2. Effects assessment

The industrial use of formaldehyde has a long history. Consequently, extensive research has been performed on the toxicology of formaldehyde and a wealth of human and animal toxicity data has been accumulated. Unfortunately, little of the available data has been acquired and reported in a way complying with current OECD and EU guidelines for the testing of chemicals. Therefore, appropriate-care needs to be taken in its interpretation. Nevertheless, it provides the information required for an assessment of the human health effects of formaldehyde.

Absorption, Distribution, Excretion, and Metabolism

In rats and mice, gastrointestinal absorption of ^{14}C-formaldehyde was reported to be rapid and virtually complete. Within 12 hours, 40 % of radioactivity was exhaled as CO_2, or excreted with urine (10 %) or, to a minor extent, with faeces (1 %) in rats. Total body ^{14}C-residues were 20 % after 24 hours and 10 % after 96 hours in mice.

After i. p. administration of a single dose ^{14}C-formaldehyde to male SD rats, 70 % of radioactivity was exhaled as CO_2 within 12 h, 5.5-9 % of radioactivity were found in urine.

The available data on dermal absorption indicate that formaldehyde is quantitatively absorbed from the skin surface. When absorbed from solution, the absorption process is obviously in direct competition with evaporation and systemic absorption may be delayed and/or limited by covalent binding at the site of application. Nevertheless, a significant fraction of the absorbed material or its (radioactive) metabolites enters the systemic circulation to be distributed widely and excreted with urine, faeces, and exhaled air. Taking this into account, a dermal absorption of 100 % formaldehyde is considered appropriate for risk assessment of its liquid formulations. The default values of 75% and 25% for dilutions and concentrates according to EFSA Guidance on Dermal Absorption (2012) do not apply when experimental data suggest other values (CA-July July13-Doc.6.2.b – Final). Product/use specific information can be submitted for refinement at the product authorisation stage.

As a highly water soluble gas, inhaled formaldehyde readily passes over into the lining mucosa. Formaldehyde gas inhalation had no significant effect on the existing background levels in blood. This is indicative for rapid formaldehyde conversion at the site of entry resulting in metabolites and/or adducts that are apparently absorbed and distributed systemically. Thus, an inhalation absorption factor of 100 % is considered appropriate for risk assessment of formaldehyde gas.

In rats, and mice, preferential absorption in the anterior regions of the nasal cavity was observed. Due to species-specific differences in anatomy and breathing pattern, larger fractions are predicted to be absorbed in the tracheobronchial region in man with more than 100-fold lower deposition in the pulmonary region.

Within animal tissues, formaldehyde reacts spontaneously and non-enzymatically with a range of sulfhydryl- and amino-compounds to form adducts, some of which can at least in part dissociate or decompose to release formaldehyde. Adducts with genomic DNA are sufficiently stable to react with proteins into cross-linked products.

Experimental evidence suggests that the spontaneous reaction with glutathione is the most important pathway for the detoxification of formaldehyde in animals and humans. This reaction is followed by enzymatic oxidation by alcohol dehydrogenase 5 (ADH5). Products of further hydrolysis are GSH and formate.

Following saturation of this pathway or in absence of glutathione, GSH-independent aldehyde dehydrogenase 1 (ALDH1, cytosolic) and 2 (ALDH2, mitochondrial) contribute significantly to oxidation of formaldehyde into formate.

Resulting formate can be excreted renally or following addition to tetrahydrofolate further consumed in one-carbon-transfer reactions or oxidised to form THF, CO_2 and NADPH.

As the major urinary metabolites in rats, adducts of formaldehyde with urea were identified in addition to formate.

Acute Toxicity

LD_{50} values in rats were between 640 and 800 mg/kg bw. Guinea pigs appeared more sensitive than rats, resulting in a LD_{50} value of 260 mg/kg bw.

Mortality after dermal administration occurred at similar doses as suggested by a dermal LD_{50} of 270 mg/kg bw in rabbits.

In rats, inhalation of formaldehyde resulted in LC_{50} values of 0.5 to 1.0 mg/L following exposure for 0.5 to 4 hrs. Exposure to 0.28 mg/L formaldehyde in air was associated with restlessness, excitation, laboured breathing, gasping and assumption of a lateral position in rats. Higher concentrations (0.6-1.7 mg/L) resulted in haemorrhage and oedema of the lung as well as oedema in liver and kidneys and hepatocyte necrosis.

Mortality following injection (s.c.) of formaldehyde was observed at similar doses compared to gavage administration with LD_{50} values of 420 and 300 mg/kg bw for rats and mice, respectively.

Irritation and Corrosivity

Studies on skin irritation performed to current testing guidelines are not available.

However, single and unoccluded administration of a concentration of 7-9 % formaldehyde in water was irritating in rat skin and a concentration of 15-18 % formaldehyde was reported to cause erosion in the skin of rats, mice and guinea pigs.

Previous risk assessments performed by OECD and WHO considered formaldehyde as skin irritant based on effects observed after administration of 0.1-20 % solutions to rabbit skin and a 1 % solution to guinea pig skin. In humans, single dermal application of 1 % formaldehyde in water (occluded) produced irritant responses in 5 % of individuals. Case reports of oral poisonings with 37-40 % formaldehyde solutions are in support of corrosive properties on mucosal tissues. Further dose-response data for skin irritation is available from repeated-dose testing (see below).

Eye irritation studies in rabbits, rats and mice revealed corneal opacity following application of formaldehyde solutions with concentrations between 7 % and 15 % which was not reversible within the observation period. Therefore, formaldehyde should be regarded as “causing serious damage to eyes”. This is also in full agreement with the corrosive properties identified in skin irritation studies.

Exposure to formaldehyde in the air may cause local irritation of eyes, nose, throat and lung. In humans, irritation of the eyes was usually identified as the most sensitive endpoint. Pulmonary function was not affected. A NOAEC of 0.6 µg/L x 4 h (0.5 ppm) based on objective eye irritation and conjunctival redness in response to peaks of 1.2 µg/L is derived for risk assessment purposes. In addition, an experimental NOAEC of 0.36 µg/mL (0.3 ppm; acute) for subjective conjunctival (eye) irritation, and a population NOAEC of 0.12 µg/L (0.1 ppm) considering interindividual variability was suggested based on extensive review of the literature.

Skin sensitisation

Formaldehyde is a known skin sensitiser inducing Type IV allergic contact dermatitis. The sensitising properties of formaldehyde are confirmed by a large number of tests in laboratory animals, including guinea pig maximisation tests and local lymph node assays. In the local lymph node assays, EC_3 values between 0.33 % and 0.96 % formaldehyde in several vehicles were reported.

A substantial database on allergic skin reactions in humans is available from patch testing with the 1 % aqueous solution of formaldehyde. Incidences for existing sensitisation were 3 % (n=9986), 2.5 % (n=120) and 3.5 % (n=255) in dermatitis patients and 1.8 % (n=23564) in workers without contact dermatitis. In addition, dose-response data is available indicating a LOAEC for elicitation at 0.025 % (w/w) formaldehyde with a NOAEC (response rate ≤ 5 %) at 0.005 % (w/w).

However, the currently available methodology is not considered suitable for derivation of an acceptable exposure level protecting from sensitisation by formaldehyde which is relevant to human health. Nevertheless, the available data is in support of the current legal classification limit for formaldehyde formulations of ≥ 0.2 % (w/w) with regard to its sensitising properties

and the resulting labelling provisions with EUH208 at ≥ 0.02 % (w/w).

Respiratory sensitisation

Regarding respiratory sensitisation, the majority of studies and reports in humans were not able to detect a relationship between asthma or allergic respiratory diseases and specific IgE antibodies against formaldehyde. This is supported by animal studies investigating IgE, IL-10 and IFN-gamma responses. Thus, the available data appear not to be sufficient to classify formaldehyde for respiratory sensitisation.

Short-term Toxicity

The submitted repeated dose studies generally suffer from a lack of guideline-conform reporting with respect to organs other than those that come into direct contact with formaldehyde in the process of substance administration, i.e. the stomach for oral and the respiratory tract for inhalation exposure. Such deficiencies severely constrain any independent evaluation of systemic toxicity of formaldehyde after repeated administration.

In rats, local effects after oral administration of paraformaldehyde via drinking water were observed in the forestomach (focal hyperkeratosis) and the glandular stomach (focal gastritis) and decreased plasma levels of albumin and total protein were seen at an exposure level of 125 mg/kg bw/day. The NOAEL for these effects was 25 mg/kg bw/day, but histopathology was not complete.

Two oral 90-day studies in rats and dogs reported reduced body weight gains from a dose level of approximately 100 mg/kg bw/d and suggested a NOAEL of approx. 50 mg/kg bw/d for both species. No local lesions were reported in the subchronic tests. An overall NOAEL of 15 mg/kg bw/d for local and systemic effects is derived from the limited subacute and subchronic, and a full chronic study in rats. This value also covers the effects reported from the 90-day dog study.

Data on toxicity after repeated dermal exposure to formaldehyde-containing solutions is limited. A NOAEC of 0.1 % has been previously derived based on reversible skin irritation following 3 weeks administration of 0.5 % formaldehyde in female mice with local observation of the application site.

Local effects on the epithelia of the respiratory tract were the main findings in rats, mice and cynomolgus monkeys after inhalation exposure to formaldehyde gas. The type of the lesions, squamous metaplasia and hyperplasia, was identical in all three species, indicating comparability of the mechanisms involved. Hamsters and mice appeared to be less sensitive.

In rats, at sufficiently high concentrations (≥ 12 µg/L), a single exposure for 6 hours resulted in vacuolar degeneration, cell necrosis, exfoliation and multifocal erosions of the nasal epithelium. These lesions progressed with repeated exposure, with ulcerations and inflammatory cell infiltrates being evident after 4 days and epithelial hyperplasia and metaplasia developing by day 9. A short-term NOAEC of 2.4 µg/L for local effects on the nasal epithelium may be derived from the study in rats treated for up to 42 days. A medium-term NOAEC of 1.2 µg/L is suggested by the results of 6-mo studies in rats and monkeys. Taking into account the dose-response after chronic inhalation exposure (LOAEC 2.4 - 7.2 µg/L), it is reasonable to conclude that the threshold dose for local lesions remains practically constant with increasing time, while the nature of the lesions reflects the progressing pathology. Hence, an overall (short/medium/long-term) inhalation NOAEC of 1.2 µg/L for local effects based on the 6-mo study in rats and monkeys is proposed.

There is evidence that inhalation exposure to formaldehyde concentrations exceeding the threshold for local inhalation toxicity may potentially be associated with systemic effects: changes in clinical chemistry parameters were indicative for possible adverse liver changes in

male rats.

Inhalation exposure of rats over 2 weeks caused a dose-dependent increase in plasma lipoxygenase, plasma protein carbonyls, plasma and liver lipid peroxidation as well as lymphocyte and liver cell DNA damage along with indications for an on-going inflammatory response. Other inhalation studies indicated adverse effects on the male reproductive system at exposure concentrations of 10 and 6 µg/L at the level of testis histopathology and serum testosterone, respectively. It is, however, unclear if the systemic effects discussed above are primary, i.e. directly resulting from formaldehyde or its metabolites, or secondary to local lesions and inflammatory reactions. This uncertainty is reflected by derivation of a systemic reference dose to protect from potential internal effects following prolonged exposure to low concentrations of the active substance.

Genotoxicity

In vitro tests:

Formaldehyde revealed mutagenic and clastogenic activity *in vitro* in bacterial and mammalian cell systems, including the Ames test, TK and HPRT tests, sister chromatid exchange assays, chromosomal aberration and micronucleus tests without metabolic activation.

Formaldehyde is known to induce single strand breaks and DNA-protein crosslinks (DPX) resp. DNA-DNA crosslinks which can cause base pair substitutions and deletions.

For DPX, time- and concentration-dependent repair of the lesions *in vitro* was reported.

***In vivo* tests:**

Local genotoxic effects at the site of first contact

Following gavage administration of formaldehyde, increases in micronuclei and other nuclear abnormalities in the epithelial cells of the stomach, but also in duodenum, ileum and colon in rats were observed.

After inhalation exposure to formaldehyde gas, the formation of DNA-protein cross-links (DPX) in the nasal epithelium has been demonstrated in rats and monkeys, as well as in the trachea, larynx and major airways of monkeys. In rats, at higher concentrations a steep dose-response relationship for DPX formation within the nasal mucosa suggests saturation of detoxification and/or repair mechanisms.

After repeated inhalation exposure of rats to formaldehyde an increase in chromosomal aberrations was reported in alveolar macrophages. In humans, there is evidence for clastogenicity in the nasal epithelium and in buccal cells after repeated exposure to formaldehyde.

Overall, there is convincing evidence, that formaldehyde exposure can induce local genotoxic effects at the site of contact.

Systemic genotoxicity:

Standard cytogenetic, micronucleus and comet assays failed to show systemic effects in samples of bone marrow or peripheral blood after inhalation exposure of rats and oral administration of formaldehyde in aqueous solution to mice.

Following i.p. injection of formaldehyde, a dose-dependent increase of sperm head abnormalities and genotoxic effects in germ cells were observed in rats and mice, respectively. It was noted that the relevance of this route is limited to hazard identification. Moreover, some older studies demonstrated mutations in *Drosophila melanogaster* germ cells.

Investigations on exposed human subjects resulted in negative, inconclusive or positive findings. An increase in the number of micronuclei and chromosomal aberrations in peripheral lymphocytes were reported following inhalation exposure to formaldehyde over 12 wks. Further studies assessing chromosomal aberrations, micronuclei and sister chromatid exchange in peripheral lymphocytes of exposed human subjects were extensively reviewed in 2006. For each of these endpoints, approximately balanced numbers of reliable studies indicating presence and absence of systemic genotoxicity were found.

A recent study revealed a possible influence of formaldehyde exposure on haematopoietic functions: a pancytopenic effect in exposed workers as well as a decrease in colony formation from progenitor cells in formaldehyde-exposed workers compared to workers in a non-exposed control group as well as increases in monosomy of chromosome 7 and trisomy of chromosome 8 - typical genetic aberrations for acute myeloic leukaemia (AML) - were observed in cultivated cells (*ex vivo)*.

Chronic Toxicity / Carcinogenicity

Currently, there is no evidence for carcinogenicity of formaldehyde when administered via the oral route. In an acceptable study with exposure of rats through drinking water, local effects in the forestomach (focal papillary epithelial hyperplasia, hyperkeratosis, ulceration) and the glandular stomach (atrophic gastritis, focal ulceration, glandular hyperplasia) and renal papillary necrosis was evident with a long-term oral NOAEL of 15 mg/kg bw/d (0.026 % in drinking water). No other tissues appeared to be affected and no treatment related tumours were reported.

Reconsidering the NOAEL of 25 mg/kg bw/d from the 28-d oral rat study and the effects observed at 125 mg/kg bw/d, it seems reasonable to assume that the threshold dose for local lesions remains practically constant with time, while the nature of the lesions reflects the progressing pathology. Hence, it is proposed to use the long-term NOAEL of 15 mg/kg bw/d as an overall value for subacute, subchronic and chronic oral exposure.

Preliminary data are available for the chronic exposure via the dermal route. In a mouse study over 60 weeks, concentrations of 1 and 10 % formaldehyde induced a slight hyperplasia of the epidermis and possibly some small skin ulcers at the higher dose level. No treatment-related tumours were detected in the skin or any other organ. However, the number of animals is insufficient to exclude a risk with an acceptable level of certainty. In another study, an initial dose of 50 µl of a 10 % formaldehyde solution was administered to the skin followed by thrice weekly applications of 100 µL 0.1, 0.5, or 1 % solution for 26 weeks in mice. No skin tumour formation but minimal local irritation of the skin was reported at concentrations of 0.5 and 1 %, but not at 0.1 %. This database is not found suitable to derive a long-term dermal NOAEC for formaldehyde.

Long-term inhalation exposure to formaldehyde induced local effects, ranging from inflammatory processes to mainly squamous cell carcinoma in the nasal cavity of male and female rats. Squamous cell carcinoma formation in the nasal epithelia became notable after 18-19 months of exposure to 12 µg/L and after approx. 12 months of exposure to 18 µg/L. The lowest concentration at which squamous cell carcinoma formation was observed was 7.2 µg/L.

In mice, squamous cell carcinoma was observed in animals exposed for 24 months to 18 µg/L formaldehyde. Lifetime exposure of hamsters to 12 µg/L formaldehyde in air for 5 h/d and 5 d/wk caused nasal epithelial metaplasia and hyperplasia in a small but significant number of animals.

In conclusion, experimental evidence in rats and mice demonstrates that long-term

formaldehyde gas inhalation causes tumours in the upper respiratory tract from exposure concentrations of 7.2 µg/L.

Taking into account the dose-response for non-neoplastic lesions after subacute, subchronic and chronic inhalation exposure, it can further be concluded that the threshold dose for local lesions remains practically constant with increasing time, while the nature of the lesions reflects the progressing pathology. Hence, an overall inhalation NOAEC of 1.2 µg/L for local effects based on the 6-mo studies in rats and monkeys is derived.

Reproduction Toxicity

Developmental Toxicity:

Data in rats and mice do not indicate a teratogenic potential of formaldehyde after systemic exposure. Maternal toxicity, manifesting as body weight loss, was observed in rats following inhalation exposure to 47 µg/L x 6 h/d. Embryofoetal toxicity was present at the same dose and resulted in decreased foetal weight and reduced or delayed ossification of thoracic vertebrae and sternal bodies.

A gavage study in pregnant mice provided evidence of severe maternal and slight embryo-foetal toxicity at a dose of 185 mg/kg bw/d. No relevant effects on the dam or the foetus were observed at the dose level of 148 mg/kg bw/d. Overall, there is no concern for developmental toxicity of formaldehyde.

Reproduction Toxicity:

No fertility studies performed in animals according to relevant OECD or EC guidelines have been submitted and the epidemiological data on reproductive effects in exposed humans are inconclusive.

Inhalation studies revealed effects on the male reproductive system including reduced testosterone production, reduced spermatogenesis, impaired sperm function and reduced GSH levels as well as increased rates of sperm abnormalities and elevated malone dialdehyde concentrations following exposure to ≥ 6 or 10 µg/L, indicating that the testis may be a target tissue for formaldehyde toxicity. Unfortunately, a NOAEC was not determined and animals have not been mated to assess effects on fertility.

Overall, the observations (and the absence of corresponding alerts within the human data) support the general presumption that effects on male reproductive functions may be relevant for inhalation exposure only at higher concentrations concurrent with other local and/or systemic toxicity.

Neurotoxicity

No evidence of neurotoxicity was reported in the repeated dose toxicity studies. However, studies conducted to assess specific behavioural consequences of formaldehyde inhalation in rats measured an acute decrease of exploratory behaviour and showed impairment of learning ability in a water maze test. Overall, the effects observed are considered to be related to an unspecific irritation of the nasal/olfactory mucosa and their relevance to human health remains unlikely.

Medical Data

Epidemiologic studies in humans have produced convincing evidence that formaldehyde has a carcinogenic potential in humans. Associations between inhalation exposure to formaldehyde and an increase in standardised mortality ratios (SMR) and/or relative risk (RR) were found for cancers of both, the upper respiratory tract (nasopharyngeal cancer) and the lymphatic system (especially myeloid leukaemia) in large cohort studies, respectively.

Cancers of the upper respiratory tract

In a cohort study, an increased incidence of nasopharyngeal cancer (NPC) was positively associated with exposure metrics (average intensity, peak exposure) that specify a high concentration of formaldehyde at the sensitive sites. An almost 2-fold excess of deaths due to nasopharyngeal cancer was observed in workers with high peak exposure as compared to the group of non-exposed workers and a 4-fold excess was observed for high cumulative exposure as compared to low-exposed groups working at the same production plant. The increases in RR did not gain statistical significance. However, trend tests for both exposure metrics were significantly positive indicating that tumour-related deaths were dose-related. Furthermore, the RR for selected upper respiratory tract tumours (6 tumour types including nasopharyngeal cancer) was significantly increased when an average intensity concentration of 1.2 µg/L (1 ppm) was exceeded.

In various case-control studies inconsistent results have been found. Some of them failed to show significant effects, whereas others and meta-analysis revealed significant increases in risks for cancer in the nasopharyngeal region.

Nevertheless, there is sufficient evidence to assume a causal relationship between formaldehyde exposure and induction of nasopharyngeal cancer in humans: Rodents and non-human primates show dose related cytotoxic-proliferative and metaplastic lesions with an anterior to posterior gradient and with species-specific distribution in rats and monkeys. In the most affected area, squamous cell carcinoma was induced in rats. Considering the upper respiratory tract epithelium as the target tissue, along with the physiological and anatomical differences between rodents and humans (e.g. breathing pattern and morphology of the upper respiratory tract), recent results from cohort-studies showing enhanced mortality rates of nasopharyngeal cancer in formaldehyde exposed workers are in line with the experimental data in rats. It is therefore proposed to classify air-borne formaldehyde as a human carcinogen.

Haematopoietic cancers

The results of recently published cohort studies support an association between both, high peak exposure as well as extended periods of formaldehyde exposure and neoplasms of the haematopoietic system. Other cohort studies and case control studies, however, failed to show such associations. Although the data base on *in vivo* genotoxicity studies on lymphocytes and progenitor cells was considered currently inconclusive, positive findings were typically reported in highly exposed humans and potential mechanisms for such effects were postulated.

Summary & Conclusion

Thresholds for carcinogenic effects

Regarding the carcinogenicity in the upper respiratory tract, the epidemiological data as well as the dose-response curve in animal carcinogenicity studies and previous dose-response modelling exercises clearly support the existence of a practical threshold.

According to the current understanding, a risk for potential induction of haematopoietic cancers by formaldehyde may be regarded unlikely in humans and animals at doses that do not saturate local detoxification at the site of first contact. This conclusion is confirmed by an assessment of the Committee on Mutagenicity of Chemicals in Food, Consumer Products and Environment which concluded that formaldehyde should be treated as genotoxic carcinogen with a practical threshold, allowing for derivation of reference values. This is supported by results from long-term studies in rats after inhalation exposure which provide no firm indications that formaldehyde is able to induce neoplasms of the haemotopoietic system in animals.

Derivation of Reference Values

The overall NOAEL of 15 mg/kg bw/d for subacute, subchronic and chronic oral exposure based

on stomach lesions, renal papillary necrosis and reduced body weight gain observed in rats following exposure to ≥ 82 mg/kg bw/d in the drinking water provides the relevant starting point for derivation of oral and systemic reference doses. By setting a default assessment factor (AF) of 100 and taking into account an oral absorption of 100 %, identical values for systemic exposure to formaldehyde are proposed. ADI and ARfD are not considered necessary based on the 2014 evaluation of the EFSA FEEDAP Panel (SCIENTIFIC REPORT OF EFSA, Endogenous formaldehyde turnover in humans compared with exogenous contribution from food sources. EFSA Journal 2014;12(2):3550). It concluded that the relative contribution of exogenous formaldehyde from consumption of animal products (milk, meat) from target animals exposed to formaldehyde-treated feed was negligible compared with formaldehyde turnover and the background levels of formaldehyde from food sources. This can also be assumed for animal products from animals exposed to formaldehyde-based biocidal products.

