

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

Evaluation of active substances

Assessment Report



Peracetic acid

Product-types 11 and 12
(Preservatives for liquid cooling and processing systems)
(Slimecides)

August 2016

Finland

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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 Peracetic acid as product-types 11 and 12 (PT 11: Preservatives for liquid cooling and processing systems, PT 12: Slimicides), 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.

Peracetic acid (CAS no. 79-21-0) was notified as an existing active substance, by CEFIC Peracetic Acid Registration Group (PAR), hereafter referred to as the applicant, in product-types 11 and 12 (and 1-6).

Commission Regulation (EC) No 1451/2007 of 4 December 2007¹ 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, Finland 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 Peracetic acid as an active substance in Product Types 11 and 12 was 30 October 2008, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 3 October 2008, Finland competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 18 December 2008.

On 3 July 2015, the Rapporteur Member State submitted to the ECHA 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 Peracetic acid for product-types 11 and 12, 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.

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

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

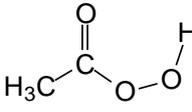
However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data for that purpose has been granted to that applicant.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

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

Identification of the active substance

CAS-No.	79-21-0
CAS name	Ethaneperoxoic acid
EINECS-No.	201-186-8
Other No. (CIPAC, ELINCS)	Not available
IUPAC Name	Peroxyethanoic acid
Common name, synonyms	Common name: Peracetic acid Synonyms: Acetyl hydroperoxide, Ethaneperoxoic acid, Peroxyacetic acid
Molecular formula	C ₂ H ₄ O ₃
Structural formula	
Molecular weight (g/mol)	76.05 g/mol

The active substance is peracetic acid in an aqueous solution containing acetic acid and hydrogen peroxide.

Peracetic acid is produced by reacting hydrogen peroxide with acetic acid in aqueous solution. In this process, peracetic acid is obtained as aqueous solutions containing peracetic acid, acetic acid, hydrogen peroxide. The manufacturing process leads into products with characteristics of a chemical equilibrium. The concentration of peracetic acid in solutions is typically in the range of 0.1 % - 15 % (w/w). Isolated peracetic acid, hence without water, does neither exist commercially nor is it used in the production/formulation of peracetic acid biocidal products.

This evaluation covers the use of peracetic acid in product types 11 and 12. Two representative theoretical equilibrium products containing 5 % and 15 % peracetic acid have been defined in this dossier.

Specifications: The pure peracetic acid cannot be isolated due to stability reasons, and the possible impurities can only be originate from the starting materials. Hence the specification is based on the starting materials acetic acid and hydrogen peroxide.

The specification of acetic acid is >99.8% (w/w) in accordance with the Commission Regulation (EU) No 231/2012. For hydrogen peroxide the specification in its aqueous solution is 35 – 69.9 % (w/w), as indicated in the approval of Hydrogen peroxide CAR in product types 1-6.

Impurities: The maximum impurities of acetic acid are in accordance with the Commission Regulation (EU) No 231/2012. The impurities of hydrogen peroxide are as defined in the CAR for Hydrogen peroxide PTs 1-6.

Additives: the following additives can be included in the solutions of peracetic acid produced. Stabilizers: 1-hydroxyethane-1,1-diphosphonic acid (HEDP) (max 14 g/kg) and/or dipicolinic acid (max 1.6 g/kg). A Catalyzer: sulphuric acid (max 10 g/kg).

Companies of the CEFIC Peracetic Acid Registration Group (PAR) for which compliance with the set specification was not demonstrated must provide quality control data to the

evaluating Competent Authority (Finland) to demonstrate compliance no later than 6 months before the date of approval of the active substance.

Remarks on products

Some peracetic acid solutions for special uses may contain product specific co-formulants which have not been evaluated in this CAR.

A concentrated solution of peracetic acid (with minor amounts of acetic acid and hydrogen peroxide) can be produced by vacuum distillation from aqueous equilibrium solutions of peracetic acid. Such products (with 25–40% peracetic acid), with no equilibrium characteristics, intended for industrial uses in PT 2 and PT 6, or PT 12, have not been assessed and are not covered in this CAR. The starting materials and catalyzers must comply with set specifications.

The hazard as well as the risk assessment in this CAR is only covering products containing peracetic acid concentrations up to 15% as the exposure assessments have not been performed with higher peracetic acid concentrations. For products containing peracetic acid in concentrations > 15%, further assessment shall be required for toxicological and physico-chemical risks.

Physico-Chemical Properties

Due to the explosiveness of pure (100%) peracetic acid it is technically impossible to perform experimental studies according to the guidelines to determine the physico-chemical properties of pure peracetic acid. Thus, tested or calculated literature data is given whenever meaningful and possible in Table 2-1.

All peracetic acid solutions are clear, colourless liquids with a pungent vinegar-like odour and are soluble in polar solvents, aromatics and acetates (Swern, 1970). The physical and chemical properties of the aqueous solutions of peracetic acid are specific to the concentration ratio of the individual components in the formulations.

Peracetic acid solutions have oxidising and explosive properties. Peracetic acid must be classified as oxidizing following the criteria defined in Commission Directive 2001/59/EC, paragraph 2.2.2.1, (remarks concerning peroxides). Consequently, no test is required. In CLP the classification procedure and criteria for oxidizing substances is not applicable for organic peroxides. According to the criteria of CLP, Annex I, 2.15.1.1, peracetic acid is an organic peroxide. This term covers formulations. Under CLP, organic peroxides are comprised in a separate hazard class (CLP Annex I, 2.15). The explosive properties, detonation, deflagration and thermal explosion, are described in the decision logic Figure 2.15.1 of CLP. Therefore, explosive property determination as described for the hazard class 'explosives' needs not to be conducted for organic peroxides. For peracetic acid, the information submitted is not sufficient to follow the decision logic in Figure 2.15.1 of CLP, and therefore the Category D of organic peroxides could not be confirmed.

According to information, which has not been confirmed, in concentrated solutions the flashpoint can be lower than 60 °C suggesting that pure peracetic acid should be classified in Category 3, in line with the harmonized classification of peracetic acid in CLP. In product authorisation test data on products should be presented.

Due to the presence of hydrogen peroxide in the aqueous solution of peracetic acid, Regulation (EU) No 98/2013 on the marketing and use of Explosive Precursors has to be considered for applications for authorisation for non-professional use.

Table 2-1. Physico-chemical properties of pure (100% *) peracetic acid (CAS 79-21-0)

Subsection	Results	Reference
Physical state	Clear, colourless liquid	
Melting point	-0	Swern (1970)
Boiling point	105-110 °C	Mücke & Sprössig (1969)
Bulk density/ relative density	1.22 g/cm ³ liquid at 20°C	(OVA 2009)
Vapour pressure	1.3 - 2.6 kPa, at 20°C (293 K) variable sources 1.9 kPa, at 25°C (298 K) 1.41 kPa, at 20°C (293K)	(OVA 2009, CIS 2009) (EPIWIN 3.20 experimental database) Swern (1970)
Solubility in water	Miscible in water in all proportions	Swern (1970)
Henry´s Law Constant H	0.217 Pa·m ³ /mol at 25°C	Lind & Kok (1986)
Dissociation constant	pKa= 8.24 at 25°C	Mekelburger (2007), Doc. No. 115-002, A3.6/01
Surface tension	54.0 mN/m at 20°C for the neat solution (5%) 47.7 mN/m at 20°C (ring method) for the neat solution (15 %)	Mekelburger (2007), Doc. No. 216-002 Mekelburger (2007), Doc. No. 216-003
Partition coefficient n-octanol/ water	log Kow = -0.46 at pH 5 log Kow = - 0.60 at pH 7 log Kow = - 0.66 at pH 9 -0.23 (calc. neutral form)	Byers (1998) Brachhold (2007)
Flammability	15% product "PEROXYACETIC ACID 15%": Auto-ignition temperature: 280 °C 5% product "PEROXYACETIC ACID 5%": Auto-ignition temperature: 435 °C Other information will be added.	Mekelburger (2007), Doc.242-005, B3.4/02 Mekelburger (2007), Doc.242-004, B3.4/01
Flash-point	According to information which has not been confirmed, in concentrated solutions the flashpoint can be lower than 60 °C suggesting that pure peracetic acid should be classified in Category 3, in line with the harmonized classification of peracetic acid in CLP.	Safety Data Sheet (combined)
Explosive properties	The liquid itself can be made to explode. Vapour/air explosive limit: Pure or highly concentrated stabilized PAA may form explosive vapour/air mixtures above 40.5°C. Detailed explosive limits are unknown in the literature.	CIS (2009)
Oxidizing properties	Oxidizing	