Acute Acceptable Exposure Level (AEL_{acute}) = 0.15 mg/kg bw/d
Medium-term Acceptable Exposure Level ($AEL_{medium\text{-}term}$) = 0.15 mg/kg bw/d
Long-term Acceptable Exposure Level ($AEL_{long\text{-}term}$) = 0.15 mg/kg bw/d

Due to the high reactivity of formaldehyde, local effects dominate the toxicity profile of the substance. Ocular (conjunctival) and nose/throat irritation were reported in humans at concentrations around 1 µg/L formaldehyde in the air. Lesions of the nasal epithelium were observed in rats at slightly higher exposure concentrations that correspond to inhaled doses of 1.8-3 mg/kg bw/d. This is considerably lower than the oral NOAEL forming the basis for the Systemic Reference Dose (see above). Therefore, additional external Acute Exposure Concentrations are derived for inhalation exposure.

The most sensitive endpoint in humans exposed by inhalation is subjective conjunctival (eye) irritation, for which an experimental NOAEC of 0.36 µg/L (acute) and a population based NOAEC of 0.12 µg/L (acute-chronic) have been concluded. An assessment factor of 3 accounting for intraspecies toxicodynamic variability would be used to derive an AEC of 0.12 µg/L from the recent acute study in human volunteers. This value is supported by the identical population based NOAEC concluded from an extensive evaluation of a collection of studies on workers, volunteers and exposed population.

In addition, the overall NOAEC of 1.2 µg/L based on degenerative and pre-neoplastic lesions of the nasal mucosa observed in rats and monkeys following subchronic exposure to formaldehyde gas concentrations of ≥ 3.6 µg/L for 22 h/day, as well as equivalent changes observed in rats following subacute or chronic exposure to similar formaldehyde concentrations provides another relevant starting point for the derivation of inhalation reference concentrations. The evaluated data including regulatory reviews support the view that humans are not more sensitive to local inhalation toxicity of formaldehyde than rats, allowing for reduction of the AF for interspecies extrapolation to 1.

Comparison of effect levels from studies of different duration suggest that the threshold levels remain constant, while the nature of the observed lesions may reflect a progressing pathology.

Therefore, identical **Acceptable Exposure Concentrations** are proposed for **acute**, **medium-term** and **long-term inhalation exposure**:

$AEC_{acute\ inhalation}$ = 0.12 µg/L air

$AEC_{medium\text{-}term\ inhalation}$ = 0.12 µg/L air

$AEC_{long\text{-}term\ inhalation}$ = 0.12 µg/L air

based on combined human and animal data.

This value provides a MoE of 20 between the proposed AEC and the NOAEC of 2.4 µg/L for carcinogenic effects in the upper respiratory tract observed in rats and mice at exposure concentrations not lower than 7.2 µg/L. Since it can be reasonably assumed that there is a practical threshold for the carcinogenicity of formaldehyde in the upper respiratory tract it is

therefore concluded, that the proposed AEC provides an acceptable level of protection from these effects.

Based on the reported data suggesting that effects of formaldehyde on internal organs, namely kidneys and testes, are associated with local toxicity, internal effects are unlikely to occur if exposure does not exceed the levels corresponding to the inhalation AEC: The proposed AEC of 0.12 µg/L provides a MoE of 50 to the lowest LOAEC of 6 µg/L for male reproductive effects in rats (no NOAEC est.). The proposed AEC further corresponds to an inhaled dose of approximately 0.01 mg/kg bw/d in working man with 8 h exposure per day, resulting in a MoE of 1500 to the oral NOAEL of 15 mg/kg bw/d for kidney toxicity in rats. Based on the steep dose-response relationship of formaldehyde with an early onset of prominent local effects, these margins are currently considered sufficient to provide adequate protection.

Irritation of the skin and sensitisation were observed following dermal administration of doses considerably lower than the oral NOAEL forming the basis for the Systemic Reference Dose. However, the current methodology regarding sensitisation is not considered suitable to derive a health-based dermal reference value (AEC dermal). Accordingly, risk assessment for skin irritating and sensitising properties follows the qualitative approach and is based on the respective classification and specific classification limits. As the methodology advances, a quantitative approach to the assessment of risk for local effects of formaldehyde on the skin may become feasible at the product authorisation stage based on the available dose-response information. For skin irritation, a NOAEC of 0.1 % (w/w) was derived from repeated dermal exposure of mice for 3 and 26 weeks. With regard to allergic reactions of the skin, a NOAEC of 0.005 % is suggested for elicitation in sensitised patients, while EC3 estimates of 0.33-0.96 % (w/w) in different matrices may provide a starting point for assessment of induction.

2.2.1.3. Exposure assessment

Task Force:

The active substance formaldehyde is produced within the EU as an aqueous solution (40 %). The biocidal product is the active substance as manufactured and is a dummy product. Formaldehyde is applied as aqueous solution for disinfection in veterinary hygiene.

The following scenarios are covered by the exposure assessment in this report:

- disinfection of animal housing – wet disinfection (scenario 1)
- disinfection of animal housing – fogging disinfection (scenario 2)
- disinfection of eggs – hatchery (scenario 3)
- disinfection of vehicles in epidemic cases (scenario 4)
- disinfection of animals' feet – footbath (scenario 5)
- secondary exposure towards the biocidal product. (scenario 6)

Before the different uses the 40 % formaldehyde solution are diluted to final 1.2 – 20 % formaldehyde disinfectant solutions. According to the participant, formaldehyde is intended for a wet disinfection (spraying/sprinkling application) in animal housing buildings (scenario 1). After the dilution of the biocidal product (40 % active substance) with water to a concentration of 1.2 % active substance, the solution is sprayed with low pressure. The following tasks have to be considered:

- mixing and loading of the formaldehyde to obtain the final disinfection solution

- application of the disinfection solution

- cleaning of equipment

It is assumed that the manual diluting step and the equipment cleaning is done outdoors. For mixing and diluting and cleaning of equipment (post-application) the inhalation exposure assessed using the ART model. The assessment of the inhalation exposure during spray application based on CONSEXPO 4.1 for the exposure to vapour and Model 2 (Spraying) of the *TNsG Human Exposure to Biocidal Products* (Part 2, p. 145) for the exposure to aerosol. The duration and the frequency of exposure to the active substance are assumed to be daily for 120 minutes per day. The dermal exposure could occur in all phases of the application process and is assessed with different models. The rapporteur assessed the dilution and loading and spraying with Model 2 (Spraying) of the *TNsG Human Exposure to Biocidal Products* (part 2, p. 145). A dermal exposure during cleaning of spray equipment (pot-application phase) is expected and is assessed with an analogy.

The second use (scenario 2) is disinfection of animal housing by fogging. The equipment is loaded with disinfectant outdoors, placed in the unit and started outside. The application itself is a fully automatic in a complete closed stable.

For dilution from a 40 % formaldehyde solution to a concentration of 16 % a.s. the inhalation exposure is based on using the ART model. During the fogging itself, during following ventilation and entering the room after ventilation inhalation exposure is not expected. The dermal exposure could occur only at the mixing and loading phase. The rapporteur assessed the dilution and loading step by Mixing & Loading Model 4 (TNsG part 2, p.136, TNsG Human Exposure 2008, p. 65, refined by use of new data available for the relating UK POEM Model). For the application and post-application dermal exposure is not expected.

In the following, typical disinfections in a hatchery are described (scenario 3). Disinfection of eggs takes place two times: once in the fumigation chambers (1. disinfection) and once in the hatchers (2. disinfection). Potential inhalation exposure is to be expected during mixing and diluting, loading the equipment and opening doors after residence time. The formaldehyde concentration is modelled on the basis of task specific parameters using CONSEXPO 4.1. The disinfection rooms (chamber and hatchers) are entirely sealed and followed by a ventilation period. It is assumed that when chambers or hatchers are opened no formaldehyde exposure is supposed to be present any more (due to the long ventilation period). The rapporteur assessed the dilution and loading step by Mixing & Loading Model 4 (TNsG part 2, p.136, TNsG Human Exposure 2008, p. 65, refined by use of new data available for the relating UK POEM Model). During the disinfection in chambers or hatchers no dermal exposure is expected. After the incubation and ventilation time all surfaces are dried and all spread formaldehyde/water is evaporated. It is assumed that one worker (disinfector) is involved in the described process.
The disinfection of vehicles with formaldehyde occurs only during an outbreak of an epidemic plague (scenario 4). It is performed outdoors at the entrance of the safety barrier by a spraying application. The mixing and loading of the formaldehyde is considered to be a dilution step from the 40 % product to 4 %. This dilution step is taken in a basin. And the disinfection solution is pumped to the spraying application and sprayed at all surfaces. The inhalation exposure is assessed for all phases done outdoors by using the ART model. Moreover, aerosol exposure by manual spraying has to be considered. For spraying the inhalation exposure is assessed with Model 2 Spraying (TNsG Human exposure part 2, p. 145, TNsG user Guidance document, p. 31). The dermal exposure could occur in all phases of the application process and is assessed with different models. The rapporteur assessed the dilution, loading and spraying with Model 2 (Spraying) of the *TNsG Human Exposure to Biocidal Products* (part 2, p. 145). A dermal exposure during cleaning of spray equipment (pot-application phase) is expected and is assessed with an analogy.

For disinfection of animals' feet a formaldehyde solution of 2 % are used in footbath on farms (Scenario 5). The first step is dilution and pouring of formaldehyde concentrate (40 %) in footbath. The concentrate is poured direct in water for dilution (indoor). The inhalation exposure is assessed with CONSEXPO 4.1. During the application itself the worker is present assuring the

cattle to move along the disinfection line and not bypassing. Disposal of used disinfection formulation and cleaning is assumed. Dermal exposure is also expected during the dilution step and during disposal of residues. It is not expected during the application. The dermal exposure for mixing and loading and post-application is assessed by Mixing & Loading Model 4 (TNsG part 2, p.136, TNsG Human Exposure 2008, p. 65, refined by use of new data available for the relating UK POEM Model).
For the described scenarios a detailed list of the exposure determinants and the models used is listed in Doc II B chapter 8.2.2 of the competent authority report.

Formaldehyde by spraying (scenario 1, scenario 4) and fogging (scenario 2) and disinfection of eggs in a hatchery (scenario 3) is applied by adequately trained professionals (for details please refer to section “Safety Measures for Professionals”).

Secondary exposure

At disinfection in animal housings (wet or fogging) and hatcheries (scenario 1-3) no bystanders are allowed entering premises during treatment and not involved in the treatment. Rooms have to be sealed and indirect exposure is omitted due to protection and safety requirements and long ventilation times. The general public will not enter the treated rooms or stables. From rapporteurs’ point of view a secondary exposure due to treated surfaces can be excluded.
Secondary exposure to formaldehyde vapour could occur if persons concerned by the epidemic plague (e.g. the farmer and his workers) or others allowed by authorities to attend the disinfection process. Usually this is not the case. Before entering a disinfection water gate adequately trained personal informs these people and additionally warning signs are mandatory to be set up, thus secondary exposure via inhalation is to be neglected. Dermal exposure might occur accidentally by contact to freshly disinfected surfaces with the palms of the hands. Nevertheless, this actually could only happen after the residence time, where the disinfectant is supposed to be evaporated.
In scenario 5 (animals’ foot disinfection) other persons than the professional are not expected to be present at mixing and loading and while cattle walking through the disinfection footbath.

Interhygiene GmbH:

The active substance formaldehyde and the biocidal product as an aqueous solution (24%) are produced within the EU. Formaldehyde is applied as aqueous solution for disinfection in veterinary hygiene.

The following scenarios are covered by the exposure assessment in this report

- disinfection of animal housing – wet disinfection, spraying (scenario 1)
- disinfection of animal housing – wet disinfection of small surfaces (scenario 2)
- secondary exposure to formaldehyde (scenario 3)

Formaldehyde is intended for a wet disinfection (spraying/sprinkled) in animal housing buildings (scenario 1). After the dilution of the biocidal product from a 24% formaldehyde solution to final 0.7 % formaldehyde disinfectant solution, the solution is sprayed by adequately trained professional user (for details please refer to section “Safety Measures for Professionals”) with low pressure. The following tasks have to be considered:

- mixing and loading of the formaldehyde to obtain the final disinfection solution

- application of the disinfection solution

- cleaning of equipment

It is assumed that the manual diluting step and the equipment cleaning is done outdoors. For mixing and diluting and cleaning of equipment (post-application) the inhalation exposure is assessed using the ART model. The assessment of the inhalation exposure during spray application is based on ConsExpo for vapour exposure and Model 2 (Spraying) of the TNsG Human Exposure to Biocidal Products (Part 2, p. 145) for aerosol exposure. The duration and the frequency of exposure to the active substance are assumed to be daily for 120 minutes per day. Dermal exposure could occur in all phases of the application process and is assessed with different models. The rapporteur assessed the dilution, loading and spraying with Model 2 (Spraying) of the *TNsG Human Exposure to Biocidal Products* (part 2, p. 145). A dermal exposure during cleaning of spray equipment (pot-application phase) is expected and is assessed with an analogy.

The second use (scenario 2) is wet disinfection of small surfaces using a broom (scrubbing). It is assumed that wiping is only done in a specific area before birth of an animal (estimated area of 10 m^2). The mixing and loading of formaldehyde is considered to be a dilution step. The assessment of the inhalation exposure during pouring and scrubbing with a broom based on ConsExpo. These values are only valid for professionals leaving the area immediately after disinfection.
Dermal exposure is expected to appear predominantly during the preparation of the disinfectant with 24 % formaldehyde by dilution to a 0.7 % formaldehyde water based solution due to splashes. The dilution and loading step is assessed by Mixing & Loading Model 4 (TNsG part 2, p.136, TNsG Human Exposure 2008, p. 65, refined by use of new data available for the relating UK POEM Model). For the application phase dermal exposure is expected to appear during pouring out of the disinfection solution on the floor and while scrubbing activities with a broom. The rapporteur assessed the potential dermal exposure with an approach of the ConsExpo Disinfectant Products Fact Sheet document (RIVM report 320005003, 2006). Here it is proposed to use the exposure scenario during pouring and brushing with algae removers (Chapter 3.3). All disinfection solution is used therefore no dermal exposure for the post-application phase is expected. The total duration is 20 min per day (2 events per day a 10 min).
For the described scenarios a detailed list of the exposure determinants and the models used is listed in Doc II B chapter 8.2.2.

For secondary exposure during disinfection in animal housings no bystanders are allowed entering premises and bystanders are not involved in the treatment. The general public will not enter the treated rooms or stables. Secondary exposure due to treated surfaces can be excluded due to the fast evaporation of the a.s.

Exposure of Non-Professionals

Primary Exposure
Non-professional use of formaldehyde is excluded. Therefore, non-professional primary exposure is not assessed.

Secondary Exposure

Task Force:

From all the application scenarios described by the applicant (disinfection in animal housings and hatcheries, vehicle disinfection, animals' foot disinfection) non-professional persons are not expected to be present. In particular, it is expected that the farmer is aware of the properties of formaldehyde and prevents access of children to the area where a footbath is installed. Therefore (although suggested by the applicant) the possibility of a visiting child immersing its hands into the formaldehyde solution and mouthing need not be considered.
Regarding the exposure scenario for footbaths, animals are directly exposed to the product. Therefore, relevant residues in animal products might be possible and the assessment for food products of animal origin should be finalised during product authorisation.

Animal exposure
In the animals' foot disinfection scenario described by the applicant, animals are directly exposed to the disinfection solution. Footbaths are applied to cattle and to sheep. It is assumed that a dairy cow represents the worst case as dairy cattle may walk through the footbath daily. Oral exposure is not considered relevant since cattle do not lick their hoofs and are not allowed to drink the disinfection solution. When walking through the bath, there will be dermal exposure to the disinfection solution containing up to 20 g/L formaldehyde. Inhalation exposure is assessed via the saturated vapour concentration (SVC). This represents a worst case as the active substance cannot achieve a higher concentration in the air. It can be concluded that the total systemic exposure (dermal + inhalation) is at most 0.29 mg/kg bw/d.

Table 2–8 Summary of Animal Exposure

	Value
Concentration on skin	2% (20 g/L)
Concentration in air	SVC = 0.18 mg/m3
Dermal systemic exposure	0.27 mg/kg bw/d
Inhalation systemic exposure	0.017 mg/kg bw/d
Total systemic exposure	0.29 mg/kg bw/d

With regard to animal welfare, the footbath scenario might result in sensitization. Therefore treatment should be minimized. For product authorization, an observational study should address the sensitizing potential of the treatment.

Interhygiene GmbH:

Secondary exposure of the general population from production or use of the biocidal product is not expected if appropriate risk mitigation measures are followed.

2.2.1.4. Risk characterisation

Risk Assessment for Professionals

Systemic effects

The risk characterisation for systemic effects of formaldehyde is performed with the AEL approach. In this approach total internal body burden is compared to the $AEL_{long\text{-}term}$ of 0.15 mg/kg bw/d. The long-term AEL is taken because repeated exposure at the workplace cannot be excluded for the use of formaldehyde. In the case of formaldehyde the values of acute, medium and long-term AELs are identical, because the frequency of exposure does not significantly influence systemic effects.

The AEL (an internal reference value) is based upon the oral NOAEL of 15 mg/kg bw/day (stomach: hyperkeratosis, ulcerations, atrophy, hyperplasia; renal papillary necrosis) from a 2 year chronic rat-study, and the knowledge of 100 % oral absorption rate. By using a default assessment factor of 100 an $AEL_{long\text{-}term}$ of 0.15 mg/kg bw/day is derived for long term exposure towards formaldehyde.

If the total internal body burden is lower than the reference dose, health risks leading to concern are not anticipated.

Local effects

Inhalation

Due to the high reactivity of formaldehyde, local effects especially after inhalation dominate the toxicity profile of the substance. Thus, in a second approach inhalation exposure as mean event concentrations are compared to the derived AEC in a quantitative risk characterisation for local effects after inhalation.

The AEC (an external reference value) is based upon the NOAEC of 1.2 µg/l for findings of degenerative and pre-neoplastic lesions of nasal mucosa in studies with rats and monkeys. By using an assessment factor of 10, an AEC of 0.12 µg/l (equivalent to 0.1 ppm) is derived for inhalation exposure towards formaldehyde.

If the inhalation exposure as mean event concentration is lower than the external reference dose, health risks leading to concern are not anticipated.

Dermal

Due to the skin sensitizing and skin corrosive properties of formaldehyde, a qualitative risk assessment for local dermal effects as well as semi-quantitative considerations about the sensitizing effects of formaldehyde are necessary. Based on the Guidance for Human Health Risk Assessment, Volume III – Part B, a local dermal risk assessment has been carried out in addition to the quantitative risk characterisations for systemic effects and local effects by inhalation. The local dermal risk assessment takes into account the concentrated biocidal product as well as the different dilutions thereof.

Regarding local dermal effects the active substance formaldehyde is classified as Skin Sens. 1; H317 and Skin Corr. 1B; H314. For classification of the different dilutions of formaldehyde the following specific concentration limits have to be considered:
Skin Corr. 1B, H314: C ≥ 25 %
Skin Sens. 1; H317: C ≥ 0.2 %
Skin Irrit. 2; H315: 5 % ≤C < 25 %
Eye Irrit. 2; H319: 5 % ≤C < 25 %
STOT SE 3; H335: C ≥ 5 %
A dermal NOAEC of 0.005 % for elicitation reactions was derived based on human Patch Test studies. In the study by Flyvhol et al. (1997), twenty formaldehyde-sensitive patients were exposed to concentrations starting from 25 ppm up to 10,000 ppm. At 250 ppm, patient no. 6 (5 %) showed weak reactions and this could be regarded as a LOAEC value. At 50 ppm, an elicitation reaction could not be detected in any of the patients examined (≤ 5 %). Thus, according to this study, 50 ppm could be regarded as a NOAEC value for elicitation.
Concluding qualitatively on the acceptability of risk, the acceptable maximum frequency and duration of potential exposure and potential degree of exposure for the particular hazard category is taken into account (Table 28 from Guidance for Human Health Risk Assessment). For the hazard category “high” the duration of potential dermal exposure should last for few minutes per day or less and a high level of containment, practically no exposure should be achieved.

Task Force:

Systemic effects

Although risk mitigation measures (protective gloves, protective coverall, RPE) are taken into account, exposure values in scenario 1 (disinfection in animal housings – wet disinfection) and scenario 4 (disinfection of vehicles in epidemic cases) still exceed the $AEL_{long\text{-}term}$. Therefore, no safe use is identified for these scenarios in the risk characterization for systemic effects.

If risk mitigation measures (protective gloves, RPE) are taken into account (tier 2) for scenario 2 (disinfection in animal housing – fogging disinfection), scenario 3 (disinfection of eggs - hatchery) and scenario 5 (disinfection of animals’ feet – footbath), the estimated exposure is below the reference value and safe uses are identified.

Local effects

Inhalation

To conclude on the acceptability of the scenarios considered it is essential to know, if the inhalation exposure of the professional user is sequential. In the case of formaldehyde a sequential exposure via inhalation is assumed. Therefore, no safe use is identified for scenario 1 (disinfection of animal housing – wet disinfection) and scenario 4 (disinfection of vehicles in epidemic cases) in the risk characterisation for local effects after inhalation.

For the other professional exposure scenarios (scenario 2: disinfection of animal housing – fogging disinfection, scenario 3: disinfection of eggs – hatchery and scenario 5: disinfection of animals' feet - footbath) mean event concentrations in all considered phases are below the reference value, at least in tier 2 after taking into account risk mitigation measures (RPE). Thus safe uses are identified for these scenarios.

Dermal
During spraying in scenario 1 (disinfection in animal housing – wet disinfection) actual body exposure is assumed to occur in large amounts of diluted formaldehyde solution. Moreover the duration of exposure is assumed to be 120 min. For the hazard category "high" it is required to reduce the dermal exposure to few minutes per day and a high level of containment (practically no exposure) is necessary. Therefore it is assumed that during spraying of 1.2 % formaldehyde a risk of adverse health effects regarding local dermal effects cannot be reduced to an acceptable level.
Due to the automation of the fogging process in scenario 2, the occurrence of dermal exposure is prevented but could occur incidentally. For the mixing and loading and application phase appropriate PPE should be used by the professional user[2]. Assuming PPE, good hygiene practice and use of automated fogging system the dermal exposure to formaldehyde can be avoided and the risk of adverse health effects regarding local dermal effects can be reduced to an acceptable level.
During disinfection of eggs (scenario 3) dermal contact to 40 % formaldehyde lasts for few minutes per day.
For the application phase appropriate PPE should be used by the professional user[2]. Assuming PPE and good hygiene practice the dermal exposure to formaldehyde can be avoided and the risk of adverse health effects regarding local dermal effects can be reduced to an acceptable level.
In scenario 4 (disinfection of vehicles in epidemic cases) a high degree of training of the professional user is assumed. Furthermore, the application is limited to exceptional cases. Assuming PPE and good hygiene practice the dermal exposure to formaldehyde can be avoided and the risk of adverse health effects regarding local dermal effects can be reduced to an acceptable level.
Assuming PPE and good hygiene practice the dermal exposure to formaldehyde can be avoided in scenario 5 (disinfection of animals' feet – footbath) and the risk of adverse health effects regarding local dermal effects can be reduced to an acceptable level.