*) in most cases the concentration value 100% represents extrapolated concentration, for technical reasons the actual testing has been carried out in lower than 100% concentration. For concentrations in testing see the Doc IIB.

Methods of Analysis

Analysis of biocidal product and formulation elements, peracetic acid, hydrogen peroxide, acetic acid, sulphuric acid and 1-hydroxyethane-1,1-diphosphonic (HEDP), can be performed by reactive titration, titration, potentiometric titration, ion chromatography conductivity and ion chromatography UV-VIS, respectively. Their analytical methods and validation data are acceptable for the purpose of the CAR. At WG V 2014 it was agreed that validated methods for determination for stabilizers and acetic acid will be required at product authorisation.

The analytical method for detection and identification of peracetic acid in air by HPLC-UV is acceptable.

The analytical method for detection and identification of PAA in water by HPLC-UV is acceptable for the purpose of the evaluation. However, the LOQ in the water method is not sufficiently low in comparison to the current lowest NOEC for aquatic environment. The conclusion of WG-V-2014 APCP for surface water was that LOQ might be necessary to be revised accordingly depending on the outcome of WG ENV. The RMS concluded that in product authorization the method should demonstrate sufficient specificity and a sufficient LOQ in comparison to the lowest relevant NOEC for aquatic environment available, unless a justification can be presented.

After the peer review process the applicant has submitted to RMS information on degradation of peracetic acid in water as well as information on methodologies, but those need to be evaluated.

Applicant's justification for non-submission of data for analytical method for soil is acceptable, because absorption to sediment is not likely to occur due to the physico-chemical properties of peracetic acid and rapid degradation in contact with organic material. Applicant's justification for non-submission of data for analytical method for residues in/on food or feedstuffs and other products where relevant is acceptable due to the properties of peracetic acid (highly unstable and rapid degradation upon contact with organic matter).

2.1.2. Intended Uses and Efficacy

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) i.e. bacteria, and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious. Peracetic acid has been evaluated for uses in PT 11: Treatment of cooling water in open recirculating systems and once-through cooling systems (shock dosing) and PT 12: Use as slimicide in the pulp and paper industry.

Peracetic acid exerts toxic (bactericidal, fungicidal, etc.) rather than bacteriostatic, fungistatic effects on target organisms. For PT 11, bactericidal, fungicidal and algicidal properties of peracetic acid are of relevance, while for PT 12, only bactericidal and fungicidal properties are relevant.

The innate bactericidal activity of peracetic acid was shown. Fungicidal activity was not shown at the intended use concentrations. Data on specific slimicidal activity (PT11,12) and algaecidal activity (PT 11) must be provided at the product authorization stage (field studies, i.e. under real-life conditions). 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.

Peracetic acid contributes most to the biocidal efficacy of the application solutions. The results of tests clearly show that peracetic acid has a significantly higher biocidal activity than hydrogen peroxide. However, the synergistic effects cannot be excluded. Acetic acid at the concentrations present in the application solutions will not contribute to the efficacy as the pH is way above the one required for biocidal activity of an acid.