Conclusion (Task Force)
The occupational risk assessment for formaldehyde takes into account systemic effects as well as local effects of the active substance. In addition to the systemic risk characterisation which is carried out with the AEL approach a risk characterisation for local effects after inhalation exposure is performed with an AEC as reference value. To assess the local dermal effects of formaldehyde a qualitative risk assessment according to the Guidance for Human Health Risk Assessment, Volume III – Part B is carried out.
In summary, the following table gives an overview of the conclusions of the three different risk characterisations which are carried out for formaldehyde. The acceptability for each scenario in each risk assessment is shown to be able to conclude for the overall assessment of the active substance formaldehyde.

Scenario	Conclusion risk assessment systemic effects	Conclusion risk assessment local effects via inhalation	Conclusion risk assessment local dermal effects	Overall conclusion	Included RMM
1 - disinfection of animal housing – wet disinfection	not acceptable	not acceptable	not acceptable	not acceptable	Protective gloves and coverall, RPE, safety

[2] professional adequately trained

					goggles[1)]
2 - disinfection of animal housing – fogging disinfection	acceptable	acceptable	acceptable	acceptable	Protective gloves, RPE, safety goggles[1)], automated fogging system
3 – disinfection of eggs - hatchery	acceptable	acceptable	acceptable	acceptable	Protective gloves, RPE, safety goggles[1)]
4 - disinfection of vehicles in epidemic cases	not acceptable	not acceptable	acceptable	not acceptable	Protective gloves, RPE, safety goggles[1)], automated fogging system
5 - disinfection of animals' feet - footbath	acceptable	acceptable	acceptable	acceptable	Protective gloves, RPE, safety goggles[1)]

[1)] In addition safety goggles have to be worn due to local effects if no full face mask as respiratory protective equipment (RPE) is worn. Personal protective equipment (PPE) shall be substituted by engineering, technical and/or administrative equipment according to Dir.98/24/EC and Dir.2004/37/EC if possible.

For the following exposure scenarios the risk assessment does not indicate a concern taking into account the above prescribed protection measures: scenario 2 (disinfection of animal housing – fogging disinfection), scenario 3 (disinfection of eggs – hatchery), and scenario 5 (disinfection of animals´ feet – footbath). Regarding these three scenarios, the risk characterisation is considered to be sufficiently comprehensive and reliable. It is essential to indicate, that the conclusion only applies to the active substance in the biocidal product (and not to other ingredients).

For the other scenarios (scenario 1 (disinfection of animal housing – wet disinfection) and scenario 4 (disinfection of vehicles in epidemic cases) concern is expressed despite the described risk mitigation measures.

Interhygiene GmbH**:**

Systemic effects

Although risk mitigation measures (protective gloves, protective coverall, RPE) are taken into account, exposure values in scenario 1 (disinfection in animal housings – wet disinfection) still exceed the $AEL_{long\text{-}term}$ by a factor of 1.01. Therefore, no safe use is identified for this scenario in the risk characterization for systemic effects.

If risk mitigation measures (protective gloves, protective coverall, RPE) are taken into account (tier 2) for scenario 2 (disinfection in animal housing – wet disinfection, small surfaces), the estimated exposure is below the reference value and a safe use is identified.

Local effects
Inhalation

To conclude on the acceptability of the scenarios considered it is essential to know, if the inhalation exposure of the professional user is sequential. In the case of formaldehyde a sequential exposure via inhalation is assumed. Therefore, no safe use is identified for scenario 1 (disinfection of animal housing – wet disinfection) in the risk characterisation for local effects after inhalation.

For the other professional exposure scenario (scenario 2: disinfection of animal housing – wet disinfection, small surfaces) mean event concentrations in all considered phases are below the reference value. Thus a safe use is identified for this scenario.

Dermal

During spraying actual body exposure is assumed to occur in large amounts of diluted formaldehyde solution in scenario 1 (disinfection of animal housing – wet disinfection). Moreover the duration of exposure is assumed to be 120 min. For the hazard category “high” it is required to reduce the dermal exposure to few minutes per day and a high level of containment (practically no exposure) is necessary. Therefore it is assumed that during spraying of 0.7 % formaldehyde a risk of adverse health effects regarding local dermal effects cannot be reduced to an acceptable level.

Under the prerequisite that appropriate PPE is worn and the professional user is trained in removing and maintaining the protective clothing/gloves, the occurrence of exposure should be considered as incidental and acceptable in scenario 2 (disinfection in animal housing – wet disinfection, small surfaces). Assuming PPE and good hygiene practice the dermal exposure to formaldehyde can be avoided and the risk of adverse health effects regarding local dermal effects can be reduced to an acceptable level.

Conclusion (Interhygiene)

The occupational risk assessment for formaldehyde takes into account systemic effects as well as local effects of the active substance. In addition to the systemic risk characterisation which is carried out with the AEL approach a risk characterisation for local effects after inhalation exposure is performed with an AEC as reference value. To assess the local dermal effects of formaldehyde a qualitative risk assessment according to the Guidance for Human Health Risk Assessment, Volume III – Part B is carried out.

In summary, the following table gives an overview of the conclusions of the three different risk characterisations which are carried out for formaldehyde. The acceptability for each scenario in each risk assessment is shown to be able to conclude for the overall assessment of the active substance formaldehyde.

Scenario	Conclusion risk assessment systemic effects	Conclusion risk assessment local effects via inhalation	Conclusion risk assessment local dermal effects	Overall conclusion	Included RMM
1 - disinfection of animal housing – wet disinfection	not acceptable	not acceptable	not acceptable	not acceptable	Protective gloves and coverall, RPE, safety goggles
2 - disinfection of animal housing – wet disinfection, small surfaces	acceptable	acceptable	acceptable	acceptable	Protective gloves and coverall, RPE, safety goggles

1) In addition safety goggles have to be worn due to local effects if no full face mask as respiratory protective equipment (RPE) is worn. Personal protective equipment (PPE) shall be substituted by

engineering, technical and/or administrative equipment according to Dir.98/24/EC and Dir.2004/37/EC if possible.

For the following exposure scenario the risk assessment does not indicate a concern taking into account the above prescribed protection measures: scenario 2: disinfection of animal housing – wet disinfection, small surfaces. For description of the required measures please refer to chapter 15.1.2.3. Regarding this scenario, the risk characterisation is considered to be sufficiently comprehensive and reliable. It is essential to indicate, that the conclusion only applies to the active substance in the biocidal product (and not to other ingredients).

For the other scenario (scenario 1: disinfection in animal housing – wet disinfection) concern is expressed despite the described risk mitigation measures.

Safety Measures for Professionals

For disinfection of animal's housings in the acceptable scenarios (Task Force-scenario 2, 4, 5, disinfection by fogging in animals housing, of vehicles in epidemic cases, and of animal's feet by footbath, and Interhygiene-scenario 2, wet disinfection of small surfaces in animal's housings), safety measures have to be taken because of systemic reasons as well as corrosiveness and sensitizing properties of formaldehyde.
If no other means for control are possible, the following personal protective equipment (PPE) has to be worn during all acceptable scenarios of Task Force as well as Interhygiene GmbH:

- Protective gloves (providing 90 % protection according HEEG opinion No.9)
- Respiratory protective equipment (RPE), protection factor 20 (according 'Guidance on the BPR', Vol.III, Part B, Version 1.1, 04/2015, table 18, p.194f): full face mask plus gas filter or powered helmet/hood TH2,
- Safety goggles (if, for any reason, no fullface mask is worn).

In the Interhygiene scenario 2, wearing of a chemically protective coverall (class III according Dir. 89/868/EEC) is necessary, additionally. The type of coverall (No.1 - 6) depends on the occurring form of exposure (e.g. splashes).
For product authorisation, effective engineering, technical, and/or administrative risk mitigation measures shall be described, e.g.

- automated mixing and loading (e.g. lost cartridges, dosing pumps etc.), ready-to-use products (instead of concentrates),
- automated application methods for use of formaldehyde concentrations above 0.05 %
- robot-supported application methods or a telecommanded vehicle or
- an automatic car wash site,
- spray application by persons limited to corners and crevices,
- a safety and health concept including a certificate for the user by national competent authorities comparable to German TRGS 522 presented by the participant,

a concept for deduction of risk mitigation measures for the handling of carcinogens according to the German Announcement on Hazardous Substances (BekGS) No. 910.

An "adequately trained professional" for fumigation and spraying of formaldehyde (including use in sterilizers and incubators e.g. in hatchery) is expected to be experienced in regard to:

a. procedures and equipment technology (e.g. effectiveness, resources supply, wear parts),
b. legal basis (infection protection, occupational safety, chemical agents law, etc.),
c. intrinsic properties of formaldehyde (e.g. mode of action, thresholds, storage capability of materials),
d. first aid (e.g. poisoning symptoms, reanimation, procedural measures, e.g. water supply, emergency access),
e. work stages:
    i. prearrangement (e.g. sealing, constructional aspects, delimination of a danger zone, labelling of fumigated objects),
    ii. fumigation (e.g. procedure, safety technology, measures concerning malfunction),

iii. airing (e.g. impact on the environment, legal aspects),
iv. clearance measurement and declaration of decontrol (including on-going degassing of some materials).

f. Measurement technology (adequate devices and techniques, calibration, maintenance, error sources, reports).

Based on national regulation e.g. in Germany the “adequately trained professional” is certified and the reliability (proven by a police clearance certificate) and mentally-physically fitness (proven by a personal medical attendance report, including odour perception and fitness for wearing of respiratory protection) is proven.

Risk Assessment for Non-Professionals

Task Force:

As non-professional exposure is not expected, no health risk is expected.

Regarding the exposure scenario for footbaths, animals are directly exposed to the product. Therefore, relevant residues in animal products might be possible and the assessment for food products of animal origin should be finalised during product authorisation.

Interhygiene GmbH:

Non-professional use of the biocidal product is not intended.

Secondary exposure of the general public using the biocidal product is not expected if the following points are taken into account.

Re-entry of the general public should only be allowed after completion of treatment including an appropriate waiting period. After this period the concentration of the active substance in the building should be below the corresponding reference value (0.12 µg/L). A generally appropriate waiting period could not be determined by the information provided by the applicant. Therefore, this information has to be submitted for national authorisation.

Indirect exposure outside of treated buildings or rooms is considered unlikely if they are sealed appropriately and are kept closed until the concentration of the active substance in the building is considered acceptable for re-entry (0.12 µg/L).

Risk Assessment for Animals

Task Force:

In the scenario of daily walking through a footbath, the MOS for systemic exposure is 52. This might be considered sufficient to ensure animal welfare. Inhalation exposure will be below AEC unless possibly in the direct vicinity of the footbath. When walking through the footbath, the hoof is dermally exposed to the solution containing up to 2% formaldehyde. According to Regulation (EC) No 1272/2008 this concentration is not classified as irritating but it is considered skin sensitising (H317). As the product is used for preventive treatment of hoof rot it is assumed that the benefits for the animals outweigh the possible sensitisation.

Safety Measures for Non-Professionals

Task Force:

As non-professional exposure is not expected, no special measures are necessary when treatment is performed as described by the applicant.

Interhygiene GmbH:

The above mentioned conditions can only fulfilled if the corresponding risk mitigation measures are communicated appropriately on the label or the instructions of use. Thus, for national authorisation the applicants have to provide sufficient information on this topic.

Safety Measures for Animals

Task Force:

Treatment should be minimised. Observational studies could reveal if remarkable sensitising effects exist. Animals should not be allowed to drink the disinfection solution

2.2.2. Environmental Risk Assessment

The estimation of predicted environmental concentrations (PECs) as well as the derivation of predicted no effect concentrations (PNECs) were performed for all relevant environmental compartments according to the Emission Scenario Document (ESD) for veterinary hygiene biocidal products PT 03 (EC 2011) and the EU Technical Guidance Document (TGD) on Risk Assessment (EC 2003), respectively. As two dossiers have been submitted in order to support an Annex I inclusion of formaldehyde in product type (PT) 03, the RMS decided to present the results of the environmental risk assessment for both application in a combined document (Doc. I). In the following, the consortium EWABO/Lysoform/Synthite and the applicant Interhygiene are referred to as Task Force and Interhygiene GmbH, respectively.

2.2.3. Fate and distribution in the environment

Biodegradation

Formaldehyde was shown to be ready biodegradable fulfilling the 10d-window criterion. Nearly the whole dissolved organic carbon (99%) was degraded in a DOC Die-away test (OECD guideline 301 A) after 28 days, of which more than 90 % DOC have already been degraded on day five. Further supportive information underlines the rapid biodegradation of formaldehyde under different test conditions (OECD 301 D, C). In simulation tests of industrial STPs, formaldehyde was eliminated to a high extent under aerobic and anaerobic conditions. Due to the ready biodegradability of formaldehyde, no higher tier degradation studies in water, water/sediment and soil are required.

Abiotic Degradation

Hydrolysis of formaldehyde can be excluded because of the absence of a hydrolysable group in the molecule. At room temperature formaldehyde undergoes complete hydration in water, forming the formaldehyde hydrate methylene glycol. As a hydrate formaldehyde has no chromophore that is capable of absorbing sunlight and thus should not decompose by direct photolysis in water. The UV spectrum of formaldehyde indicates a weak absorption of light at wavelengths between 240 and 360 nm assuming possible direct photolysis of formaldehyde in water and air. However, photolysis in air seems to be of minor importance in comparison to the ready biodegradability of formaldehyde in aqueous medium. In the air compartment, formaldehyde is susceptible to direct photolysis and in addition, formaldehyde is rapidly degraded via reaction with OH radicals.

Distribution and Mobility

Based on the half-life constants of formaldehyde in air ranging between 0.17 – 1.97 d, accumulation and long range transport in the atmosphere are not expected. The Henry's law constant (0.034 Pa at 25°C) as well as the vapour pressure of formaldehyde in aqueous solutions (187 Pa) is relatively low. Therefore, formaldehyde is not expected to volatilise to air from water

surfaces in significant quantities and the amount which reaches the air compartment will be washed out by rain. Unacceptable effects on global warming and stratospheric ozone depletion are not likely. Moreover, formaldehyde is not considered to adsorb onto soil or sediment. The adsorption coefficient (K_{OC}) was estimated to be 15.9 L/kg. Accordingly, only a weak adsorption to sediment or soil and a high mobility in these compartments is assumed.

Bioaccumulation

An approximate estimation of the bioconcentration factor in fish and earthworm was performed on basis of log K_{ow} = 0.35 according to the equations given in EU TGD (EC, 2003). Both resulting BCF values were below 1, indicating that formaldehyde has only a low bioaccumulation potential for aquatic and terrestrial organisms. In consequence of the log K_{OW} < 3 and the low estimated BCF values, experimental studies are not required. Moreover, formaldehyde is not surface active or has other properties which point to an intrinsic potential for bioconcentration. With regard to the low estimated BCF values in aquatic and terrestrial indicator species, formaldehyde is not expected to accumulate in the environment.

2.2.4. Effects assessment

Aquatic Compartment

Formaldehyde is toxic to aquatic organisms. The sensitivity of fish, invertebrates and algae, representing the three trophic levels, is nearly identical in short-term tests. The lowest acute LC_{50}/EC_{50} and E_rC_{50} values for these organisms range between 5.7 mg/L for algae and fish and 5.8 mg/L for *Daphnia pulex*. Only one long-term study is available for formaldehyde. In a long-term study on the reproduction of *Daphnia magna* a NOEC of 1.04 mg/L (based on age of first reproduction) was determined. On this basis a $PNEC_{water}$ of 10.4 µg/L was estimated using an assessment factor of 100.

With an EC_{50} value of 20.4 mg/L formaldehyde had a toxic effect on micro-organisms in a sewage treatment plant (STP). The $PNEC_{STP}$ for micro-organisms is 0.2 mg/L.

Sediment

Formaldehyde is not expected to adsorb onto the sediment (Koc = 15.9 L/kg) and no tests with sediment-dwelling organisms have been provided by the applicants. Therefore, the risk characterisation for the sediment compartment is already covered by the risk characterisation for surface water**.**

Terrestrial Compartment

In the absence of valid experimental data with terrestrial organisms, the $PNEC_{soil}$ of 4.16 µg/kg ww was derived from the $PNEC_{water}$ using the equilibrium partitioning method according to the TGD.

2.2.5. PBT and POP assessment

Formaldehyde is neither persistent or bioaccumulative nor toxic in terms of the PBT assessment. Formaldehyde is readily biodegradable fulfilling the 10 d-window criterion, the estimated BCF values for aquatic and terrestrial organisms are both less than 1 and the lowest NOEC is 1.04 mg/L. In conclusion, formaldehyde does not fulfil any of the three criteria and is therefore not a PBT-substance.

2.2.6. Exposure assessment

For the environmental exposure assessment of the representative biocidal product (b.p.) the following life cycle stages are considered to be relevant:

- production of a.s.
- application of the b.p. as an aqueous solution for the disinfection of (i) animal housings, (ii) hatcheries, (iii) vehicles (in case of an epidemic) and (iv) animals' feet
- waste treatment

While the Task Force submitted a dossier for each of the above mentioned uses, Interhygiene GmbH only applied for the use of formaldehyde in animal housings. The representative b.p. is the active substance as manufactured (formaldehyde 40%, cf. Doc III B2) and, therefore, a scenario for the formulation step has been considered unnecessary. For the application of formaldehyde as disinfectant for veterinary hygiene purposes the following major environmental exposure pathways have been identified:

- release of formaldehyde to air as a result of its application by e.g. fogging/fumigation or wet disinfection and due to volatilization from treated surfaces in animal housings and hatcheries
- release of waste water containing formaldehyde to the sewage system after disinfection of transport vehicles (in case of an epidemic) and animals' feet
- release from slurry/manure after disinfection of animals' feet

Subsequently affected environmental compartments via application of sewage sludge and manure/slurry as well as atmospheric deposition are soil and ground water. Surface water and sediment are concerned by the effluent of the sewage treatment plant. Even though PEC values have been calculated for the sediment this compartment has been disregarded within the environmental risk characterisation because formaldehyde is not expected to adsorb onto the sediment and the sediment compartment is already covered by the risk characterisation for surface water. The requirements for an aggregated exposure estimation was checked. In summary, it has been concluded that an aggregated exposure assessment for formaldehyde has to be performed neither within PT 03 nor between other PTs. The PEC calculations for each environmental compartment in the corresponding use scenario are presented in Doc II-8.3.

2.2.7. Risk characterisation

The calculated PEC/PNEC ratios for each intended use and the respective environmental compartments are summarised in Table 2-14. Refined PEC/PNEC ratios taking into account risk mitigation measures (i.e. disposal of left-over formaldehyde solution as hazardous waste by specialised companies) as proposed by the applicant A for the disinfection of vehicles (in case of an epidemic) and animals' feet are only presented for the vehicle disinfection scenario. This is due to the fact that no data on the feasibility of this measure has been provided by the applicant for the animals' feet scenario and the RMS has doubts that a disposal as hazardous waste is a practical measure to avoid emissions to the environment in this scenario.

Table 2-9: Summary of PEC/PNEC ratios for the use of formaldehyde as a disinfectant in PT03. For ground water only the relevant PEC values are given, as no PEC/PNEC

ratios are calculated for this compartment.

	Scenario				
PEC/PNEC ratio	**animal housings***	**hatcheries**	**vehicle disinfection (in case of an epidemic)**		**animal's feet**
			without RMM	**with RMM****	
STP	-	0.035	67.5	-	2.2
Surface water	-	0.07	16.3	-	4.3
Soil	0.005	0.1	9.2	0.004	2.4[a)] / 301[b)]
Ground water	0.052	0.075	28.7	0.038	7.5[a)] / 3124[b)]

* The intended use of formaldehyde as a disinfectant in animal housings is applied for by applicant A and B

** Refined PEC/PNEC ratios considering the risk mitigation measure (RMM) that remaining quantities of the formaldehyde solution are collected and disposed of separately (data provided by the applicant)

a) Emission to soil via sewage sludge application
b) Emission to soil via slurry/manure application

Aquatic Compartment including STP

No unacceptable risks are indicated for the environmental compartments STP and surface water when formaldehyde is being used as a disinfectant in animal housings and hatcheries.

However, PEC/PNEC ratios for STP and surface water of > 1 are calculated for the use scenarios "disinfection of vehicles (in cases of an epidemic)" and "disinfection of animals' feet" as applied for by the Task Force, indicating that formaldehyde pose an unacceptable risk to aquatic organisms and microorganisms at the STP (see Doc. II-C, chapter 13).

Terrestrial Compartment including Groundwater

Emissions of formaldehyde to the soil occur via the application of sewage sludge or slurry/manure and additionally via aerial deposition in the various scenarios of the use phase. No unacceptable risks have been identified for the scenarios "animal housings" and "hatcheries". However, the environmental risk assessment for the scenarios "disinfection of vehicles (in case of an epidemic)" and "animals' feet" has indicated risks for the soil compartment as well as the ground water.

Atmosphere

A qualitative risk assessment has been carried out for the atmosphere compartment. As a worst case the total annual average formaldehyde concentration in air resulting from all uses (~ 2.3 µg/m^3) has been considered. Even though photochemical degradation of formaldehyde might lead to increased ozone levels in the troposphere and may also contribute to the acidity of precipitation by forming formic acid, based on the estimated half lives of 0.17 d and 1.97 d for direct photolysis and indirect photolysis, respectively, only a short atmospheric lifetime can be assumed and neither accumulation of formaldehyde in the air nor long-range transport are to be expected. It was therefore concluded that formaldehyde emissions to air from its use as a biocide can be neglected.

Conclusion from the risk characterisation

While no unacceptable risks have been identified within the environmental risk characterisation for the scenarios “animal housings” and “hatcheries”, it has been shown that all relevant environmental compartments are at an unacceptable risk in the scenarios “disinfection of vehicles (in case of an epidemic)” and “disinfection of animals’ feet”. It has to be noted that the unacceptable risks in the “animals’ feet” scenario has been identified even though specific data from the applicant instead of default values from the ESD for PT 03 has been taken into account for the PEC estimation.

Refined risk characterisation taking into account risk mitigation measures

As a risk mitigation measures (RMM) for the scenarios “disinfection of vehicles (in case of an epidemic)” and “disinfection of animals’ feet” applicant A suggested to collect the remaining quantities of formaldehyde after its use and to dispose of them as hazardous waste in order to avoid releases to the environment and thereby to mitigate the indicated risks. This RMM was evaluated quantitatively by the RMS within the risk characterisation. It was shown that formaldehyde does not pose a risk to the STP and surface water in the scenarios “disinfection of vehicles” and “animals’ feet”, if the formaldehyde solution is collected and disposed of as hazardous waste after its use. The refined PEC/PNEC ratios are all < 1 for the corresponding environmental compartments. Nevertheless, the RMS has doubts regarding the feasibility of the suggested measures, especially in the animals’ feet scenario. In contrast to the scenario “disinfection of vehicles”, no data which demonstrates the feasibility of this measure or any other information which proves that a safe disposal of left-over formaldehyde solution can be expected has been provided by the Task Force for the scenario “animals’ feet” (cf. Doc II-15.3).

As alternative application method for animals’ feet disinfection could be the use of disinfection mats. According to the applicant less amount of b.p. (app. 90 L per 300 animals) is needed when using these mats compared to 390 L per 300 animals for tubes. However, no detailed information has been provided by the applicant and no environmental risk assessment has been carried out for this scenario. It is suggested to assess the use of disinfection mats as an alternative to footbath at the stage of product authorisation.

With respect to the scenario “disinfection of vehicles (in case of an epidemic)” it has to be noted that the available information on the feasibility of the RMM in this use represents the disinfection procedure in Germany. No information is available to the RMS how the disinfection of vehicles in case of an epidemic is carried out in other EU Member States and whether a safe disposal of used formaldehyde solutions as hazardous waste is a suitable and practical risk mitigation measure with regard to national requirements.

For products used for the disinfection of vehicles (in case of an epidemic) as well as for the disinfection of animals’ feet further information or tests are recommended in order to refine the environmental risk assessment for formaldehyde:

i. One option to refine the exposure assessment is to provide information on the neutralisation or consumption of the active substance during the disinfection process. For the current exposure assessment it is assumed by default that all used formaldehyde enters the sewage system or manure/slurry after the treatment, because no information on the neutralisation or consumption of the active substance during the treatment is available.

ii. The current effect assessment of formaldehyde is based on three short-term tests (core data set) and one long-term study with invertebrates. Since a NOEC or EC10 cannot be derived from the submitted algae study, it is advised to conduct a new 72h growth inhibition test with algae (i.e. according to OECD Guideline 201) in order to obtain a second long-term effect value (NOEC or EC10) thereby reducing the assessment factor (AF) from currently 100 to 50. In addition, the refinement of $PNEC_{water}$ would also refine

the current calculation of PNEC $_{soil}$ which is estimated by the equilibrium partitioning method.

iii. Since no ecotoxicological tests with terrestrial organisms have been provided, the PNEC derivation for the soil compartment has been based on the $PNEC_{water}$ using the equilibrium partitioning method. The identified risk for the soil compartment in the use scenarios "disinfection of vehicles (in case of an epidemic" and "disinfection of animals' feet" could be refined by providing ecotoxicological data for terrestrial organisms.

2.2.8. Assessment of endocrine disruptor properties

According to the document "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment"[3], for reports submitted before 1 September 2013 the provisions of the BPD apply. Furthermore, a maximum approval period of five years is foreseen for substances that fulfil the ED criteria. Since the applicant has no obligation to provide lacking data with respect to the endocrine disruption properties of the active substance, the competent authority has to conclude on the data already provided by the applicant. In case the data is insufficient, the eCA may not be able to draw a comprehensive conclusion on the endocrine disruptor properties of that substance.

Since the evaluation of formaldehyde for PT 3 was submitted before 1 September 2013, requesting additional data would only lead to a delay without being able to finally conclude on the ED properties. Furthermore, formaldehyde already fulfils the exclusion criteria, thus, the regulatory outcome will not change. That means that in line with Article 19(4) of Regulation (EU) No 528/2012, any biocidal products containing formaldehyde will not be authorised for making available on the market for use by the general public. Furthermore, products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met. Thus, an assessment of the endocrine disrupting properties according to Regulation (EU) 2017/2100 was not conducted. The endocrine disrupting properties will be assessed in full detail in the scope of the renewal of the approval, where all relevant information can be requested from the applicant.

2.3. Overall conclusions

The outcome of the assessment for formaldehyde in product-type 03 is specified in the BPC opinion following discussions at the 13th and 33th meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2.4. List of endpoints

The most important endpoints, as identified during the evaluation process, are listed in Appendix I.

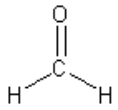
[3] See document: Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment (available from https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/48320db7-fc33-4a91-beec-3d93044190cc/details)

Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Name)	Formaldehyde
Product-type	Bactericide, fungicide and virucide

Identity

Chemical name (IUPAC)	Methanal, formaldehyde
Chemical name (CA)	Formaldehyde, methyl aldehyde, formalin, fomol
CAS No	50-00-0
EC No	200-001-8
Other substance No.	156 (CIPAC)
Minimum purity of the active substance as manufactured (g/kg or g/l)	25 – 55.5% in aqueous solution (minimum purity 87.5 % with regard to formaldehyde; dry weight)
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	≤ 7% Methanol < 0.1% Formic acid
Molecular formula	CH_2O
Molecular mass	30.0258
Structural formula	

Physical and chemical properties

Melting point (state purity)	-118°C to -92°C (formaldehyde gas) -15 °C (formalin (37%))
Boiling point (state purity)	-19.5 °C (1013 hPa) (formaldehyde gas) 96 °C (formalin (37w/w% aqueous solution, containing 10-15% methanol))
Thermal stability / Temperature of decomposition	No decomposition
Appearance (state purity)	colourless gas, pungent suffocating odour (formaldehyde gas) colourless liquid, irritating, pungent odour (formaldehyde solution (30-55% w/w))
Relative density (state purity)	$d_4^{20:}$ 0.815 (formaldehyde gas) 1.1346 g/cm3 at 25°C (aqueous solution: 50%formaldehyde, 7% methanol) 1.128g/cm³ at 20°C (formalin 37 % w/w)
Surface tension (state temperature and concentration of the test solution)	Formaldehyde is not surface active

Vapour pressure (in Pa, state temperature)	5490 hPa, 300 K (formaldehyde gas) 187 Pa, 25°C (formalin (37%))
Henry's law constant (Pa m^3 mol^{-1})	0.034 Pa*m^3/mol at 25°C (methanol-free formaldehyde, prepared from 37% formalin) (value is measured with *Bubble-Column technique*)
Solubility in water (g/l or mg/l, state temperature)	up to 55% (formaldehyde gas) (In aqueous solutions with a concentration > 55% formaldehyde polymerize irrecoverable to paraformaldehyde, Polymerization occur also at lower concentration's, the given value of up to 55% is based on the releasable formaldehyde content. (Therefore this is not a true solubility as this value is based on the polymerization effect.)
Solubility in organic solvents (in g/l or mg/l, state temperature)	Soluble in alcohol and ether (formaldehyde gas) At low temperatures soluble in all proportions in toluene, ether, chloroform, ethylacetate (liquid formaldehyde) complete soluble in ethanol, methanol and ethylenglycol at 20°C (37 %w/w total formaldehyde with <1.5 %w/w methanol)
Stability in organic solvents used in biocidal products including relevant breakdown products	Not applicable
Partition coefficient (log K_{OW}) (state temperature)	0.35 at 25°C (formaldehyde gas)
Dissociation constant	result: pKa = 13.27 (of hydrate), 25 °C (aqueous solution of formaldehyde; measurement is usually performed with aqueous formaldehyde dilution (for gas or solution))
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	330 (4), 318, (5), 308(5), 298 (4) nm (formaldehyde gas) Lambda maximum (λmax) at 988 nm (aqueous solution: 50%formaldehyde, 7% methanol) Absorption maxima at 230 and 300 nm (formaldehyde 37% w/w)
Flammability or flash point	Not flammable
Explosive properties	Not explosive
Oxidising properties	

Auto-ignition or relative self ignition temperature	

Classification and proposed labelling

with regard to toxicological data

Proposed classification of formaldehyde based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Carc. 1B Muta. 2 Acute Tox. 2 Acute Tox. 3 Acute Tox. 4 Skin Corr. 1B Skin Sens. 1A	
Hazard statements	H350 H341 H330 H311 H302 H314 H317	May cause cancer Suspected of causing genetic defects Fatal if inhaled Toxic in contact with skin Harmful if swallowed Causes severe skin burns and eye damage May cause an allergic skin reaction

Proposed labelling of formaldehyde based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	 GHS05  GHS06  GHS08	
Signal Word	Danger	
Hazard statements	H350 H341 H302 H311 H330 H314 H317	May cause cancer Suspected of causing genetic defects Harmful if swallowed Toxic in contact with skin Fatal if inhaled Causes severe skin burns and eye damage May cause an allergic skin reaction
Suppl. Hazard statements	EUH071	Corrosive to the respiratory tract
Precautionary statements	P201 P202 P272	Obtain special instructions before use Do not handle until all safety precautions have been read and understood Contaminated work clothing should not

		be allowed out of the workplace
	P281	Use personal protective equipment as required
	P301 + P330 + P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting
	P303 + P361 + P353	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing.
	P304 + P340	Rinse skin with water/shower
	P305 + P351 + P338	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
	P308 + P313	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
	P363	IF exposed or concerned: Get medical advice/ attention
	P403 + P233	Wash contaminated clothing before reuse
	P405	Store in a well-ventilated place. Keep container tightly closed
		Store locked up
	P501	Dispose of contents/container to …

Chapter 2:Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	The active substance is determined with the ISO 2227. The principle of the method is reaction of formaldehyde with sodium sulphite, and acidimetric titration of the liberated sodium hydroxide. The second possible method is the DNPH-method. The principle of the method is the derivatisation of formaldehyde with DNPH and the detection with HPLC.
Impurities in technical active substance (principle of method)	The impurity [redacted] is determined with an acid - base titration method. The ASTM Method D 2380-04 is used for the determination of Methanol. This method describes the calculation of the methanol content based on the relationship of specific gravity to formaldehyde and methanol content. Additionally the refraction index is measured. Furthermore a GC method used for the determination of Methanol is available.

Analytical methods for residues

Soil (principle of method and LOQ)	*Task Force:* Required at product authorisation unless exposure is excluded *Interhygiene:* not required, no relevant residues expected
Air (principle of method and LOQ)	residue definition: formaldehyde RP-HPLC-UV, RP18 column LOQ: 0.04 µg/m³
Water (principle of method and LOQ)	residue definition: formaldehyde GC-ECD, DB-5 and AT-1701 column LOQ: 0.08 µg/L (drinking water) LOQ: 5 µg/L (surface water)
Body fluids and tissues (principle of method and LOQ)	Monitoring is not meaningful since formaldehyde is permanently present in humans
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required, no relevant residues expected
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Required at product authorisation unless no relevant residues are expected.

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	100 % uptake, rapid (based on ^{14}C in exhaled air, urine and carcass), systemic bioavailability low (first-pass metabolism
Rate and extent of dermal absorption*:	100 % uptake (based on ^{14}C in excreta, organs and carcass, and on *in vitro* data on human skin), systemic bioavailability low (first-pass metabolism
Distribution:	^{14}C label widely distributed (introduction C1-pool)
Potential for accumulation:	No evidence for accumulation
Rate and extent of excretion:	Metabolic elimination, high, but variable rate and extent of metabolite excretion (based on ^{14}C) mainly with air and urine (initial plasma $t_{1/2}$ 12 h, terminal $t_{1/2}$ 50 h, 10-40 % ^{14}C residues after 3-4 d)
Toxicologically significant metabolite(s)	Toxicity of metabolites not assessed separately Urine: formate, hydroxymethylurea

* the dermal absorption value is applicable for the active substance and might not be usable in product authorization

Acute toxicity

Rat LD_{50} oral	640 mg/kg bw	Acute Tox. 4
Rat LD_{50} dermal	270 mg/kg bw	Acute Tox. 3
Rat LC_{50} inhalation	0.6 mg/L x 4 h	Acute Tox. 2

Skin corrosion / irritation	Corrosive	Skin Corr. 1B

Eye irritation	Corrosive	Eye Dam. 1

Respiratory tract irritation	yes

Skin sensitisation (test method used and result)	Sensitising	Skin Sens. 1A
	(GPMT, LLNA, human data)	
	EC3 (LLNA):	0.33-0.96 % (w/w)

Respiratory sensitisation (test method used and result)	No reliable data

Repeated dose toxicity

Short term

Species / target / critical effect	Rat (oral): Bw ↓; stomach: hyperkeratosis, gastritis; Dog (oral): Bw ↓ Mouse (dermal): Skin: irritation, fissuring, papules Rat (inhalation): Nasal epithelium: degeneration, necrosis, exfoliation, erosion, squamous metaplasia, hyperplasia	
Relevant oral NOAEL / LOAEL	28 day, rat: 25 / 125 mg/kg bw/d	
Relevant dermal NOAEL / LOAEL	3 wk, mouse:	0.1 / 0.5 % (w/w)
Relevant inhalation NOAEL / LOAEL	21 day, rat:	0.84 / 2.4 µg/L

Subchronic

Species/ target / critical effect	Mouse (dermal): Skin: irritation, fissuring, papules Rat/monkey (inhalation): Nasal epithelium: degeneration, necrosis, exfoliation, erosion, squamous metaplasia, hyperplasia	
Relevant oral NOAEL / LOAEL	no reliable data	
Relevant dermal NOAEL / LOAEL	26 wk, mouse:	0.1 / 0.5 % (w/w)
Relevant inhalation NOAEL / LOAEL	6-mo, rat / monkey:	1.2 / 3.6 µg/L

Long term

Species/ target / critical effect	Rat (oral): Bw ↓; stomach: hyperkeratosis, ulcerations, atrophy, hyperplasia; kidney: papillary necrosis Rat, mouse (inhalation): Nasal epithelium: rhinitis, dysplasia, squamous metaplasia
Relevant oral NOAEL / LOAEL	2 yr, rat: 15 / 82 mg/kg bw/d
Relevant dermal NOAEL / LOAEL	No reliable data
Relevant inhalation NOAEL / LOAEL	24-mo, rat: <2.4 / 2.4 µg/L

Genotoxicity

Clastogenic locally *in vivo* Muta.2

Carcinogenicity

Species/type of tumour	Rat (inhalation): Carc. 1B squamous cell carcinoma of the nasal epithelium
Relevant NOAEL/LOAEL	24 mo, rat: 2.4 / 7.2 µg/L

Reproductive toxicity

Developmental toxicity

Species/ Developmental target / critical effect	Rat, Mouse: not teratogenic
Relevant maternal NOAEL	Rat (inhalation): 24 µg/L x 6 h/d Mouse (oral): 148 mg/kg bw/d
Relevant developmental NOAEL	Rat: 340 mg/kg bw/d (highest dose tested) Rabbit: (embryotoxicity): 300 mg/kg bw/d (teratogenicity): 1000 mg/kg bw/d

Fertility

Species/critical effect	Rat: testes atrophy, sperm count and viability ↓, sperm head abnormalities, male fertility ↓, testosterone ↓
Relevant parental NOAEL	no data
Relevant offspring NOAEL	no data
Relevant fertility NOAEL	Rat: < 10 µg/L

Neurotoxicity

Species/ target/critical effect: no data

Developmental Neurotoxicity

Species/ target/critical effect: no data

Immunotoxicity

Species/ target/critical effect	no data

Developmental Immunotoxicity

Species/ target/critical effect	no data

Other toxicological studies

Ocular and respiratory irritation, human:
Eye irritation: ≥ 0.36 µg/L x 4 h with peaks of 0.72 µg/L,
Nasal irritation: ≥ 0.6 µg/L x 4 h with peaks of 1.2 µg/L;
NOAEC: 0.36 µg/L
population NOAEC: 0.12 µg/L

Medical data

Cohort study: Limited evidence for association of occupational inhalation exposure with increase in SMR for upper respiratory tract cancer (NPC); Increase in RR with peak exposure and average intensity.
Patch testing: Incidence of sensitisation ~3 % in dermatitis patients and 1.8 % in workers, NOAEC / LOAEC (elicitation): 0.025 / 0.005 %.

Summary

	Value	Study	Safety factor
$AEL_{long-term}$ $AEL_{medium-term}$ $AEL_{short-term}$	0.15 mg/kg bw/d	Rat, overall (28-d, 90-d, 2-yr)	100
$AEC_{acute, inhalation}$ $AEC_{medium-term, inhalation}$ $AEC_{long-term, inhalation}$	0.12 µg/L	Human, eye irritation (subjective)	3
		Human, overall ocular/respiratory irritation	1[#]
		Rat, Monkey, 6-mo	10[*]
ADI[4]	Not allocated		
ARfD	Not allocated		

MRLs

[4] If residues in food or feed.

Relevant commodities	

Reference value for groundwater

According to BPR Annex VI, point 68	

Dermal absorption

Study (*in vitro*/*vivo*), species tested	*in vivo*, rat and *in vitro*, human
Formulation (formulation type and including concentration(s) tested, vehicle)	aqueous solution (various concentrations and exposure times)
Dermal absorption values used in risk assessment	100 %

Acceptable exposure scenarios (including method of calculation)

Formulation of biocidal product	Not assessed by the rapporteur under the requirements of the BPR
Intended uses	
Industrial user	Formulation of the biocidal product is not assessed by the rapporteur under the requirements of the BPR.
Professional user	See below
Task Force:	
Fogging disinfection of animal housing (scenario 2) **Mixing and loading:** dilution of 40% to 16 % formaldehyde **Application and Post-Application:** During fumigation itself and following ventilation time the professional worker is not present in the fumigated object. After ventilation time the releases formaldehyde is evaporated.	Model (inhalation): ART 1.0 Model (dermal): Model 4 M&L (TNsG 2002) , refined by use of new data available for the relating UK POEM Model
Disinfection of eggs in hatchery (scenario 3) **Mixing and loading:** dilution of 40% to 20 % formaldehyde **Application and Post-Application:**	Model (inhalation): ConsExpo 4.1 Model (dermal): Model 4 M&L (TNsG 2002) , refined by use of new data available for the relating UK POEM Model

During fumigation/disinfection itself and following ventilation time the professional worker is not present (closed system). After ventilation time the releases formaldehyde is evaporated	
<u>Disinfection of animals' feet-footbath (scenario 5)</u> **Mixing and loading:** dilution of 40% to 2 % formaldehyde **Application:** Control – stand by Form of exposure: exposure to vapour **Post-Application:** Cleaning disposal of residue formaldehyde	Model (inhalation): ConsExpo 4.1 Model (dermal): Model 4 M&L (TNsG 2002) , refined by use of new data available for the relating UK POEM Model Model (inhalation): ConsExpo 4.1 Dermal: not expected Model (inhalation): ConsExpo 4.1 Model (dermal): Model 4 M&L (TNsG 2002) , refined by use of new data available for the relating UK POEM Model
<u>Interhygiene GmbH</u>:	
<u>Wet disinfection, small surfaces (scenario 2)</u> **Mixing and loading:** Dilution of 24 % to 0.7 % formaldehyde **Application:** pouring out of the disinfection solution on the floor and scrubbing activities with a broom (0.7 % formaldehyde) **<u>Post-Application:</u>** Not expected	Model (inhalation): ConsExpo 4.1 Model (dermal): Model 4 M&L (TNsG 2002) , refined by use of new data available for the relating UK POEM Model Model (inhalation): Cons Expo 4.1 Model (dermal): ConsExpo Disinfectant Products Fact Sheet document (RIVM report 320005003, 2006) - exposure scenario during pouring and brushing with algae removers (Chapter 3.3)
Secondary Exposure (Task Force/ Interhygiene) Professional users	Secondary exposure of the professional bystander is not expected.
Non-professional users	Non-professional use of the biocidal product is excluded
Indirect exposure as a result of use (e.g.via food or feed)	Task Force: Secondary exposure of the general public via food of animal origin is possible. Interhygiene GmbH: Secondary exposure of the general public using the biocidal product is not expected if

	appropriate risk mitigation measures (i.e. waiting period before re-entry) are implemented.
Animal exposure	Task Force: Exposure of animals does not exceed 0.29 mg/kg bw/d Interhygiene GmbH: Exposure of animals is not expected.

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	Stable, absence of hydrolysable group
pH 5	
pH 9	
Other pH: *[indicate the value]*	
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Stable, absence of chromophore
Readily biodegradable (yes/no)	Yes, fulfilling the 10-day window criterion
Inherent biodegradable (yes/no)	
Biodegradation in freshwater	
Biodegradation in seawater	Not relevant
Non-extractable residues	Not applicable
Distribution in water / sediment systems (active substance)	Not applicable
Distribution in water / sediment systems (metabolites)	Not applicable

Route and rate of degradation in soil

Mineralization (aerobic)	Not applicable
Laboratory studies (range or median, with number of measurements, with regression coefficient)	Not applicable
DT_{50lab} (20°C, aerobic):	
DT_{90lab} (20°C, aerobic):	
DT_{50lab} (10°C, aerobic):	
DT_{50lab} (20°C, anaerobic):	
degradation in the saturated zone:	

Field studies (state location, range or median with number of measurements)	Not applicable
DT_{50f}:	
DT_{90f}:	
Anaerobic degradation	Not applicable
Soil photolysis	
Non-extractable residues	Not applicable
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	Not applicable
Soil accumulation and plateau concentration	Not applicable

Adsorption / desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	15.9 L/kg (QSAR) [study waiving so far questionable]

Fate and behaviour in air

Direct photolysis in air	Degradation by photolyse is 1.5 times higher than by OH radicals. Worst case assumption: Half life = 1.97 d (see photo-oxidative degradation below)
Quantum yield of direct photolysis	n.a.
Photo-oxidative degradation in air	
Volatilization	Not relevant

Reference value for groundwater

According to BPR Annex VI, point 68	

Monitoring data, if available

Soil (indicate location and type of study)	Not applicable
Surface water (indicate location and type of study)	Not applicable
Ground water (indicate location and type of study)	Not applicable
Air (indicate location and type of study)	Not applicable

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity
Fish			
Monore saxatilis	96 h	LC50	5.7 mg/L
Invertebrates			
Daphnia magna	21 d	NOEC (age of first reproduction	1.04 mg/L
Daphnia pulex	48 h	EC50	5.8 mg/L
Algae			
Desmodesmus subspicatus	472 h	ErC50	5.7 mg/L (geo.mean value from 2 tests)
Microorganisms			
Activated sludge	3 h	EC_{50}	20.4 mg/L

Effects on earthworms or other soil non-target organisms

Acute toxicity to ……..	n.a.
Reproductive toxicity to ……	n.a.

Effects on soil micro-organisms

Nitrogen mineralization	n.a.
Carbon mineralization	

Effects on terrestrial vertebrates

Acute toxicity to mammals	See chapter 3
Acute toxicity to birds	n.a.
Dietary toxicity to birds	n.a.
Reproductive toxicity to birds	n.a.

Effects on honeybees

Acute oral toxicity	n.a.
Acute contact toxicity	n.a.

Effects on other beneficial arthropods

Acute oral toxicity	n.a.
Acute contact toxicity	n.a.
Acute toxicity to ……..	n.a.