As the mode of action of peracetic acid is very unspecific, it is very unlikely that resistance to peracetic acid can develop. The development of specific resistance management strategies for the use of peracetic acid does not seem to be an urgent task. Nevertheless, the general principle of alternating use of disinfectants with different modes of action is recommended.

2.1.3. Classification and Labelling

Peracetic acid is included in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) (**peracetic acid...%, Index number 607-094-00-8**). The classification, as presented in the table below, is the translation of the harmonised classification made for the substance under Directive 67/548/EEC.

In accordance with Regulation (EC) No 1272/2008, Annex VI Table 3.1, peracetic acid is classified and labelled as follows:

Hazard Class and Category Code(s)	Flam. Liq. 3 H226 Org. Perox. D **** H242 Acute Tox. 4 * H332 Acute Tox. 4 * H312 Acute Tox. 4 * H302 Skin Corr. 1A H314 Aquatic Acute 1 H400			
Hazard Statement Code(s)	H226 Flammable liquid and vapour. H242 Heating may cause a fire. H332 Harmful if inhaled. H312 Harmful in contact with skin. H302 Harmful if swallowed. H314 Causes severe skin burns and eye damage. H400 Very toxic to aquatic life.			
Supplemental Hazard Statement Code(s)	-			
Pictogram(s) and Code(s)	GHS02 	GHS05 	GHS07 	GHS09 
Signal Word (Code)	Danger (Dgr)			
Specific Concentration Limits M Factors	* STOT SE 3; H335: C ≥ 1 %			
Notes	B D			

The evaluating Competent Authority (Finland) (eCA) is of the opinion that based on the data evaluated there is a need to update the harmonised classification. Regarding the acute toxicity the concentration limits according to the DPD (Xn; R20/21/22: C ≥ 10 %) and the presently evaluated data should be reflected in the classification. In order to derive a correct classification/ATE (Acute Toxicity Estimate) value for a mixture containing peracetic acid, a 100% substance should be classified even if the substance cannot exist in such a high concentration. Aquatic Chronic 1 (H410, M-factor 10) classification should be applied according to the 2nd ATP to CLP Regulation (Regulation (EC) No 286/2011).

A CLH dossier will be submitted by the eCA (Finland) to ECHA during 2016 at the earliest.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Absorption, distribution, metabolism and excretion

Peracetic acid is reactive and it degrades rapidly in contact with organic material. The rapid degradation upon contact with skin explains the absence of systemic effects from exposure to peracetic acid. However, damage to skin may result in some systemic dose for a very short period of time. In vitro studies showed a rapid degradation of peracetic acid in rat blood. In rat blood diluted 1000 times, the half-life of peracetic acid was less than 5 minutes. For this reason the distribution of peracetic acid in the body is expected to be very limited after exposure to peracetic acid solutions. Hydrogen peroxide is also presumed to degrade rapidly into oxygen and water. Eventually, the degradation products, i.e. acetic acid, oxygen, and water are processed via the physiological metabolic pathways.

No standard dermal penetration studies with aqueous peracetic acid have been successfully conducted. Based on the physico-chemical properties of PAA, 100% dermal penetration should be used in the absence of more accurate information. However, in this particular case, in the absence of clear systemic effects, no dermal penetration parameter was needed in order to conclude on human health risks from the presented uses of peracetic acid. **In conclusion, it was acceptable to "waive" the dermal penetration study.**

Acute toxicity

The results of acute oral toxicity studies performed in rats with formulations containing peracetic acid at concentrations from 5 % to 15 % demonstrated acute oral LD₅₀ values in the range of 1020.5-1922 mg/kg bw indicating that peracetic acid, at the tested concentrations, is moderately toxic by the oral route (85-271 mg PAA/kg). The acute dermal LD₅₀ of formulations containing 5 – 15 % peracetic acid was between 1147 and 1957 mg/kg bw in the rabbit indicating that peracetic acid, at the tested concentrations, is moderately toxic by the dermal route (56.1-229 mg PAA/kg). The acute inhalation LC₅₀ value for the test substance containing 5% peracetic acid was 4.08 mg/l/4 h (0.204 mg PAA/l).