Bioconcentration

Bioconcentration factor (BCF)	Fish: 0.396 L/kg estimated from log Kow of 0.35 Earthworm: 0.867 L/kg estimated from log Kow of 0.35
Depration time (DT_{50})	
Depration time (DT_{90})	
Level of metabolites (%) in organisms accounting for > 10 % of residues	

Chapter 6: Other End Points

A substantiated estimation of consumer exposure to formaldehyde residues is food from use in PT 3 biocidal products should be presented at product authorisation level. This should include an estimation of animal exposure to formaldehyde residues from the intended use of PT3 biocidal products (see also Doc IIIB6.7.1)

Appendix II: List of Intended Uses

Summary of intended uses

Object and/or situation (a)	Member State or Country	Product name	Organisms controlled (c)	Formulation		Application			Applied amount per treatment			Remarks: (m)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	number min max (k)	interval between applications (min)	g as/L min max	water L/m² min max	g as/m² min max	
PT 3 animal houses, wet disinfection	Europe: Germany, UK	n.a. model product	Obligate or facultative pathogenic bacteria, fungi and viruses	**n**.a. model product	a.s. as manufactured (40%)	sprayed to all surfaces	1	44 days	0.35 – 1.2% ≈ 3.5 - 12 g/L	0.4 L/m2		
PT 3 animal houses, fumigation	Europe: Germany, UK					fumigation/ fogging	1	44 days	16% ≈ 160 g/L	0.0375 L/m3		
PT 3 hatcheries	Europe: Germany, UK					fumigation	n.a. application per hatchery depends on dimension of sluice and hatcher		20% ≈ 200 g/L		7 g/m3	
PT 3 vehicles	Europe: Germany, UK					sprayed	1	1 year (epidemic: worst-case assumption)	4% ≈ 40 g/L			in cases of epidemic
PT 3 animal's feet	Europe: UK					footbath mat	1	min 1 day	2% ≈ 20 g/L			typically sheeps, sporadic diary cattles
PT 3	EU	0901001	bacteria and viruses	liquid concentrate	24.00 %w/w	spraying using low pressure	stables for: chicken: 7/a pigs: 4/a cows, sheep etc: 2/a		0.7% ≈ 7g/L	0.1-0.4 L/ m²	0.7-2.8 g -/m²	

(a) *e.g.* biting and suckling insects, fungi, molds; (b) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(c) GCPF Codes - GIFAP Technical Monograph No 2, 1989 ISBN 3-8263-3152-4); (d) All abbreviations used must be explained
(e) g/kg or g/l;(f) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench;
(g) Kind, *e.g.* overall, broadcast, aerial spraying, row, bait, crack and crevice equipment used must be indicated;
(h) Indicate the minimum and maximum number of application possible under practical conditions of use;
(i) Remarks may include: Extent of use/economic importance/restrictions

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 60 of Regulation (EU) No 528/2012.

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIA 3.1	Benkmann HG, Agarwal DP, Saha N, Goedde HW	1991	Monomorphism of formaldehyde dehydrogenase in different populations. Hum Hered 41(4):276-8, published	No	published
IIA 3.1	Cook RJ, Champion KM, Giometti CS	2001	Methanol toxicity and formate oxidation in NEUT2 mice. Arch Biochem Biophys 393(2):192-8, published	No	published
IIA 3.1	Edman K, Maret W	1990	An MspI RFLP in the human ADH5 gene. Nucleic Acids Res 18(9):2836, published	No	published
IIA 3.1	Edman K, Maret W	1992	Alcohol dehydrogenase genes: restriction fragment length polymorphisms for ADH4 (pi-ADH) and ADH5 (chi-ADH) and construction of haplotypes among different ADH classes. Hum Genet 90(4):395-401, published	No	published
IIA 3.1	Einbrodt HJ, Prajsnar D, Erpenbeck J	1976	Der Formaldehyd- und Ameisensäurespiegel im Blut und Urin beim Menschen nach Formaldehydexposition. Zentralbl Arbeitsmed Arbeitsschutz Prophyl 26(8):154-158, published	No	published
IIA 3.1	Franks SJ	2005	A mathematical model for the absorption and metabolism of formaldehyde vapour by humans. Toxicol Appl Pharmacol 206(3):309-20, published	No	published
IIA 3.1	Heck HD, White EL, Casanova-Schmitz M	1982	Determination of formaldehyde in biological tissues by gas chromatography/mass spectrometry. Biomed Mass Spectrom 9(8):347-53, published	No	published
IIA 3.1	Kimbell JS, Subramaniam RP, Gross EA, Schlosser PM, Morgan KT	2001a	Dosimetry modeling of inhaled formaldehyde: comparisons of local flux predictions in the rat, monkey, and human nasal passages. Toxicol Sci 64(1):100-10, published	No	published
IIA3.1	Kimbell JS, Overton JH, Subramaniam RP, Schlosser PM, Morgan KT, Conolly RB, Miller FJ	2001b	Dosimetry modeling of inhaled formaldehyde: binning nasal flux predictions for quantitative risk assessment. Toxicol Sci 64(1):111-21, published	No	published
IIA 3.1	Krupenko SA, Oleinik NV	2002	10-formyltetrahydrofolate dehydrogenase, one of the major folate enzymes, is down-regulated in tumor tissues and possesses suppressor effects on cancer cells. Cell Growth Differ 13(5):227-36, published	No	published

IIA 3.1	Li H, Wang J, König R, Ansari GA, Khan MF	2007	Formaldehyde-protein conjugate-specific antibodies in rats exposed to formaldehyde. J Toxicol Environ Health A 70(13):1071-1075, published	No	published
IIA 3.1	Luo X, Kranzler HR, Zuo L, Wang S, Schork NJ, Gelernter J	2007	Multiple ADH genes modulate risk for drug dependence in both African- and European-Americans. Hum Mol Genet 16(4):380-90, published	No	published
IIA 3.1	Maier KL, Wippermann U, Leuschel L, Josten M, Pflugmacher S, Schröder P, Sandermann H Jr, Takenaka S, Ziesenis A, Heyder J	1999	Xenobiotic-metabolizing enzymes in the canine respiratory tract. Inhal Toxicol 11(1):19-35, published	No	published
IIA 3.1	Mashford PM, Jones AR	1982	Formaldehyde metabolism by the rat: a re-appraisal. Xenobiotica 12(2):119-24, published	No	published
IIA 3.1	Myers JA, Mall J, Doolas A, Jakate SM, Saclarides TJ	1997	Absorption kinetics of rectal formalin instillation. World J Surg 21(8):886-9, published	No	published
IIA 3.1	Neely WB	1964	The metabolic fate of formaldehyde 14-C intraperitoneally administered to the rat. Biochem Pharmacol 13:1137-42, published	No	published
IIA 3.1	The Human Genome Nomenclature Committee	2008	Human Genome Database HGNC ID: 253. http://www.genenames.org/, published	No	published
IIA 3.1	Uotila L	1979	Glutathione thiol esterases of human red blood cells. Fractionation by gel electrophoresis and isoelectric focusing. Biochim Biophys Acta 580(2):277-88, published	No	published
IIA 3.1	Waydhas C, Weigl K, Sies H	1978	The disposition of formaldehyde and formate arising from drug N-demethylations dependent on cytochrome P-450 in hepatocytes and in perfused rat liver. Eur J Biochem 89(1):143-50, published	No	published
IIA 3.2	Bono R, Vincenti M, Schiliro' T, Scursatone E, Pignata C, Gilli G	2006	N-Methylenvaline in a group of subjects occupationally exposed to formaldehyde. Toxicol Lett 161(1):10-17, published	No	published
IIA 3.2	European Chemicals Bureau	2000	IUCLID Dataset, Substance ID: 50-00-0, published	No	published

IIA3.4	Pesonen M, Jolanki R, Larese Filon F, Wilkinson M, Kręcisz B, Kieć-Świerczyńska M, Bauer A, Mahler V, John SM, Schnuch A, Uter W; ESSCA network	2015	Patch test results of the European baseline series among patients with occupational contact dermatitis across Europe - analyses of the European Surveillance System on Contact Allergy network, 2002-2010. Contact Dermatitis 72:154-163.	No	published
IIA3.4	De Groot AC, van Joost T, Bos JD, van der Meeren HL, Weyland JW	1988	Patch test reactivity to DMDM hydantoin. Relationship to formaldehyde allergy. Contact Dermatitis 18:197-201.	No	published
IIA3.4	Flyvholm MA, Hall BM, Agner T, Tiedemann E, Greenhill P, Vanderveken W, Freeberg FE, Menné T	1997	Threshold for occluded formaldehyde patch test in formaldehyde-sensitive patients. Relationship to repeated open application test with a product containing formaldehyde releaser. Contact Dermatitis 36:26-33.	No	published
IIA3.4	Fischer T, Andersen K, Bengtsson U, Frosch P, Gunnarsson Y, Kreilgård B, Menné T, Shaw S, Svensson L, Wilkinson J	1995	Clinical standardization of the TRUE Test formaldehyde patch. Curr Probl Dermatol. 22:24-30.		published
IIA3.4	Trattner A, Johansen JD, Menné T	1998	Formaldehyde concentration in diagnostic patch testing: comparison of 1% with 2%. Contact Dermatitis. 38:9-13	No	published
IIA 3.6	Speit G, Zeller J, Schmid O, Elhajouji A, Ma-Hock L, Neuss S	2009	Inhalation of formaldehyde does not induce systemic genotoxic effects in rats. Mutat Res. 677(1-2):76-85, published	No	published
IIA 3.5/ IIA 3.7	McGregor D, Bolt H, Cogliano V, Richter-Reichhelm HB	2006	Formaldehyde and glutaraldehyde and nasal cytotoxicity: case study within the context of the 2006 IPCS Human Framework for the Analysis of a cancer mode of action for humans. Crit Rev Toxicol 36(10): 821-835, published	No	published
IIA 3.8	Li KC, Powell DC, Aulerich RJ, Walker RD, Render JA, Maes RK, Bursian SJ	1999	Effects of formalin on bacterial growth in mink feed, feed consumption and reproductive performance of adult mink, and growth of mink kits. Vet Hum Toxicol 41(4):225-232, published	No	published

IIA 3.8	Odeigah P	1997	Sperm head abnormalities and dominant lethal effects of formaldehyde in albino rats. Mutation Research 389(2-3), 141-148, published	No	published
IIA 3.8	Özen OA, Akpolat N, Songur A, Kus I, Zararsiz I, Ozacmak VH, Sarsilmaz M	2005	Effect of formaldehyde inhalation on Hsp70 in seminiferous tubules of rat testes: an immunohistochemical study. Toxicology and Industrial Health 21(9), 249-254, published	No	published
IIA 3.8	Tang M, Xie Y, Yi Y, Wang W et al.	2003	Effect of formaldehyde on germ cells of male mice. J Hygiene Research 32(6), 544-548, published	No	published
IIA 3.8	Zhou DX, Qiu SD, Zhang J, Tian H, Wang HX	2006	The protective effect of vitamin E against oxidative damage caused by formaldehyde in the testes of adult rats. Asian J Androl 8(5):548-588, published	No	published
IIA 3.8	Zhou DX, Qiu SD, Zhang J, Wang ZY	2006	[Reproductive toxicity of formaldehyde to adult male rats and the functional mechanism concerned]. Sichuan Da Xue Xue Bao Yi Xue Ban 37(4):566-569, published	No	published
IIA 3.9	Lu Z, Li CM, Qiao Y, Yan Y, Yang X	2008	Effect of inhaled formaldehyde on learning and memory of mice. Indoor Air 18(2):77-83, published	No	published
IIA 3.9	Malek FA, Möritz KU, Fanghänel J	2004	Effects of a single inhalative exposure to formaldehyde on the open field behavoir of mice. Int J Hyg Environ Health 207: 151-158, published	No	published
IIA 3.9	Pitten FA, Kramer A, Herrmann K, Bremer J, Koch S	2000	Formaldehyde neurotoxicity in animal experiments. Pathol Res Pract 196(3):193-198, published	No	published
IIA 3.10	Beane Freeman LE, Blair A, Lubin JH, Stewart PA, Hayes RB, Hoover RN, Hauptmann M	2009	Mortality from lymphohematopoietic malignancies among workers in formaldehyde industries: the National Cancer Institute Cohort. J Natl Cancer Inst. 101(10):751-61, published	No	published
IIA 3.10	Commission of the European Communities	2007	COM/07/S5, Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment, FORMALDEHYDE: EVIDENCE FOR SYSTEMIC MUTAGENICITY, published	No	published
IIA 3.11	Bolt HM, Huici-Montagud A	2008	Strategy of the scientific committee on occupational exposure limits (SCOEL) in the derivation of occupational exposure limits for carcinogens and mutagens. Arch Toxicol. 82(1):61-4, published	No	published

IIA 4	EC 2006		Technical Guidance Document (TGD) on Risk Assessment in support of Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No. 1488/94 on risk assessment for existing substances (Parts I, II, III and IV) and Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocidal products on the market. European Commission 2003	No	published
IIB 8	EC	2002	TNsG Human Exposure Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Human Exposure to Biocidal Products - Guidance on Exposure Estimation [„Report 2002“ http://ecb.jrc.it/biocides]	No	published
IIB 8	EC	2007	TNsG Human Exposure Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Human Exposure to Biocidal Products - Guidance on Exposure Estimation	No	published
IIB 8	RIVM, 1996	1996	Montfoort, J.A., P. van der Poel and R. Luttik (1996) The use of disinfectants in livestock farming (Supplement to the evaluation method of non-agricultural pesticides of the Uniform System for Evaluation of Substances (USES)), RIVM report no. 679102033, Bilthoven, Netherlands	No	published
IIB 8	RIVM	2001	van der Poel, P., Bakker, J. (2001) RIVM report 601450009: Emission Scenarios for all 23 product types of the Biocidal Products Directive (EU Directive 98/8/EC	No	published
IIB 8	OECD, 2006	2006	OECD (2006) OECD Series on Emission Scenario Documents, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems. ENV/JM/MONO(2006)4 – JT00197426 - 25.01.2006	No	published

IIB 8	Spindler, 2006	2006	Spindler , B. (2006) Reinigung und Desinfektion in der Nutztierhaltung [Cleaning and disinfection in livestock husbandry]. Referat von Dr. Birgit Spindler, Institut für Tierhygiene, Tierschutz und Nutztierethologie, Hannover, In: Grund- und Fortbildungslehrgang “Raumdesinfektion mit Formaldehyd“ gem. TRGS 522, Wuelfel, Hannover	No	published
IIB 8	TRGS 522	2001	TRGS 522 (2001) Technische Regeln für Gefahrstoffe. Raumdesinfektion mit Formaldehyd. [Technical Guidelines for Hazardous Substances. Room Disinfection with Formaldehyde]. Ausgabe Juni 1992, zuletzt geändert: BArbBl. Heft 9/2001	No	published
IIB 8	ITEM	2009-1	ITEM (2009) Results of a data search for the disinfection in hatcheries using formaldehyde performed in order of the applicants. N. Costa Pinheiro; June 2009	Yes	unpublished
IIB 8	ITEM	2009-2	ITEM (2009) Compilation of pictures and information for the use of formaldehyde for disinfection of vehicles (epidemic) gathered in order of the applicants. N. Costa Pinheiro, Fraunhofer ITEM, 18 June 2009	Yes	unpublished
IIB 8	ITEM	2009-3	ITEM (2009) Compilation of data gathering for the use of formaldehyde for disinfection of animals´ feet, N. Costa Pinheiro, Fraunhofer ITEM, 15 June 2009	Yes	unpublished
IIB 8	Ullmann	2005	Ullmann (2005) ”Formaldehyde” in Ullmann's Encyclopedia of Industrial Chemistry, Wiley-VCH Verlag GmbH & Co. KGaA. Online Version	No	published
IIB 8	ART 1.0	2010	Advanced REACH Tool Version 1.0 http://www.advancedreachtool.com/	No	published
IIB 8	EC	2011	JRC Scientific and Technical Reports: Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products	No	-
IIB 8	ITEM	2013	Evaporation of formaldehyde after wet or room disinfection in animal housings, expert statement, unpublished	Yes	Ewabo, Lysoform, Synthite

IIB 8	ITEM	2009	ITEM (2009) Results of a data search for the disinfection in hatcheries using formaldehyde performed in order of the applicants. N. Costa-Pinheiro, Fraunhofer ITEM, June 2009.	Yes	Ewabo, Lysoform, Synthite
IIB 8	ITEM	2009	Compilation of pictures and information for the use of formaldehyde for disinfection of vehicles (epidemic) gathered in order of the applicants. N. Costa-Pinheiro, Fraunhofer ITEM, 18 June 2009 GLP not applicable, unpublished	Yes	Ewabo, Synthite, Lysoform
IIB 8	ITEM	2009	Compilation of data gathering for the use of formaldehyde for disinfection of animals´ feet	Yes	Ewabo Lysoform Synthite
IIB 8	Deutsche Veterinärmedizinische Gesellschaft (DVG)	2012	Auszug aus der 13. Desinfektionsmittelliste für die Tierhaltung	No	-
IIB 8	Strauch, D. & Böhm, R.	2002	Reinigung und Desinfektion in der Nutztierhaltung und Veredelungswirtschaft, 2. überarbeitete Auflage, Enke Verlag, Stuttgart	No	-
IIB 8	Spindler, B.	2006	Reinigung und Desinfektion in der Nutztierhaltung, Referat von Dr. Birgit Spindler, Institut für Tierhygiene, Tierschutz und Nutztierethologie, Hannover, In: Grund- und Fortbildungslehrgang “Raumdesinfektion mit Formaldehyd“ gem. TRGS 522, Wuelfel, Hannover	No	-
IIB 8	Ausschuss für Gefahrstoffe, AGS-Geschäftsführung - BAuA		Technische Regeln für Gefahrstoffe (TRGS 522), Raumdesinfektion mit Formaldehyd (Entwurf)	No	-
IIB 8	Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit	2002	Erste Allgemeine Verwaltungsvorschrift zum Bundes–Immissionsschutzgesetz (Technische Anleitung zur Reinhaltung der Luft – TA Luft	No	-
IIB 8	OECD	2006	Series on Emission Scenario Documents, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems	No	-

IIB 8	Montfoort et al.	1996	The use of disinfectants in livestock farming - Supplement to the evaluation method of non-agricultural pesticides of the Uniform system for Evaluation of substances (USES), RIVM report no. 679102033	No	-
IIB 8 (Interhygiene)	OECD, 2006	2006	OECD (2006) OECD Series on Emission Scenario Documents, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems. ENV/JM/MONO(2006)4 – JT00197426 - 25.01.2006	No	published
IIB 8 (Interhygiene)	Cherrie, J.W.	1999	The effect of room size and general ventilation on the relationship between near and far-field concentrations, Appl. Occ. And Env. Hyg. Vol. 14(8), 539-546	No	published
IIB 8 (Interhygiene)	Eickmann	2003	Udo Eickmann, 2003, Modellierung der Formaldehydblastung bei Arbeiten im Gesundheitsdienst [Modelling of the formaldehyde exposure when working in the health service], Gefahrstoffe Reinhaltung der Luft, Berufsgenossenschaft für Gesundheitsdienst und Wohlfahrtspflege (BGW), Gefahrstoffe Reinhaltung der Luft, 63, no. 7-8, 325-330 (published	No	published
IIB 8 (Interhygiene)	RIVM	2006	Bremmer et al., RIVM report 320104003/2006: Clenaing Product Fact Sheet – To assess the risks for the consumer	No	IIB 8 (Interhygiene)
IIB 8 (Interhygiene)	Marquart	2006	Marquart, H., Warren, N., Laitinen, J., van Hemmen, J.; Default values for assessment of potential dermal exposure of the hands to industrial chemicals in the scope of regulatory risk assessments; Ann.Occup.hyg., Vol.50, pp.469-489, 2006	No	IIB 8 (Interhygiene)
IIB 8 (Interhygiene)	Strauch	2002	Strauch, D.,Böhm,R.; Cleaning and disinfection in livestock husbandry and improvment economy, 2., überar. Aufl. Enke verlag, Stuttgart	No	IIB 8 (Interhygiene)
IIC12	Api AM, Basketter DA, Cadby PA, Cano MF, Ellis G, Gerberick GF, Griem P, McNamee PM, Ryan CA, Safford R	2008	Dermal sensitization quantitative risk assessment (QRA) for fragrance ingredients. Regul Toxicol Pharmacol 52:3-23.	No	published

IIC 13	Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit	2002	Erste Allgemeine Verwaltungsvorschrift zum Bundes–Immissionsschutzgesetz (Technische Anleitung zur Reinhaltung der Luft – TA Luft	No	IIC 13
IIC 13	EC	2000	IUCLID Dataset, ammonia anhydrous, CAS No. 7664-41-7 based on data reported by the European Chemicals Industry following 'Council Regulation (EEC) No. 793/93 on the Evaluation and Control of the Risks of Existing Substances'	No	IIC 13
IIC 13	Lyman WJ, Reehl WF, Rosenblatt, DH (eds.)		Handbook of Chemical Property Estimation Methods	No	IIC 13
IIC 13	EC	2008	Comprehensive Risk Assessment Report for methenamine in the frame of Council Regulation (EEC) No. 793/93, EC 27/05/2008. http://echa.europa.eu/documents/10162/d3cf452f-b948-4d63-a28f-5908ce289ee5	No	IIC 13
IIC 15	German Federal ministry of labour and social affairs (BMAS), in particular: Committee for Hazardous Substances (AGS	2001 (currentl y updated)	Technical Rules for Hazardous Substances (TRGS) 522 (room disinfection - only in German): **http://www.baua.de/nn_16738/de/Themen-von-A-Z** /Gefahrstoffe/TRGS/pdf/TRGS-522.pdf		IIC 15
IIC 15	German Federal ministry of labour and social affairs (BMAS), in particular: Committee for Hazardous Substances (AGS)		Technical Rules for Hazardous Substances (TRGS) 512 (fumigation): http://www.baua.de/cln_135/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/TRGS-512.html		
IIC 15	German Federal ministry of labour and social affairs (BMAS), in particular: Committee for Hazardous Substances (AGS		Technical Rules for Hazardous Substances (TRGS) 513 (disinfection in stationary systems, only in German): http://www.baua.de/cln_135/de/Themen-von-A-Z/Gefahrstoffe/TRGS/TRGS-513.html		

IIC 15	German Federal ministry of labour and social affairs (BMAS), in particular: Committee for Hazardous Substances (AGS)		Technical Rules for Hazardous Substances (TRGS) 523 (pest control): http://www.baua.de/cln_135/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/TRGS-523.html		
IIC 15 (Task Force)	German Federal ministry of labour and sozial affairs (BMAS), in particular: AGS	2008	Announcement on Hazardous Substances (BekGS) 910: "Risk figures and exposure-risk relationships in activities involving carcinogenic hazardous substances" http://www.baua.de/cln_137/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/Announcement-910.html		
IIC 15 (Task Force)	UK-Health and Safety Executive (HSE		Control Guidance Fact Sheet: http://www.oehc.uchc.edu/news/Control_Guidance_Factsheets.pdf , G217: http://www.coshh-essentials.org.uk/assets/live/G217.pdf , G312: http://www.coshh-essentials.org.uk/assets/live/G312.pdf		
IIC 15	German federal institute for occupational safety and health (BauA		German Control guidance sheet (SLF) No. 312: http://www.baua.de/cae/servlet/contentblob/674280/publicationFile/49943/Schutzleitfaden-312.pdf)		
IIC 15	German Committee for Hazardous Substances (AGS		working programme of the German Committee for Hazardous Substances (AGS): http://www.baua.de/cae/servlet/contentblob/666768/publicationFile/90233/Bearbeitungsliste-TRGS-900.pdf , http://www.baua.de/cae/servlet/contentblob/666740/publicationFile/90173/AGS-Arbeitsprogramm.pdf		
IIC 15	German Federal ministry of labour and sozial affairs (BMAS		German Ordinance on Hazardous Substances, annex III No. 5 (fumigation; http://www.baua.de/cae/servlet/contentblob/664800/publicationFile/48362/Hazardous-Substances-Ordinance.pdf;jsessionid=56ADAC86C484FCD35ABAA9640FD0B299, former version),		
IIC 15 (Task Force)	Hirst N, Brocklebank M, Ryder M	2002	Containment Systems - a design guide ISBN 0 7506 7612 4	No	published