Irritation, corrosivity and sensitization

5 % peracetic acid causes burns. Higher concentrations result in even more severe skin damage and such concentrations warrant classification in the highest subcategory, i.e. Skin Corr. 1A.

Peracetic acid causes concentration dependent eye lesions. At higher concentrations, severe and irreversible damage to the rabbit eye has been demonstrated. Whereas, very diluted formulations exert only mild and completely reversible irritating effects.

Both animal data and human experience indicate that peracetic acid causes respiratory tract irritation. Two different mechanisms are possible depending on the concentration of PAA. Based on animal data the irritation at lower concentrations is sensory in nature, the reaction being mediated by stimulation of the trigeminal nerve and manifested as depression of the respiration rate in the test animals. At higher concentrations, also the corrosive nature of the substance is manifested as irritation of the airways. In animal studies an RD₅₀ value for peracetic acid of approx. 15 mg/m³ (5 ppm) in mice vs. clinical signs of irritation in an acute toxicity study at 87 mg/m³ (28 ppm) have been observed.

Peracetic acid is not considered to be a potential skin sensitiser.

Repeated dose toxicity

Repeated dose toxicity of peracetic acid has been studied via, oral, dermal and inhalation route. Following sub-chronic exposure to peracetic acid by gavage, no systemic effects were

evident in rat. Apart from local reactions at the site of first contact (stomach and GIT) related to the known irritating/corrosive properties of peracetic acid and its high reactivity, no other observations were made which would be indicative of systemic distribution resulting in specific systemic effects. Based on the results from functional observation battery (FOB) and motor activity (MA) tests there was no indication of neurotoxic potential of PAA either. The NOAEL is set at the mid dose level which was 15 mg/kg bw/d (test substance, 0.75 mg/kg PAA) (at the lowest) from day 23 onwards. There was no mortality or other significant treatment related effects during dosing at that level. In this study, the only observed effects were local effects that are concentration related. It is therefore reasonable to define a NOAEC for local effects at 0.055 % peracetic acid from the oral gavage study in rats.

The experiments via dermal and inhalation route do not provide additional information with regard to toxicity profile of PAA following repeated exposure.

Reproductive toxicity

For peracetic acid, no multi-generation study in rats is available. The subchronic study in rats showed that 5 % peracetic acid solution at doses up to 50 mg/kg bw/day (nominal) did not have any effect on the reproductive organs of both sexes to the extent macroscopically and microscopically examined in the study. However, due to the rapid degradation of peracetic acid and the obvious limitation of toxic effects at the site of first contact, a new two generation reproductive toxicity study is not justified.

The developmental toxicity and teratogenicity of peracetic acid has been investigated in rats with a formulation containing 32 – 38 % (w/w) peracetic acid and 10 –14 % (w/w) hydrogen peroxide. In this study, the dams were given 100, 300 or 700 mg peracetic acid/l, (corresponding to 12.5, 30.4 and 48.1 mg peracetic acid/kg bw/day) via drinking water from day 5 to 20 of gestation. Based on the effects on water consumption and body weight gain the NOAEL for maternal toxicity is considered to be 100 mg/L (12.5 mg/kg bw/day). With regard to the foetuses, at and from the mid dose upwards disturbed ossification was observed. The NOAEL for foetal (developmental) effects is therefore 100 mg/L (12.5 mg/kg bw/day).

Performance of a developmental toxicity / teratogenicity study in a second species (rabbit) is not considered to be necessary based on the known mode of action and lack of systemic effects which equally applies to all mammalian (test) species.

Genotoxicity

The results of mutagenicity and genotoxicity tests, show one single positive result (*in vitro* chromosome aberration assay with human lymphocytes), which is not confirmed in an independent second study (*in vitro* chromosome aberration assay with Chinese hamster lung fibroblasts). All *in vivo* studies, i.e. *in vivo* MNT and *in vivo* UDS show negative/equivocal results. The biological meaning of any result from the *in vivo* studies is questionable in view of uncertainty of the availability of the test substance in the target organ. On the Weight of Evidence basis it can also be concluded that studies on germ cell effects are not relevant. Based on the overall results it can be concluded that peracetic acid is not of concern regarding mutagenicity or genotoxicity for humans after possible internal dose, whereas the possibility of genotoxic insult in cells which are in direct contact with peracetic acid cannot be excluded. However, TM IV 2013 agreed that further *in vivo* genotoxicity testing is not required as at the site of contact genotoxicity can be anticipated. Due to the corrosive and irritating properties of peracetic acid, the risk mitigation measures include the use of personal protective equipment. The eCA considers the protection sufficient, and does not consider the local genotoxicity as a relevant endpoint for a risk assessment.

Chronic toxicity/ carcinogenicity

No guideline chronic toxicity /carcinogenicity studies with peracetic acid are available, but no new studies are considered necessary. The available studies and the absence of a

systemic availability support the conclusion that the toxicity of peracetic acid is mediated mainly by local irritation at the site of first contact. The possibility of systemic effects cannot be completely ruled out.

The available studies related to possible carcinogenicity of peracetic acid show that the substance has a tumour promoting activity and weak carcinogenic potential (slight increase of non-cancerous skin tumours) was also shown. These effects are believed to be secondary to local irritation. No new carcinogenicity studies are considered necessary due to the known mode of action and the lack of structural alerts for carcinogenicity.

Neurotoxicity

There is no need to conduct specific neurotoxicity tests. There are no structural alerts for neurotoxicity and the available acute and repeated dose toxicity studies did not reveal clinical signs related to neurotoxicity.

Human data

Use of washing solutions of 0.2-0.5 % PAA to disinfect hands has been reported to cause irritation or desquamation of skin. A Patch test with 87 persons (48h, occlusive) showed that up to 0.25 % PAA solution was non-irritating and approx. 0.33 % solution was a mild irritant. A dilution containing 0.2 % peracetic acid was well tolerated by the 20 volunteers of an operating team when disinfecting hands after having washed them with soap. In the same study, occasional burning was reported in case of small wounds in the skin.

Humans exposed for a few minutes to air concentrations of 0.5 ppm (total peroxygens, as H₂O₂) from fogging did not experience discomfort, whereas, levels of 0.5 to 1.0 ppm caused some mild discomfort. 1.0 ppm caused tolerable discomfort and 2 ppm extreme discomfort in the same study. Occupational observations also imply that approximately 0.3-0.4 ppm (total peroxygens, vapour) levels is not immediately irritating but would be unpleasant for an extended period of time, whereas, 0.13-0.17 ppm are considered tolerable and not unpleasant.

In conclusion, the primary human health hazard associated with exposure to peracetic acid is irritation of the skin, eyes and respiratory tract (i.e. sites of first contact). Local effects may arise both after short-term and repeated / long-term exposure.

2.2.1.2. Effects assessment

Peracetic acid in aqueous solution is composed of peracetic acid, hydrogen peroxide and acetic acid. After application of peracetic acid in the intended uses, all three ingredients contribute to the human health effects and the subsequent risks, and have to be taken into account in the overall risk characterisation. The toxicity tests have been performed with the aqueous solution. Hence, the results also inherently contain the effects of each ingredient. In practice, both peracetic acid and hydrogen peroxide are highly reactive and degrade rapidly at the site of first contact with organic material. Acetic acid is also metabolised relatively quickly. Based on the evaluated information, peracetic acid is the most critical ingredient of solutions with regard to possible health risks and the conclusions of the risk assessment of peracetic acid are driven by effect data on peracetic acid itself and the exposure estimates for each intended use.