IIC 15 (Interhygiene)	German Federal ministry of labour and sozial affairs (BMAS)		German Ordinance on Hazardous Substances, annex I No. 4 (fumigation; http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Hazardous-Substances-Ordinance.html	No	published
IIC 15 (Interhygiene)	Robert-Koch-Institut, Berlin	2004	Anforderungen an die Hygiene bei der Reinigung und Desinfektion von Flächen – Empfehlungen, Bundesgesundheitsbl-Gesundheitsforsch-Gesundheitsschutz, 47, 2004	No	published
	Hose JE, Lightner DV	1980	Absence of formaldehyde residues in penaid shrimp exposed to formalin. Aquaculture 21: 197-201 non GLP, published	No	published
	Kamata E	1966	Aldehydes in lake and sea waters. Bulletin of the Chemical Society of Japan 39: 1227-1229 non GLP, published	No	published
	Murdanoto AP, Sakai Y, Konishi T, Yasuda F, Tani Y, Kato N	1997	Purification and properties of methyl formate synthase, a mitochondrial alcohol dehydrogenase, participating in formaldehyde oxidation in methylotrophic yeasts. Appl. Environ. Microbiol. 63: 1715–1720 non GLP, published	No	published
	OECD	2004	Methanol, ICCA documentation on methanol http://cs3-hq.oecd.org/scripts/hpv/	No	published
	Offhaus K	1973	Evaluation of waste water purification by analytical procedures (Beurteilung der Abwasserreinigung durch analytische Verfahren). Münchner Beitr. Abwasser-, Fisch.-Flussbiol. 24, 169-196	No	published
	Sills JB, Allen JL	1979	Residues of formaldehyde undetected in fish exposed to formalin. Prog. Fish-Cult. 41: 67-68 non GLP, published	No	published
	Vorholt JA	2002	Cofactor-dependent pathways of formaldehyde oxidation in methylotrophic bacteria. Arch. Microbiol. 178: 239–249 GLP not applicable, published	No	published
A2.6	Ullmann	2005	Formaldehyde. Authors: Reuss G, Disteldorf W, Gamer AO, Hilt A, in Ullmann's Encyclopedia of Industrial Chemistry, Wiley-VCH Verlag GmbH & Co. KGaA. Online Version.	No	published

			GLP not applicable, published		
A2.10/01 (Task Force)	[redacted]	2008	[redacted], unplublished	Yes	[redacted]
A2.10/01 (Task Force)	Ullmann	2005	"Formaldehyde" in Ullmann's Encyclopedia of Industrial Chemistry, Wiley-VCH Verlag GmbH & Co. KGaA. Online Version GLP not applicable, published	No	published
A2.10/02 (Task Force)	[redacted]	2006	[redacted], unpublished	Yes	[redacted]
A2.10/02 (Task Force)	[redacted]	2009	[redacted], unpublished	Yes	[redacted]
A2.10/02 (Task Force)	[redacted]	2008	[redacted] unplublished	Yes	[redacted]
A2.10/02 (Task Force)	Ullmann	2008	"Formaldehyde" in Ullmann's Encyclopedia of Industrial Chemistry, Wiley-VCH Verlag GmbH & Co. KGaA. Online Version GLP not applicable, published	No	published
A3 (Interhygiene)	INEOS PARAFORM	1999 2009	Produktspezifikation Formaldehyd 37 G%, 25.09.1999, EG-Sicherheitsdatenblatt Formaldehyd 30-55%, 00544-0008 v. 02.10.2009	Yes	INEOS
A3 (Interhygiene)	Interhygiene 2009, Tessmer	2009	Partialdruckmessung in verschiedenen Lösungen	YES	Interhygiene
A3 (Interhygiene)	Chemiebüro Widulle, Dr. Herbert Widulle	2010	Phasenübergänge im Temperaturbereich zwischen 270 K und 333 K im System Formaldehyd-Wasser		
A3.1	CRC	2001	CRC Handbook of Chemistry and Physics, Lide DR (Editor), 82th edition, CRC Press, Boca Raton, 3-166 GLP not applicable, published	No	-published

A3.1	Kirk-Othmer	1994	Kirk-Othmer Encyclopedia of Chemical Technology. 4th edition, Volume 11, John Wiley and Sons, New York, NY, 929-951 GLP not applicable, published	No	published
A3.1	Merck	1996	The Merck Index, Budavari S (Editor), 12th edition, Merck & Co, Inc Whitehouse station, NJ, 717-718 GLP not applicable, published	No	published
A3.1/01 (Interhygiene)	Overlack Chemische Produkte, Mönchengladbach	2008	Sicherheitsdatenblatt Formaldehyd 37%	No	
A3.1/02 (Interhygiene)	Sciencelab Com. Inc., Houston Texas	2008	Sicherheitsdatenblatt Formaldehyd 37%	No	
A3.1/03 (Interhygiene)	INEOS Paraform, Mainz-Mombach	2007	Produtinformationen Formaldehyd wässrige Lösung	No	-
A3.1/04 (Interhygiene)	Aug. Hedinger GmbH & Co.KG, Stuttgart	2006	Sicherheitsdatenblatt Paraformaldehyde	No	
A3.1.3	[redacted]	2009	[redacted]	Yes -	[redacted]
A3.2	Boublik T, Fried V & Hala E	1984	The vapour pressure of pure substances - Selected values of the temperature dependence of the vapour pressures ofsome pure substances in the normal and low pressure region. Physical science data vol. 17. Elsevier, Amsterdam, Netherlands GLP not applicable, published	No	published
A3.2	CRC	2001	CRC Handbook of Chemistry and Physics, Lide DR (Editor), 82th edition, CRC Press, Boca Raton, 3-166 GLP not applicable, published	No	published
A3.2	Yaws CL	1997	Vapor pressure. In: Handbook of chemical compound data for hydrocarbons and organic chemicals, selected data for inorganic chemicals. Gulf Publishing, Houston, Texas, 27-53 GLP not applicable, published	No	published
A3.2.1	Betterton EA & Hoffman MR	1988	Henry´s law constants of some environmentally important aldehydes. Environ. Sci. Technol. 22 (12): 1415 –1418 non GLP, published	No	published

A3.2.1	Staudinger J & Roberts PV	1996	A critical review of Henry´s law constants for environmental applications. Crit. Rev. Environ. Sci. Technol. 26 (3): 205 – 297 GLP not applicable, published	No	published
A3.2.1	Staudinger J & Roberts PV	2001	A critical compilation of Henry´s law constant temperature dependence for organic compounds in dilute aqueous solutions. Chemosphere 44: 561 – 576 GLP not applicable, published	No	published
A3.2.1	Zhou X & Mopper K	1990	Apparent partition coefficients of 15 carbonyl compounds between air and seawater and between air and freshwater; implications for air-sea exchange. Environ. Sci. Technol. 24 (12): 1864 – 1869 non GLP, published	No	published
A3.3	Merck	1996	The Merck Index, Budavari S (Editor), 12th edition, Merck & Co, Inc Whitehouse station, NJ, 717-718 GLP not applicable, published	No	published
A3.4	Lide DR & Milne GWA	1994	Handbook of data on organic compounds. 3rd edition, CRC Press (vol 1), Boca Raton, 2808-2809 GLP not applicable, published	No	published
A3.4	SDBS	2006	SDBS ^{1}H-NMR No. 9410HPM-02-816 SDBS Web : http://www.aist.go.jp/RIODB/SDBS/ (National Institute of Advanced Industrial Science and Technology) GLP not applicable, published	No	published
A3.4	NIST Spectrometry Data Center	2008a	Formaldehyde – IR spectrum GLP not applicable, published	No	published
A3.4	NIST Spectrometry Data Center	2008b	Formaldehyde – mass spectrum GLP not applicable, published	No	published
A3.4	[redacted]	2009a	[redacted]	Yes	[redacted]
A3.4	[redacted]	2009b	[redacted]	Yes	[redacted]
A3.5	Merck	1996	The Merck Index, Budavari S (Editor), 12th edition, Merck & Co, Inc Whitehouse station, NJ, 717-718	No	published

			GLP not applicable, published		
A3.5	Pickrell JA, Mokler BV, Griffis LC, Hobbs CH & Bathija A	1983	Formaldehyde Release rate coefficients from selected consumer products. Environ. Sci. Technol. 17, 753-757 GLP not applicable, published	No	published
A3.6	Serjeant EP & Dempsey B	1979	Ionisation constants of organic acids in aqueous solution. IUPAC Chemical Data Series No. 23, p. 9 GLP not applicable, published	No	published
A3.7	Merck	1996	The Merck Index, Budavari S (Editor), 12th edition, Merck & Co, Inc Whitehouse station, NJ, 717-718 GLP not applicable, published	No	published
A3.7	Ullmann	2005	Formaldehyde. Authors: Reuss G, Disteldorf W, Gamer AO, Hilt A, in Ullmann's Encyclopedia of Industrial Chemistry, Wiley-VCH Verlag GmbH & Co. KGaA. Online Version. GLP not applicable, published	No	published
A3.9	Hansch C, Leo A & Hoekman D	1995	Exploring QSAR -Hydrophobic, Electronic, and Steric Constants. American Chemical Society, Washington, DC, 3 GLP not applicable, published	No	published
A3.9	Sangster J	1989	Octanol-Water Partition Coefficients of Simple Organic Compounds. J. Phys. Chem. Ref. Data, 18 (3): 1163 GLP not applicable, published	No	published
A3.11	CRC	2001	CRC Handbook of Chemistry and Physics, Lide DR (Editor), 82th edition, CRC Press, Boca Raton, 3-166 GLP not applicable, published	No	published
A3.11	Kirk-Othmer	1994	Kirk-Othmer Encyclopedia of Chemical Technology. 4th edition, Volume 11, John Wiley and Sons, New York, NY, 929-951 GLP not applicable, published	No	published
A3.12	CRC	2001	CRC Handbook of Chemistry and Physics, Lide DR (Editor), 82th edition, CRC Press, Boca Raton, 3-166 GLP not applicable, published	No	published
A3.12	Sax	2004	Formaldehyde. In: Sax's dangerous properties of industrial materials, 11th edition, Lewis RJ (Editor), Wiley (vol 2 A-G), Hoboken, New Jersey, 1813-1815 GLP not applicable, published	No	published
A3.13	Hasegawa T, Tsuji M,	1993	Effects of disinfectants on erythrocytes and isolated	No	published

	Nakayama S & Oguchi K		hepatocytes from rats and surface tension. Folia Pharm. Jpn. 101 (5): 337-347 non GLP, published		
A3.14	Ullmann	2005	Formaldehyde. Authors: Reuss G, Disteldorf W, Gamer AO, Hilt A, in Ullmann's Encyclopedia of Industrial Chemistry, Wiley-VCH Verlag GmbH & Co. KGaA. Online Version. GLP not applicable, published	No	published
A3.15	ICSC	2004	International Chemical Safety Cards, ICSC 0275 – Formaldehyde. International Programme on Chemical Safety (IPCS) and the Commission of the European Communities CEC 2004, http://www.inchem.org/pages/icsc.html GLP not applicable, published	No	published
A3.15	Sax	2004	Formaldehyde. In: Sax's dangerous properties of industrial materials, 11th edition, Lewis RJ (Editor), Wiley (vol 2 A-G), Hoboken, New Jersey, 1813-1815 GLP not applicable, published	No	published
A3.16	Sax	2004	Formaldehyde. In: Sax's dangerous properties of industrial materials, 11th edition, Lewis RJ (Editor), Wiley (vol 2 A-G), Hoboken, New Jersey, 1813-1815 GLP not applicable, published	No	published
A3.17	Kirk-Othmer	1994	Kirk-Othmer Encyclopedia of Chemical Technology. 4th edition, Volume 11, John Wiley and Sons, New York, NY, 929-951 GLP not applicable, published	No	published
A3.17	Ullmann	2005	Formaldehyde. Authors: Reuss G, Disteldorf W, Gamer AO, Hilt A, in Ullmann's Encyclopedia of Industrial Chemistry, Wiley-VCH Verlag GmbH & Co. KGaA. Online Version. GLP not applicable, published	No	published
A4.1_01	ASTM	2007	Standard Test Method for Concentration of Formaldehyde Solutions, D 2194-02 (Reapproved 2007). ASTM International 2007 GLP not applicable, published	No	published
A4.1_01	[redacted]	2009	[redacted]	Yes	[redacted]

A4.1_02	ASTM	2004	Standard Test Methods for Specific Gravity, Apparent, of Liquid Industrial Chemicals, ASTM D891 - 95(2004). ASTM International 2004 GLP not applicable, published	No	published
A4.1_03	ASTM	2004	Standard Test Method for Methanol Content of Formaldehyde Solutions, D 2380-04. ASTM International 2004 GLP not applicable, published	No	published
A4.1_04	ASTM	2004	Standard Test Method for Acidity of Formaldehyde Solutions, D 2379-04. ASTM International 2004 GLP not applicable, published	No	published
A4.1_05	ASTM	2006	Standard Test Method for Iron in Formaldehyde Solutions, D 2087-06. ASTM International 2006 GLP not applicable, published	No	published
A4.1_06	ISO	1972	ISO 2227 - Formaldehyde solutions for industrial use – Determination of formaldehyde content International Organisation for Standardization, 1972 GLP not applicable, published	No	published
A4.2a	US EPA	1996a	Method 8315A – Determination of carbonyl compounds by high-performance liquid chromatography (HPLC) Revision 1, December 1996, 1-34, URL: http://www.epa.gov/epaoswer/hazwaste/test/pdfs/8315a.pdf GLP not applicable, published	No	published
A4.2b/01	BGIA	2002	Messverfahren für Gefahrstoffe (Analysenverfahren), Lfg. 28 – IV/2002, Formaldehyd Methode 7520 (Messverfahren 2 & 3) BGIA Arbeitsmappe digital, p. 1-8 GLP not applicable, published	No	published
A4.2b/02	US EPA	1996a	Method 8315A – Determination of carbonyl compounds by high-performance liquid chromatography (HPLC) Revision 1, December 1996, 1-34, URL: http://www.epa.gov/epaoswer/hazwaste/test/pdfs/8315a.pdf GLP not applicable, published	No	published
A4.2b/02	US EPA	1996b	Method 0100 – Sampling for formaldehyde and other carbonyl compounds in indoor air Revision 0, December 1996, 1-15, URL: http://www.epa.gov/epaoswer/hazwaste/test/pdfs/0100.pdf GLP not applicable, published	No	published

A4.2b/03	NIOSH	2003	NIOSH Manual of Analytical Methods (NMAM), Forth Edition, method 2016, 15 March 2003 GLP not applicable, published	No	published
A4.2b/04	HSE	1994	Methods for the Determination of Hazardous Substances - MDHS 78, Health and Safety Executive, Occupational Medicine and Hygiene Laboratory, May 1994 GLP not applicable, published	No	published
A4.2c/01	ASTM	1998	ASTM D 6303-98 - Standard test method for formaldehyde in water Annual book of ASTM standards, American Society for Testing and Materials, West Conshohocken, PA, 1007 - 1012 GLP not applicable, published	No	published
A4.2c/02	US EPA	1996a	Method 8315A – Determination of carbonyl compounds by high-performance liquid - chromatography (HPLC) Revision 1, December 1996, 1-34 URL: http://www.epa.gov/epaoswer/hazwaste/test/pdfs/8315a.pdf GLP not applicable, published	No	published
A4.2d/01	Heck H d'A, Casanova-Schmitz M, Dodd, PB, Schacher EN, Witek TJ & Tosun T	1985	Formaldehyde (CH_2O) concentrations in the blood of humans and Fischer-344 rats exposed to CH_2O under controlled conditions. Am Ind Hyg Assoc J 46: 1-3 non GLP, published	No	published
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A6.8.2	OECD	2002	Formaldehyde, ICCA documentation on formaldehyde http://cs3-hq.oecd.org/scripts/hpv/ GLP not applicable, published	No	published
A6.8.2	Özen OA, Akpolat N, Songur A, Kus I, Zararsiz I, Özacmak VH & Sarsilmaz M	2005	Effect of formaldehyde inhalation on Hsp70 in seminiferous tubules of rat testes: an immunohistochemical study. Toxicol Ind Health 21 : 249-254 non GLP, published	No	published
A6.8.2	Tang M, Xie Y, Yi Y & Wang W	2003	Effects of formaldehyde on germ cells of male mice. J Hyg Res 32 : 544-548 non GLP, published	No	published
A6.8.2	Til HP, Woutersen R, Feron V, Hollanders V,	1989	Two-years drinking-water study of 81nglish81g81de in rats. Fd Chem Toxic 27: 77-87 non GLP, published	No	published

	Falke H & Clary J				
A6.8.2	Tobe M, Naito K & Kurokawa Y	1989	Chronic toxicity study on formaldehyde administered orally to rats. Toxicology, 56: 79-86 non GLP, published	No	published
A6.8.2	Ward JB, Hokanson J, Smith E, Chang L, Pereira M, Whorton E, & Legator M	1984	Sperm count, morphology and fluorescent body frequency in autopsy service workers exposed to formaldehyde. Mutat Res, 130: 417-424 non GLP, published	No	published
A6.8.2	WHO	1989	Formaldehyde. IPCS (International Programme on Chemical Safety), Environmental Health Criteria No. 89, WHO, Geneva GLP not applicable, published	No	published
A6.8.2	Zhou D-X, Qiu SD, Zhang J, Hong T & Wang HX	2006a	The protective effect of vitamin E against oxidative damage caused by formaldehyde in the testes of adult rats. Asian J Androl 8(5) : 584-588 non GLP, published	No	published
A6.8.2	Zhou D-X, Qiu SD, Zhang J & Wang Z-Y	2006b	Reproductive toxicity of formaldehyde to madult male rats and the functional mechanism concerned Journal of Sichuan University (Medical Science Edition) 37 : 566-569 (only abstact in 82nglish) Non GLP, published	No	published
A6.12.4/01	Coggon D, Harris EC, Poole J & Palmer K	2003	Extended follow-up of a cohort of British chemical workers exposed to formaldehyde. J Nat Cancer Inst, 95: 1608-1615 non GLP, published	No	published
A6.12.4/02	Marsh GM, Youk A, Buchanich J, Cassidy L, Lucas L, Esmen N & Gathuru I	2002	Pharyngeal cancer mortality among chemical plant workers exposed to formaldehyde. Toxicol Ind Health, 18: 257-268 non GLP, published	No	published
A6.12.4/03	Pinkerton LE, Hein M & Stayner L	2004	Mortality among a cohort of garment workers exposed to formaldehyde. Occup Environ Med, 61:193-200 non GLP, published	No	published
A6.12.4/04	Hauptmann M, Lubin J, Stewart P, Hayes R & Blair A	2003	Mortality from lymphohematopoietic malignancies among workers in formaldehyde industries. J Nat Cancer Inst, 95: 1615-1623 non GLP, published	No	published
A6.12.4/04	Hauptmann M, Lubin J, Stewart P,	2004	Mortality from solid cancers among workers in the formaldehyde industries.	No	published

	Hayes R & Blair A		Am J Epidemiol, 159: 1117-1130 non GLP, published		
A6.12.4/05	Beane Freeman LE, Blair A, Lubin JH, Stewart PA, Hayes RB, Hoover RN & Hauptmann M	2009a	Mortality from lymphohematopoietic malignancies among workers in formaldehyde industries: the National Cancer Institute Cohort. J Natl Cancer Institute 101 : 751-761 non GLP. Published	No	published
A6.12.4/06	Bosetti O, McLaughlin JK, Tarone RE, Pira E & La Vecchia O	2008	Formaldehyde and cancer risk: a quantitative review of cohort studies through 2006. Ann Oncol 19 : 29-43 non GLP, published	No	published
A6.12.4/07	Bachand AM, Mundt KA, Mundt DJ & Montgomery RR	2010	Epidemiological studies of formaldehyde exposure and risk of 83nglish83g and nasopharyngeal cancer: a meta-analysis. Crit Rev Toxicol 40 : 85-100 non GLP, published	No	published
A6.12.4/09	Zhang L, Steinmaus C, Eastmond DA, Xin XK & Smith MT	2009a	Formaldehyde exposure and 83nglish83g: a new meta-analysis and potential mechanisms. Mutation Research 681 : 150-168 non GLP, published	No	published
A6.12.4/10	Hauptmann M, Stewart PA, Lubin JH, Beane Freeman LE, Hornung RW, Herrick RF, Hoover RN, Fraumeni JF Jr, Blair A & Hayes RB	2009	Mortality from lymphohematopoietic malignancies and brain cancer among embalmers exposed to formaldehyde. J Natl Cancer Inst 101 : 1696-1708 non GLP, published	No	published
A7.1.1.1.1	Kumar S	1986	Reactive scavenging of pollutants by rain: a 83nglish83g approach. Atmosph. Environ. 20(5): 1015-1024 non GLP, published	No	published
A7.1.1.1.1	Harris JC	1990	Rate of hydrolysis. In: Handbook of chemical property estimation methods (Eds: Lyman WJ, Reehl WF, Rosenblatt DH), American Chemical Society, Washington DC, 7-1 – 7-48. Non GLP, published	No	published
A7.1.1.1.1	Ullmann	2005	Formaldehyde. Authors: Reuss G, Disteldorf W, Gamer AO, Hilt A, in Ullmann's Encyclopedia of Industrial Chemistry, Wiley-VCH Verlag GmbH & Co. KgaA. Online Version. GLP not applicable, published	No	published

A7.1.1.1.2	Chameides WL & Davis DD	1983	Aqueous-phase source of formic acid in clouds. Nature 304(4): 427-429 non GLP, published	No	published
A7.1.1.1.2	Chin M & Wine PH	1994	A temperature-dependent competitive kinetics study of the aqueous-phase reactions of OH radicals with formate, formic acid, acetate, acetic acid, and hydrated formaldehyde. In: Aquatic and surface photochemistry (Ed.: Helz GR), Chapter 5, Lewis Publ., Boca Raton, Fla., 85-96	No	published
A7.1.1.2.1/01	Gerike P & Gode P	1990	The biodegradability and inhibitory threshold concentration of some disinfectants. Chemosphere 21: 799-812 non GLP, published	No	published
A7.1.1.2.1/02	National Institute of Technology and Evaluation, Japan	1989	The Official Bulletin of Economy, Trade and Industry. URL: http://www.safe.nite.go.jp/84nglish/kizon/KIZON_start_hazkizon.html (last accessed on 24rd Oct 2006) GLP no data, published	No	published
A7.1.1.2.1/03	Gotvajn AZ & Zagorc-Koncan J	1999	Laboratory simulation of biodegradation of chemicals in surface waters: Closed Bottle and Respirometric Test. Chemosphere 38(6): 1339-1346 non GLP, published	No	published
A7.1.1.2.2 Just non-sub	Eiroa M, Kennes C & Veiga MC	2004	Formaldehyde biodegradation and its inhibitory effect on nitrification. J. Chem. Technol. Biotechnol 79: 499-504 non GLP, published	No	published
A7.1.1.2.2 Just non-sub	Krzemieniewski M, Debowski M, Janczukowicz W & Pesta J	2003	Formaldehyde biodegradation by activated sludge under anaerobic conditions. Environ. Protect. Engin. 29(3-4): 55-68 non GLP, published	No	published
A7.1.2.1.1/01	Eiroa M, Kennes C & Veiga MC	2005	Simultaneous nitrification and formaldehyde biodegradation in an activated sludge unit. Bioresource Technology 96: 1914-1918 non GLP, published	No	published
A7.1.2.1.1/02	Garrido JM, Mendez R & Lema JM	2000	Treatment of wastewaters from a formaldehyde-urea adhesives factory. Water Sci. Technol. 42(5-6): 293-300 non GLP, published	No	published
A7.1.2.1.2	Eiroa M, Vilar A, Kennes C & Veiga MC	2006	Formaldehyde biodegradation in the presence of methanol under denitrifying conditions.	No	published

			J. Chem. Technol. Biotechnol. 81: 312-317 non GLP, published		
A7.1.3	[redacted]	2006	[redacted] unpublished	No	[redacted]
A7.3.1/01	Atkinson R, Baulch DL, Cox RA, Hampson Jr RF, Kerr JA, Rossi MJ & Troe J	1997	Evaluated Kinetic, Photochemical and Heterogeneous Data for Atmospheric Chemistry: Supplement V, IUPAC Subcommittee on Gas Kinetic Data Evaluation for Atmospheric Chemistry. In: J. Phys. And Chem. Ref. Data, Vol 26, No.3., Editor: MW Chase Jr- GLP not applicable, published	No	published
A7.3.1/01	Gardner EP, Wijayaratne RD & Calvert JG	1984	Primary Quantum yields of Photodecomposition of Acetone in Air under Tropospheric Conditions. J. Phys. Chem. 88, 5069-5076 GLP not applicable, published	No	published
A7.3.1/01	Horowitz A & Calvert JG	1978	Wavelength Dependence of the Quantum Efficiencies of the Primary Processes in Formaldehyde Photolysis. Int. J. Chem. Kin., Vol. X: 805-819 GLP not applicable, published	No	published
A7.3.1/01	Lelieveld J	1990	The role of clouds in tropospheric photochemistry. Proefschrift, Rijksuniversiteit Utrecht, verdedigen 13.3.1990, p. 46 GLP not applicable, published	No	published
A7.3.1/02	Atkinson R	1994	Gas-phase Tropospheric Chemistry of Organic Compounds. Phys. Chem. Rev. Data, Monograph 2: 118-120 GLP not applicable, published	No	published
A7.3.1/02	Atkinson R, Baulch DL, Cox RA, Hampson Jr RF, Kerr JA, Rossi MJ & Troe J	1997	Evaluated Kinetic, Photochemical and Heterogeneous Data for Atmospheric Chemistry: Supplement V, IUPAC Subcommittee on Gas Kinetic Data Evaluation for Atmospheric Chemistry. In: J. Phys. And Chem. Ref. Data, Vol 26, No.3., Editor: MW Chase Jr GLP not applicable, published	No	published

A7.3.1/02	EPIWIN	2006	Estimation of phototransformation in air using AOPWIN v1.91 GLP not applicable, unpublished	No	-
A7.3.2	[redacted]	2008	[redacted] GLP not applicable, unpublished	Yes	[redacted]
A7.3.2	WHO	2002	Concise international chemical assessment document No. 40, Formaldehyde GLP not applicable, published	No	published
A7.4.1.1/01	Juhnke I & Lüdemann D	1978	Ergebnisse der Untersuchung von 200 chemischen Verbindungen auf akute Fischtoxizität mit dem Goldorfentest. Wasser- und Abwasser-Forschung 11: 161-164 non GLP, published	No	published
A7.4.1.1/02	Wellborn T	1969	The toxicity of nine therapeutic and herbicidal compounds to striped bass. The Progressive Fish-culturist 31: 27-32 non GLP, published	No	published
A7.4.1.1/03	Bills TD, Marking LL & Chandler JH	1977	Formalin: Its Toxicity to Nontarget Aquatic Organisms, Persistence and Counteraction. In: Investigations in Fish Control 73. United States Department of the Interior Fish and Wildlife Service, Washington D.C. non GLP, published	No	published
A7.4.1.1/04	Wellens H	1982	Vergleich der Empfindlichkeit von *Brachydanio rerio* und *Leuciscus idus* bei der Untersuchung der Fischtoxizität von chemischen Verbindungen und Abwässern. Z Wasser Abwasser Forsch 15: 49-52 non GLP, published	No	published
A7.4.1.1/05	Reardon IS & Harrell RM	1990	Acute toxicity of Formalin and Copper Sulfate to Striped Bass fingerlings held in varying salinities. Aquaculture 87: 255-270 non GLP, published	No	published
A7.4.1.1/06	Geiger DL, Brooke LT, Call DJ	1990	Acute toxicities of organic chemicals to fathead minnows (*Pimephales promelas*), volume V. Center for Lake Superior Environmental Studies, University of Wisconsin-Superior non GLP, published	No	published

A7.4.1.1/07	Hohreiter DW, Rigg DK	2001	Derivation of Ambient Water Quality Criteria for Formaldehyde. Chemosphere 45, 471-486 non GLP, published	No	published
A7.4.1.2/01	Bringmann G & Kühn R	1982	Ergebnisse der Schadwirkung wassergefährdender Stoffe gegen *Daphnia magna* in einem weiterentwickelten standardisierten Testverfahren. Z Wasser Abwasser Forsch 15: 1-6 non GLP, published	No	published
A7.4.1.2/02	Janssen CR & Persoone G	1993	Rapid toxicity screening tests for aquatic biota. 1. Methodology and experiments with *Daphnia magna*. Environ Toxicol Chem 12: 711-717 non GLP, published	No	published
A7.4.1.2/03	Tisler T & Zagorc-Koncan J	1997	Comparative assessment of toxicity of phenol, formaldehyde, and industrial wastewater to aquatic organisms. Water, Air and Soil Pollution 97: 315-322 non GLP, published	No	published
A7.4.1.3	Eisenträger A, Dott W, Klein J & Hahn S	2003	Comparative studies on algal toxicity testing using fluorometric microplate and Erlenmeyer flask growth-inhibition assays. Ecotoxicol Environ Safety 54: 346-354 non GLP, published	No	published
A7.4.1.4/01	Klecka GM, Landi LP & Bodner KM	1985	Evaluation of the OECD activated sludge, respiration test. Chemosphere 14: 1239-1251 non GLP, published	No	published
A7.4.1.4/02	Tisler T & Zagorc-Koncan J	1997	Comparative assessment of toxicity of phenol, formaldehyde, and industrial wastewater to aquatic organisms. Water, Air and Soil Pollution 97: 315-322 non GLP, published	No	published
A7.4.2/01	Jung SH, Kim JW, Jeon IG & Lee YG	2001	Formaldehyde residues in formalin-treated olive flounder (*Paralichthys olivaceus*), black rockfish (*Sebastes schlegeli*), and seawater. Aquaculture 194: 253-262 non GLP, published	No	published
A7.4.2/02	[redacted]	2006	[redacted]	No	-

			[redacted], unpublished		
A7.4.3.2/01	Meinelt T, Pietrock M, Burnison K & Steinberg C	2005	Formaldehyde toxicity altered by calcium and organic matter J Appl Ichthyol 21: 121-124 non GLP, published	No	published
A7.4.3.2/02	Johnson R, Tietge J, Stokes G & Lothenbach D	1993	The medaka carcinogenesis model. In: NTIS (ed.) Compendium of the FY1988 and FY1989 Research Review for the Research Methods Branch. Springfield, VA,AD-A272667:147-172 non GLP, published	No	published
A7.3.4.3/01 Just non-sub	Hohreiter DW, Rigg DK	2001	Derivation of Ambient Water Quality Criteria for Formaldehyde. Chemosphere 45, 471-486 non GLP, published	No	published
A7.4 (Interhygiene)		2009	chronische Toxizität Daphnia magna (wird nachgereicht), GLP: yes, unpublished	Yes	Interhygiene
A7.4.3.4	[redacted]	2008	[redacted], unpublished	Yes	[redacted]
A7.5 Just non-sub	WHO	2002	Concise international chemical assessment document No. 40; Formaldehyde. WHO, Geneva GLP not applicable, published	No	published
A7.5.1.2	Lockhart CL	1972	Control of nematodes with formaldehyde. Can Plant Dis Surv 52: 104 non GLP, published	No	published
A7.5.5	[redacted]	2006	[redacted], unpublished	No	-
A7.6.3 (Interhygiene)	Autorenkollektiv (Becker, H. et al)	1974	Organicum organisch-chemisches Grundpraktikum VEB Deutscher Verlag der Wissenschaften, Berlin , 15. Auflage	No	published
A7.8 (Interhygine)	Widulle H	2009	Studie über den verbleib von dach desinfektion von modernen Tierställen, Chemiebüro Widulle, unplublished	Yes	Interhygiene
Interhygiene	Interhygiene, INEOS Paraform	2008 2009,2010	Prüfprotokolle und Abnahmeprüfzeugnisse Formalin 37%	Yes	Interhygiene

Interhygiene	EuAB 4	2002	EuAB 4, Grundwerk, Prüfung auf Reinheit	No	
Interhygiene	Silber GmbH	2010	Untersuchungsbericht Formalin 37% Analysen-Nr. SB 7252-7256	No	
Interhygiene	Interhygiene	2008, 2009, 2012	Prüfprotokolle Ausgangsstoff	Yes	Interhygiene
B3 (Interhygiene)	EuAB 4	2002	EuAB 4, grundwerk	EuAB 4	
B3 (Interhygiene)	Widulle für Interhygine	2010	Auswertung der Analysen von Formaldehydlösungen durch die Leibnitz-Universität Hannover und Labor Silber	Yes	Inter-hygiene
B3 (Interhygiene)	Leibniz Universität	2010	Gerald Draeger Bericht Formaldehyd 55% Hannover,02.02.2010	Yes	Inter-hygiene
B3 (Interhygiene)	Labor Silber	2010	Untersuchungsbericht SB 6487, 03.12.2009	Yes	Inter-hygiene
B3.9 (Interhygiene)	A. Kramer und O. Assadian, eds	2008	Wallhäußers Praxis der Sterilisation, Desinfektion, Antiseptik und Konservierung	No	Thieme Verlag
B 5.10	Martin LS & McDougal JS	1987	Inactivation of human T-lymphotropic virus type III/lymphadenopathy-associated virus by formaldehyde-based reagents. Appl. Environ. Microbiol. 53:708-709 GLP not applicable, published	N	published
B 5.10	Mazzola PG, Penna TCV & da Martins AMS	2003	Determination of decimal reduction time (D- value) of chemical agents used in hospitals for disinfection purposes. BMC Infect. Dis. 3:24-33 GLP not applicable, published	N	published
B 5.10	Penna TCV, Mazzola PG & da Martins AMS	2001	The efficacy of chemical agents in cleaning and disinfection. BMC Infect. Dis. 1:16-23 GLP not applicable, published	N	published
B 5.10	Peters J, Thonle M, Renner P, Brauniger S & Fischer I	1998	Der Einfluß von Protamin auf die mikrobizide Wirkung von Formaldehyd. Zbl. Hyg. Umweltmed. 200:479-490. GLP not applicable, published	N	published
B 5.10	Sauerbrei A, Sehr K, Brandstädt A, Heim A, Reimer K & Wutzler P	2004	Sensitivity of human adenoviruses to different groups of chemical biocides. J. Hosp. Inf. 57:59-66. GLP not applicable, published	N	published
B 5.10	Spicher G & Peters J	1976	Resistenz mikrobieller Keime gegenüber Formaldehyd. I. Vergleichende quantitative Untersuchungen an einigen ausgewählten Arten vegetativer Bakterien, bakterieller Sporen, Pilze, Bakteriophagen und Viren.	N	published

			Zbl. Bakt. I. Abt. Orig. B 163:486-508 GLP not applicable, published		
B 5.10	Trujillo R & Lindell KF	1973	New formaldehyde base disinfectants. Appl. Microbiol. 26:106-110. GLP not applicable, published	N	published
B5.10 (Interhygiene)	Brill H	2009	Eignung von Ml-Muster 0901001 zur Desinfektion im Veterinärbereich, Dr. Brill & Partner GLP: yes, unpublished	Yes	Inter-hygiene
B5.10 (Interhygiene)	Steinmann J	2009	Viruzide Wirkung von 0901001 am Beispiel von Polioviren (wird nachgereicht), Mikrolab GmbH, GLP: yes, unplublished	Yes	Inter-hygiene
B5.10 (Interhygiene)	Kaleta	1992	Ergebnisse der Viruzidie-Prüfungen analog zu den DV Richtlinien	Yes	Inter-hygiene
B5.10 (Interhygiene)	Baljier G	2004	Prüfung des Deisnfektionsmittels “Intercid N” auf Viruzidie nach den Richtlinien der DVG, Gutachten für Interhygiene, 2004	Yes	Inter-hygiene
B5.10 (Interhygiene)	Trenner	1993	Gutachten über die viruzide Wirksamkeit von Intercid FA	Yes	Inter-hygiene
B5.10 (Interhygiene)	Baljer G	2004	Prüfung des Desinfektionsmittels „intercid N“ auf Viruzidie nach den Richtlinie der DVG	Yes	Inter-hygiene
B6 (Interhygiene)	Tessmer L	2009	Messung des Formaldehyddrucks im Gleichgewicht mit verschiedenen Lösungen, Labor der Interhygiene GmbH, GMP, unpublished	Yes	Inter-hygiene
B6 (Interhygiene)	Tessmer L	2009	Messing der Formaldehydexposition beim Ausbringen des Produktes 0901001 unter Praxisbedingungen, Labor der Interhygiene GmbH, GMP, unpublished	Yes	Inter-hygiene
B6.1 (Interhygiene)	Widulle H	2009	Berechnung der akuten Toxizität des Biozidproduktes 0901001 entsprechedn den Algorythmen der Zulassungsrichtinie, Chemiebüro Widulle, unpublished	Yes	Inter-hygiene
B6.6 (Interhygiene)	Chemiebüro Widulle, Dr. Herbert Widulle	2010	Berechnung der Formaldehydkonzentration in der Atemluft von professionellen Anwendern bei der Applikation von formaldehydhaltigen Desinfektionsmitteln und Abschätzung der Gesamtbelastung	Yes	Inter-hygiene
B6.6 (Interhygiene)	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin Koch, Berger-Preiß,		Arbeitsplatzbelastungen bei der Verwendung von Biozid-Produkten Tel 1: Inhalative und dermale Expositionsdaten für das Versprühen von flüssigen Biozidprodukten	No	

	Boehncke, Könnecker, Mangelsdorf				
B6.6 (Interhygiene)	Chemiebüro Widulle, Dr. Herbert Widulle	2010	Bestimmung des Anteils an gebundenem Formaldehyd in dem Biozidprodukt 0901001	Yes	Inter-hygiene
B6.6 (Interhygiene)	Chemiebüro Widulle, Dr. Herbert Widulle	2010	Bestimmung des Anteils an gebundenem Formaldehyd in dem Biozidprodukt 0901001	Yes	Inter-hygiene
B6.6/01 (Task Force)	Koch, W, Berger-Preiß, E., Boehncke, A, Könnecker, G., Mangelsdorf, I.	2004	Arbeitsplatzbelastungen bei der Verwendung von Biozid-Produkten Teil 1: Inhalative und dermale Expositionsdaten für das Versprühen von flüssigen Biozid-Produkten [Workplace exposure after application of biocidal products. Part 1: Inhalational and dermal exposures during spray application of biocides], Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA), Dortmund, Germany (Hrsg.) GLP not applicable, published	N	published
B6.6/01 (Task Force)	Montfoort, J.A., P. van der Poel and R. Luttik	1996	The use of disinfectants in livestock farming (Supplement to the evaluation method of non-agricultural pesticides of the Uniform System for Evaluation of Substances (USES)), RIVM report no. 679102033, Bilthoven, the Netherlands GLP not applicable, published	N	published
B6.6/01 (Task Force)	OECD	2006	OECD Series on Emission Scenario Documents, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems. ENV/JM/MONO(2006)4 – JT00197426 - 25.01.2006 GLP not applicable, published	N	published
B6.6/01 (Task Force)	SCC	2009	Draft Supplement to the Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, Drafted by Nickel, G, Schimmelpfennig, H., February 2009 GLP not applicable, unpublished	N	-
B6.6/01 (Task Force)	Seedorf, J., Hartung, J., Schröder, M. u.a.	1998	A survey of ventilation rates in livestock buildings in Northern Europe. J. agric. Engng. Res. 70, 39-47 GLP not applicable, published	N	published
B6.6/01 (Task Force)	Spindler, B.	2006	Reinigung und Desinfektion in der Nutztierhaltung [Cleaning and disinfection in livestock husbandry]. Referat von Dr. Birgit Spindler, Institut für Tierhygiene, Tierschutz und Nutztierethologie, Hannover, In: Grund- und Fortbildungslehrgang	N	published

			"Raumdesinfektion mit Formaldehyd" gem. TRGS 522, Wuelfel, Hannover GLP not applicable, published		
B6.6/01 (Task Force)	Strauch, D., Böhm, R.	2002	Reinigung und Desinfektion in der Nutztierhaltung und Veredelungswirtschaft [Cleaning and disinfection in livestock husbandry and improvement economy]. 2., überarb. Aufl. Enke Verlag, Stuttgart GLP not applicable, published	N	published
B6.6/01 (Task Force)	TRGS 513	2008	TRGS 513 Technische Regeln für Gefahrstoffe. Begasungen mit Ethylenoxid und Formaldehyd in Sterilisations- und Desinfektionsanlagen. Ausgabe Juni 1996 (BArbBl. Heft 6/1996, S. 53-8), geändert Feb. 2000 (BArbBl. Heft 2/2000, S. 80), zuletzt geändert und ergänzt: Juni 2008 GLP not applicable, published)	N	published
B6.6/01 (Task Force)	TRGS 522	2001	Technische Regeln für Gefahrstoffe. Raumdesinfektion mit Formaldehyd. [Technical Guidelines for Hazardous Substances. Room Disinfection with Formaldehyde]. Ausgabe Juni 1992, zuletzt geändert: BArbBl. Heft 9/2001 GLP not applicable, published	N	published
B6.6/01 (Task Force)	Ullmann	2005	"Formaldehyde" in Ullmann's Encyclopedia of Industrial Chemistry, Wiley-VCH Verlag GmbH & Co. KGaA. Online Version GLP not applicable, published	N	published
B6.6/02 (Task Force)	Montfoort, J.A., P. van der Poel and R. Luttik	1996	The use of disinfectants in livestock farming (Supplement to the evaluation method of non-agricultural pesticides of the Uniform System for Evaluation of Substances (USES)), RIVM report no. 679102033, Bilthoven, the Netherlands GLP not applicable, published	N	published
B6.6/02 (Task Force)	OECD	2006	OECD Series on Emission Scenario Documents, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems. ENV/JM/MONO(2006)4 – JT00197426 - 25.01.2006 GLP not applicable, published	N	published
B6.6/02 (Task Force)	SCC	2009	Draft Supplement to the Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, Drafted by Nickel, G, Schimmelpfennig, H., February 2009 GLP not applicable, unpublished	N	-

B6.6/02 (Task Force)	Seedorf, J., Hartung, J., Schröder, M. u.a.	1998	A survey of ventilation rates in livestock buildings in Northern Europe. J. agric. Engng. Res. 70, 39-47 GLP not applicable, published	N	-
B6.6/02 (Task Force)	Spindler, B.	2006	Reinigung und Desinfektion in der Nutztierhaltung [Cleaning and disinfection in livestock husbandry]. Referat von Dr. Birgit Spindler, Institut für Tierhygiene, Tierschutz und Nutztierethologie, Hannover, In: Grund- und Fortbildungslehrgang "Raumdesinfektion mit Formaldehyd" gem. TRGS 522, Wuelfel, Hannover GLP not applicable, published	N	-
B6.6/02 (Task Force)	Strauch, D., Böhm, R.	2002	Reinigung und Desinfektion in der Nutztierhaltung und Veredelungswirtschaft [Cleaning and disinfection in livestock husbandry and improvement economy]. 2., überarb. Aufl. Enke Verlag, Stuttgart GLP not applicable, published	N	-
B6.6/02 (Task Force)	TRGS 513	2008	TRGS 513 Technische Regeln für Gefahrstoffe. Begasungen mit Ethylenoxid und Formaldehyd in Sterilisations- und Desinfektionsanlagen. [Technical Guidelines for Hazardous Substances. Vaporisation with ethylene oxide and formaldehyde with equipments for sterilization and disinfection]. Ausgabe Juni 1996 (BArbBl. Heft 6/1996, S. 53-8), geändert Feb. 2000 (BArbBl. Heft 2/2000, S. 80), zuletzt geändert und ergänzt: Juni 2008 GLP not applicable, published)	N	-
B6.6/02 (Task Force)	TRGS 522	2001	TRGS 522 Technische Regeln für Gefahrstoffe. Raumdesinfektion mit Formaldehyd. [Technical Guidelines for Hazardous Substances. Room Disinfection with Formaldehyde]. Ausgabe Juni 1992, zuletzt geändert: BArbBl. Heft 9/2001 GLP not applicable, published	N	published
B6.6/03 (Task Force)	B.Braun Melsungen AG	2009	Chemical Resistance Vasco® / Manufix® in accordance with EN 374-3, 12.02.2009, Document no.: MG – Chem, B. Braun Melsungen AG OPM Division, Carl-Braun-Straße 1, 34212 Melsungen, Germany GLP not applicable, published	N	published
B6.6/03 (Task Force)	Hüttner, B., Landgraf, H., Conrad, C.	1969	Versuche zur Brutbeigasung mit Formalin [Trials for hatching eggs funigation with formalin],	N	published

			Tieraerztl. Umschau 24, 421-424 (in German) GLP not applicable, published		
B6.6/03 (Task Force)	Hüttner, B.	1973	Versuche zur Brutbeigasung mit Formalin [Trials for hatching eggs funigation with formalin], Tieraerztl. Umschau 28, 20-26 (in German) GLP not applicable, published	N	published
B6.6/03 (Task Force)	[redacted]	2009	Results of a data search for the disinfection in hatcheries using formaldehyde performed in order of the applicants GLP not applicable, unpublished	Y	EWABO Lysoform Synthite
B6.6/03 (Task Force)	Montfoort, J.A., P. van der Poel and R. Luttik	1996	The use of disinfectants in livestock farming (Supplement to the evaluation method of non-agricultural pesticides of the Uniform System for Evaluation of Substances (USES)), RIVM report no. 679102033, Bilthoven, the Netherlands GLP not applicable, published	N	published
B6.6/03 (Task Force)	PROFAS	2004	☐Permeation von Cjemikalien nach DIN EN 374-2 [Permeation of Chemicals according to DIN EN 374-3], PRO-FAS GmbH & Co. KG, Elso-Klöver-Str. 6, 21337 Lüneburg (in German) GLP not applicable, published	N	published
B6.6/03 (Task Force)	Prud'homme de Lodde, et al. (RIVM)	2006	RIVM Consexpo fact sheets, RIVM report no. 320005003/2006, GLP not applicable, published	N	published
B6.6/03 (Task Force)	TRGS 513	2008	TRGS 513 Technische Regeln für Gefahrstoffe. Begasungen mit Ethylenoxid und Formaldehyd in Sterilisations- und Desinfektionsanlagen. Ausgabe Juni 1996 (BArbBl. Heft 6/1996, S. 53-8), geändert Feb. 2000 (BArbBl. Heft 2/2000, S. 80), zuletzt geändert und ergänzt: Juni 2008 GLP not applicable, published)	N	published
B6.6/03 (Task Force)	TRGS 522	2001	TRGS 522 Technische Regeln für Gefahrstoffe. Raumdesinfektion mit Formaldehyd. [Technical Guidelines for Hazardous Substances. Room Disinfection with Formaldehyde]. Ausgabe Juni 1992, zuletzt geändert: BArbBl. Heft 9/2001 GLP not applicable, published	N	published
B6.6/03 (Task Force)	van der Poel, P., Bakker, J.	2001	RIVM report 601450009: Emission Scenarios for all 23 product types of the Biocidal Products Directive (EU Directive 98/8/EC) GLP not applicable, published	N	published
B6.6/03 (Task Force)	Williams, J.E., Siegel, H.S.	1969	Formaldehyde levels on and in chickens eggs following preincubation fumigation, Poultry	N	published

			Science 48(2), 552-558 GLP not applicable, published		
B6.6/04 (Task Force)	B.Braun Melsungen AG	2009	Chemical Resistance Vasco® / Manufix® in accordance with EN 374-3, 12.02.2009, Document no.: MG – Chem, B. Braun Melsungen AG OPM Division, Carl-Braun-Straße 1, 34212 Melsungen, Germany GLP not applicable, published	N	published
B6.6/04 (Task Force)	Bundesamt für Bevölkerungsschutz und Katastrophenhilfe	2007	Handbuch zum Bevölkerungsschutz [„Handbook for Civil Protection“ of German Federal office of Civil Protection and Disaster Assistance (in German), 3. edition, 2007, ISBN 3-939347-06 GLP not applicable, published	N	published
B6.6/04 (Task Force)	[redacted]	2009	Compilation of pictures and information for the use of formaldehyde for disinfection of vehicles (epidemic) gathered in order of the applicants GLP not applicable, not published	Y	EWABO Lysoform Synthite
B6.6/04 (Task Force)	Katastrophenschutz Landkreis München	2001	Merkblatt für Vorbereitung, Aufbau und Betrieb von Desinfektionspunkten zur Bekämfpung der Maul- und Klauenseuche GLP not applicable, published	N	published
B6.6/04 (Task Force)	Koch, W, Berger-Preiß, E., Boehncke, A, Könnecker, G., Mangelsdorf, I.	2004	Arbeitsplatzbelastungen bei der Verwendung von Biozid-Produkten Teil 1: Inhalative und dermale Expositionsdaten für das Versprühen von flüssigen Biozid-Produkten [Workplace exposure after application of biocidal products. Part 1: Inhalational and dermal exposures during spray application of biocides], Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA), Dortmund, Germany (Hrsg.) GLP not applicable, published	N	published
B6.6/04 (Task Force)	Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittel-sicherheit (LAVES)	2009	Leitfaden zum Einsatz von landwirtschaftlichem Fachpersonal im Tierseuchenkrisenfall GLP not applicable, published	N	published
B6.6/04 (Task Force)	PROFAS	2004	☐Permeation von Cjemikalien nach DIN EN 374-2 [Permeation of Chemicals according to DIN EN 374-3], PRO-FAS GmbH & Co. KG, Elso-Klöver-Str. 6, 21337 Lüneburg (in German) GLP not applicable, published	N	published
B6.6/04 (Task Force)	Bundesministerium für Ernährung,	2006	Verordnung über Schutzmaßnahmen beim Auftreten von Geflügelpest bei Nutzgeflügel (Nutzgeflügel-	N	published

	Landwirtschaft und Verbraucherschutz (BMELV)		Geflügelpestschutzverordnung) i. d. Fassung vom 15. März 2006, veröff. im Elektronischen Bundesanzeiger. 12 p. GLP not applicable, published		
B6.6/05 (Task Force)	B.Braun Melsungen AG	2009	Chemical Resistance Vasco® / Manufix® in accordance with EN 374-3, 12.02.2009, Document no.: MG – Chem, B. Braun Melsungen AG OPM Division, Carl-Braun-Straße 1, 34212 Melsungen, Germany GLP not applicable, published	N	published
B6.6/05 (Task Force)	Behörde für Arbeit, Gesundheit und Soziales, Hamburg (BAGS)	2000	Standards zur Expositionsabschätzung, GLP not applicable, published	N	published
B6.6/05 (Task Force)	Geyer, Lischer et al.	2000	Handbuch zur Pflege und Behandlung der Klauen beim Rind [Handbook for care and treatment of cattles´ hooves], Thieme Verlag, SBN 3826333314. p. GLP not applicable, published	N	published
B6.6/05 (Task Force)	Horizont Group GmbH		leaflet "Hufpflege" (admission for usage of picture given by Alan Aiden, Cosnet La Gee) GLP not applicable, published	N	published
B6.6/05 (Task Force)	Montfoort, J.A., P. van der Poel and R. Luttik	1996	The use of disinfectants in livestock farming (Supplement to the evaluation method of non-agricultural pesticides of the Uniform System for Evaluation of Substances (USES)), RIVM report no. 679102033, Bilthoven, the Netherlands GLP not applicable, published	N	published
B6.6/05 (Task Force)	[redacted]	2009	Compilation of data gathering for the use of formaldehyde for disinfection of animals´ feet GLP not applicable, published	Y	EWABO Lysoform Synthite
B6.6/05 (Task Force)	OECD	2006	OECD Series on Emission Scenario Documents, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems GLP not applicable, published	N	EWABO Lysoform Synthite
B6.6/05 (Task Force)	PROFAS	2004	☐Permeation von Cjemikalien nach DIN EN 374-2 [Permeation of Chemicals according to DIN EN 374-3], PRO-FAS GmbH & Co. KG, Elso-Klöver-Str. 6, 21337 Lüneburg (in German) GLP not applicable, published	N	published
B6.6/05 (Task Force)	van der Poel, Bakker (RIVM)	2001	RIVM report 601450009: Emission Scenarios for all 23 product types of the Biocidal Products Directive (EU Directive 98/8/EC) GLP not applicable, published	N	published

B6.6/06 (Task Force)	Koch, W, Berger-Preiß, E., Boehncke, A, Könnecker, G., Mangelsdorf, I.	2004	Arbeitsplatzbelastungen bei der Verwendung von Biozid-Produkten Teil 1: Inhalative und dermale Expositionsdaten für das Versprühen von flüssigen Biozid-Produkten [Workplace exposure after application of biocidal products. Part 1: Inhalational and dermal exposures during spray application of biocides], Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA), Dortmund, Germany (Hrsg.) GLP not applicable, published	N	published
B7.1/01 (Task Force)	[redacted]	2006	Estimation of the distribution behaviour in the environment of formaldehyde. S. Hahn, T. Hahn, O. Licht, J. Regelmann, Fraunhofer Institute of Toxicology and Experimental Medicine, Department Chemical Risk Assessment, 2006 GLP not applicable, unpublished	Y	EWABO Lysoform Synthite
B7.1/01 (Task Force)	EC	2011	JRC Scientific and Technical Reports: Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products	N	published
B7.1/01 (Task Force)	[redacted]	2013	Evaporation of formaldehyde after wet or room disinfection in animal housings, expert statement, unpublished	Y	EWABO Lysoform Synthite
B7.1/02 (Task Force)	[redacted]	2006	Estimation of the distribution behaviour in the environment of formaldehyde. [redacted] GLP not applicable, unpublished	Y	EWABO Lysoform Synthite
B7.1/02 (Task Force)	[redacted]	2009	ITEM (2009) Results of a data search for the disinfection in hatcheries using formaldehyde performed in order of the applicants. [redacted]; [redacted].	Y	EWABO Lysoform Synthite
B7.1/02 (Task Force)	EC	2011	JRC Scientific and Technical Reports: Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products	N	published
B7.1/03 (Task Force)	[redacted]	2006	Estimation of the distribution behaviour in the environment of formaldehyde. [redacted] GLP not applicable, unpublished	Y	EWABO Lysoform Synthite

B7.1/03 (Task Force)	[redacted]	2009	Compilation of pictures and information for the use of formaldehyde for disinfection of vehicles (epidemic) gathered in order of the applicants. [redacted] GLP not applicable, unpublished	N	-
B7.1/03 (Task Force)	EC	2011	JRC Scientific and Technical Reports: Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products	N	published
B7.1/04 (Task Force)	[redacted]	2006	Estimation of the distribution behaviour in the environment of formaldehyde. [redacted] GLP not applicable, unpublished	Y	EWABO Lysoform Synthite
B7.1/04 (Task Force)	EC	2011	JRC Scientific and Technical Reports: Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products	N	published
B7.1/04 (Task Force)	[redacted]	2009	Compilation of data gathering for the use of formaldehyde for disinfection of animals´ feet	Y	EWABO Lysoform Synthite

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Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.1.1-3 Add Info	BfR	2006	Assessment of the carcinogenicity of formaldehyde. Bundesinstitut für Risikobewertung, Pressestelle, Berlin, page 43-44	No	-
A6.1.1-3 Add Info	Greim H. (ed.)	2000	Toxikologisch-arbeitsmedizinische Begründungen von MAK-Werten, Gesundheitsschädliche Arbeitstoffe, Formaldehyde	No	-
A6.1.1-3 Add Info	OECD	2002	Formaldehyde, ICCA documentation on formaldehyde http://cs3-hq.oecd.org/scripts/hpv/	No	-
A6.1.1-3 Add Info	Pandey CK, Agarwal A, Baronia A & Singh N	2000	Toxicity of ingested formalin and its management. Hum Exp Toxicol, 19: 360-366 non GLP, published	No	-
A6.1.1-3 Add Info	WHO	1989	Formaldehyde. IPCS (International Programme on Chemical Safety). Environmental Health Criteria No. 89, WHO, Geneva	No	-
A6.1.4 Add Info	Arts JHE, de Heer C & Woutersen R	2006	Local effects in the respiratory tract: relevance of subjectively measured irritation for setting occupational exposure limits. Int Arch Occup Environ Health 79: 283-298 non GLP, published	No	-
A6.1.4 Add Info	ATSDR	1999	Toxicological profile of formaldehyde. Agency for Toxic Substances and Disease Registry, US Department of Health and Human Services, Public Health Service, Atlanta, Georgia, USA	No	-
A6.1.4 Add Info	Greim H. (ed.)	2000	Toxikologisch-arbeitsmedizinische Begründungen von MAK-Werten, Gesundheitsschädliche Arbeitstoffe, Formaldehyde	No	-
A6.1.4 Add Info	IARC	1995	Formaldehyde. Lyon, International Agency for Research on Cancer, IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man, Vol. 62, pp 217–362	No	-
A6.1.4 Add Info	Kochhar R, Nanda V, Nagi B & Mehta S	1986	Formaldehyde-induced corrosive gastric cicatrisation: case report. Human Toxicol, 5: 381-382 non GLP, published	No	-
A6.1.4 Add Info	OECD	2002	Formaldehyde, ICCA documentation on formaldehyde http://cs3-hq.oecd.org/scripts/hpv/	No	-

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A6.1.4 Add Info	Paustenbach D, Alarie Y, Kulle T, Schachter N, Smith R, Swenberg J, Witschi H & Harowitz SB	1997	A recommended occupational exposure limit for formaldehyde based on irritation. J Toxicol Environ Health 50: 217-263 non GLP, published	No	-
A6.1.4 Add Info	Weil CS & Scala RA	1971	Study of intra- and interlaboratory variability in the results of the rabbit eye and skin irritation tests. Toxicol Appl Pharmacol, 19: 276-360 non GLP, published	No	-
A6.1.4 Add Info	WHO	1989	Formaldehyde. IPCS (International Programme on Chemical Safety). Environmental Health Criteria No. 89, WHO, Geneva	No	-
A6.1.5 Add Info	ATSDR	1999	Toxicological profile of formaldehyde. Agency for Toxic Substances and Disease Registry, US Department of Health and Human Services, Public Health Service, Atlanta, Georgia, USA	No	-
A6.1.5 Add Info	Doi S, Suzuki S, Morishita M, Yamada M, Kanda Y, Torii S & Sakamoto T	2003	The prevalence of IgE sensitization to formaldehyde in asthmatic children. Allergy, 58: 668-671 non GLP, published	No	-
A6.1.5 Add Info	Fujii K, Tsuji K, Matsuura H, Okazaki F, Takahashi S, Arata J & Iwatsuki K	2005	Effects of formaldehyde gas exposure in a murine allegic contact hypersensitivity model. Immunopharmacol Immunotoxicol, 27: 163-175 non GLP, published	No	-
A6.1.5 Add Info	IARC	1995	Formaldehyde. Lyon, International Agency for Research on Cancer, IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man, Vol. 62, pp 217–362	No	-
A6.1.5 Add Info	OECD	2002	Formaldehyde, ICCA documentation on formaldehyde http://cs3-hq.oecd.org/scripts/hpv/	No	-
A6.1.5 Add Info	WHO	1989	Formaldehyde. IPCS (International Programme on Chemical Safety). Environmental Health Criteria No. 89, WHO, Geneva	No	-
A6.2 Add Info	Bartnik FG, Gloxhuber C & Zimmermann V	1985	Percutaneous absorption of formaldehyde in rats. Toxicol Lett 25: 167-172 non GLP, published	No	-
A6.2 Add Info	BfR	2006	Assessment of the carcinogenicity of formaldehyde.	No	-

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Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Bundesinstitut für Risikobewertung, Pressestelle, Berlin, page 43-44		
A6.2 Add Info	IARC	1995	Formaldehyde. Lyon, International Agency for Research on Cancer, IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man, Vol. 62, pp 217–362	No	-
A6.2 Add Info	Keller DA, Heck H, Randall H & Morgan K	1990	Histochemical localization of formaldehyde dehydrogenase in the rat. Toxicol Appl Pharmacol, 106: 311-326 non GLP, published	No	-
A6.2 Add Info	Loden M	1986	The in vitro permeability of human skin to benzene, ethylene glycol, formaldehyde, and n-Hexane. Acta Pharmacol Toxicol, 58: 382-389 non GLP, published	No	-
A6.2 Add Info	OECD	2002	Formaldehyde, ICCA documentation on formaldehyde http://cs3-hq.oecd.org/scripts/hpv/	No	-
A6.2 Add Info	Patterson DL, Gross E, Bogdanffy M & Morgan K	1986	Retention of formaldehyde gas by nasal passages of F344 rats. Toxicologist, 6: 55 non GLP, published	No	-
A6.2 Add Info	Uotila L & Koivusalo M	1997	Expression of formaldehyde dehydrogenase and S-formylglutathione hydrolase activities in different rat tissues. Adv Exp Med Biol, 414: 365-371 non GLP, published	No	-
A6.2 Add Info	WHO	2002	Concise international chemical assessment document No. 40; Formaldehyde. WHO, Geneva	No	-
A6.3-5.1 Add Info	ATSDR	1999	Toxicological profile of formaldehyde. Agency for Toxic Substances and Disease Registry, US Department of Health and Human Services, Public Health Service, Atlanta, Georgia, USA	No	-
A6.3-5.1 Add Info	OECD	2002	Formaldehyde, ICCA documentation on formaldehyde http://cs3-hq.oecd.org/scripts/hpv/	No	-
A6.3-5.1 Add Info	Tobe M, Naito K & Kurokawa Y	1989	Chronic toxicity study on formaldehyde administered orally to rats. Toxicology, 56: 79-86 non-GLP, published	No	-
A6.3-5.1 Add Info	Vargova M, Wagnerova J, Liskova A & Jakubovsky J	1993	Subacute immunotoxicity study of formaldehyde in male rats. Drug Chem Toxicol, 16: 255-275 non-GLP, published	No	-
A6.3-5.1 Add Info	WHO	1989	Formaldehyde. IPCS (International Programme on Chemical Safety). Environmental Health Criteria No. 89, WHO, Geneva	No	-

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Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.3-5.2 Add Info	Iversen OH	1986	Formaldehyde and skin carcinogenesis. Environ Int, 12: 541-544 non GLP, published		
A6.3-5.2 Add Info	OECD	2002	Formaldehyde, ICCA documentation on formaldehyde http://cs3-hq.oecd.org/scripts/hpv/	No	-
A6.3-5.3 Add Info	BfR	2006	Assessment of the carcinogenicity of formaldehyde. Bundesinstitut für Risikobewertung, Pressestelle, Berlin, page 43-44	No	-
A6.3-5.3 Add Info	Greim H. (ed.)	2000	Toxikologisch-arbeitsmedizinische Begründungen von MAK-Werten, Gesundheitsschädliche Arbeitstoffe, Formaldehyde	No	-
A6.3-5.3 Add Info	IARC	1995	Formaldehyde. Lyon, International Agency for Research on Cancer, IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man, Vol. 62, pp 217–362	No	-
A6.3-5.3 Add Info	OECD	2002	Formaldehyde, ICCA documentation on formaldehyde http://cs3-hq.oecd.org/scripts/hpv/	No	-
A6.3-5.3 Add Info	WHO	2002	Concise international chemical assessment document No. 40; Formaldehyde. WHO, Geneva	No	-
A6.3-5.3 Add Info	Wilmer JW, Woutersen R, Appelman L, Leeman W & Feron V	1987	Subacute (4-week) inhalation toxicity study of formaldehyde in male rats: 8-hour intermittent versus 8-hour continuous exposure. J Appl Toxicol, 7: 15-16 non-GLP, published	No	-
A6.6.1-3 Add Info	IARC	1995	Formaldehyde. Lyon, International Agency for Research on Cancer, IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man, Vol. 62, pp 217–362	No	-
A6.6.1-3 Add Info	Schmid O & Speit G	2007	Genotoxic effects induced by formaldehyde in human blood and implications for the interpretation of biomonitoring studies. Mutagebnesis 22(1): 69-74 non-GLP, published	No	-
A6.6.4-6 Add Info	BfR	2006	Assessment of the carcinogenicity of formaldehyde. Bundesinstitut für Risikobewertung, Pressestelle, Berlin, page 43-44	No	-
A6.6.4-6 Add Info	Greim H. (ed.)	2000	Toxikologisch-arbeitsmedizinische Begründungen von MAK-Werten, Gesundheitsschädliche Arbeitstoffe, Formaldehyde	No	-
A6.6.4-6 Add Info	IARC	1995	Formaldehyde. Lyon, International Agency for Research on Cancer, IARC Monographs on the Evaluation	No	-

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Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
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A6.6.4-6 Add Info	Im H, Oh E, Mun J, Khim JY, Lee E, Kang H, Kim E, Kim H, Won N, Kim Y, Jung W & Sul D	2006	Evaluation of toxicological monitoring markers using proteomic analysis in rats exposed to formaldehyde. J Proteome Res, 5: 1354-1366 non-GLP, published	No	-
A6.6.4-6 Add Info	OECD	2002	Formaldehyde, ICCA documentation on formaldehyde http://cs3-hq.oecd.org/scripts/hpv/	No	-
A6.6.4-6 Add Info	Orsiere T, Sari-Minodier I, Iarmarcovai G & Botta A	2006	(2006) Genotoxic risk assessment of pathology and anatomy laboratory workers exposed to formaldehyde by use of personl air sampling and analysis of DNA damage in peripheral lymphocytes. Mutat Res 605: 30-41 non-GLP, published	No	-
A6.6.4-6 Add Info	Shahm J, Bomstein Y, Gurvich R, Rashkovsky M & Kaufman Z	2003	DNA–protein crosslinks and p53 protein expression in relation to occupational exposure to formaldehyde. Occup Environ Med 60: 403-409 non-GLP, published	No	-
A6.6.4-6 Add Info	Speit G & Schmid O	2006	Local genotoxic effects of formaldehyde in humans measured by the micronucleus test with exfoliated epithelial cells. Mutat Res 613: 1-9 non GLP, published	No	-
A6.6.4-6 Add Info	Speit G, Schmid O, Fröhler-Keller M, Lang I & Triebig G	2007	Assessment of local genotoxic effects of formaldehyde in humans measured by the micronucleus test with exfoliated buccal mucosa cells Mutat Res 627: 129-135 non-GLP, published	No	-
A6.7 Add Info	BfR	2006	Assessment of the carcinogenicity of formaldehyde. Bundesinstitut für Risikobewertung, Pressestelle, Berlin, page 43-44	No	-
A6.7 Add Info	Greim H. (ed.)	2000	Toxikologisch-arbeitsmedizinische Begründungen von MAK-Werten, Gesundheitsschädliche Arbeitstoffe, Formaldehyde	No	-
A6.7 Add Info	IARC	1995	Formaldehyde. Lyon, International Agency for Research on Cancer, IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man, Vol. 62, pp 217–362	No	-
A6.7 Add Info	Iversen OH	1986	Formaldehyde and skin carcinigenesis. Environ Int, 12: 541-544 non GLP, published	No	-

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A6.7 Add Info	OECD	2002	Formaldehyde, ICCA documentation on formaldehyde http://cs3-hq.oecd.org/scripts/hpv/	No	-
A6.7 Add Info	Tobe M, Naito K & Kurokawa Y	1989	Chronic toxicity study on formaldehyde administered orally to rats. Toxicology, 56: 79-86 non GLP, published	No	-
A6.7 Add Info	WHO	1989	Formaldehyde. IPCS (International Programme on Chemical Safety). Environmental Health Criteria No. 89, WHO, Geneva	No	-
A6.7 Add Info	WHO	2002	Concise international chemical assessment document No. 40; Formaldehyde. WHO, Geneva	No	-
A6.8.1 Add Info	Collins JJ, Ness R, Tyl R, Krivanek N, Esmen N & Hall T	2001	A review of adverse pregnancy outcomes and formaldehyde exposure in humans and animal studies. Regulat Toxicol Pharmacol, 34: 17-34 GLP not applicable, published	No	-
A6.8.1 Add Info	IARC	1995	Formaldehyde. Lyon, International Agency for Research on Cancer, IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man, Vol. 62, pp 217–362	No	-
A6.8.1 Add Info	OECD	2002	Formaldehyde, ICCA documentation on formaldehyde http://cs3-hq.oecd.org/scripts/hpv/	No	-
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A6.9 Add Info	ATSDR	1999	Toxicological profile of formaldehyde. Agency for Toxic Substances and Disease Registry, US Department of Health and Human Services, Public Health Service, Atlanta, Georgia, USA	No	-
A6.9 Add Info	Malek FA, Möritz KU & Fanghänel J	2003 a	A study on the effects of inhalative formaldehyde exposure on water labyrinth test performance in rats. Ann Anat 185: 277-285 non-GLP, published	No	-
A6.9 Add Info	Malek FA, Möritz KU & Fanghänel J	2003 b	A study on specific behavioural effects of formaldehyde in the rat. J Exp Animal Sci 43: 160-170 non-GLP, published	No	-
A6.9 Add Info	OECD	2002	Formaldehyde, ICCA documentation on formaldehyde http://cs3-hq.oecd.org/scripts/hpv/	No	-
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