The adverse effects of peracetic acid in humans are limited to local effects at the site of first contact with the body. No clear systemic effects from PAA were observed which is plausible in the light of the mode of action, i.e. direct chemical reactivity leading to rapid degradation of peracetic acid. Corrosion and/or irritation of the skin and mucous membranes are the most prominent observations in the variety of animal studies. These effects are concentration dependent with no or only minor dependence from exposure duration.

Besides the direct chemical reactivity underlying the irritation and corrosion related lesions, peracetic acid causes sensory irritation. This phenomenon is also clearly concentration dependent and the symptoms manifest soon after start of exposure.

Dermal reference values for peracetic acid

Corrosive effects: According to the available animal data peracetic acid is corrosive at concentrations 5 % and above. Concentrations between 1 % and 5 % could be corrosive if exposure time is longer than one hour. The animal and human data support each other. Consequently, in short-term, acute (or accidental) exposure situations exposure to peracetic acid concentrations higher than 1 % should be avoided in order to exclude the possibility of irreversible damage to human skin.

Skin irritation: **Based on the "acute" animal studies a LOAEC of approx. 5 %** can be set and approx. 0.2 % PAA concentration seems to be non-irritating in human volunteers. It is considered that the human evidence comes from a sufficiently large number of people to be used as a starting point for local risk characterisation. In view of precedence of adequate and reliable human data, 0.2 % peracetic acid, based on the effects in humans, is proposed to be used as a dermal NOAEC for semi-quantitative local risk characterisation in short-term and medium-term exposure scenarios. Based on the human evidence, it is considered that the severity of effects is not considerably changed over the time scale from short-term to long-term. Instead, information from use for longer periods is scarce and not considered reliable enough. Hence, data from animals is chosen as the starting point for the dose descriptor for long-term exposure scenarios. Based on animal data from the dermal one-year study (LOAEC 0.2 %) where the test substance was applied dermally three times per week, an additional uncertainty factor of 2 is proposed to be used leading to a NOAEC value of 0.1 % peracetic acid which could be used for local risk characterisation in long-term exposure scenarios (agreed at TM-IV-2013). This study was considered as supplementary information due to its shortcomings as a chronic study but that did not compromise the dermal effects observed.

Serious eye damage/eye irritation: As a corrosive substance peracetic acid is considered to cause also serious eye damage at the higher concentrations. This is indicated in the hazard statement for skin corrosion (H314: Causes severe skin burns and eye damage). In addition, the general concentration limit for corrosion is 5 % and for eye irritation 1 % in the CLP. In the absence of more accurate data, potential exposure in the different use scenarios should be compared to dermal NOAEC.

Inhalation reference values for peracetic acid

Corrosive effects: Based on the observed corrosive effects on the skin following dermal exposure to the more concentrated solutions of peracetic acid, it is assumed that at least similar concentrations can cause irreversible damage also at the respiratory tract. In addition, the difference of the defensive strength between mucous membranes and intact skin should be taken into account. Thus, an additional assessment factor of 2 is used to extrapolate from the approximated lower range of non-corrosive concentration on the skin to a non-corrosive concentration on the eye. Hence, it is concluded that in short-term, acute (or accidental) exposure situations peracetic acid concentrations less than 0.5 % should not cause irreversible damage to the mucous membranes of exposed persons *via* direct chemical reactivity.

Respiratory irritation: Peracetic acid triggers respiratory tract irritation *via* two different mechanisms, i.e. direct chemical reactivity leading to reversible tissue damage and sensory irritation mediated by trigeminal nerve stimulation. RD₅₀ values from 3.8 ppm to 5.4 ppm (approx. mean 4.6 ppm) have been determined in mice. The data allows extrapolation of an RD₁₀ of approximately 0.6 ppm. There is no human data available specifically on sensory irritation. Humans exposed to peracetic acid have reported "non-irritating" or "no-discomfort" around the concentration levels of 0.15 ppm and 0.5 ppm respectively and at least slight discomfort at higher concentrations. Human data is taken as point of departure to derive the inhalation AEC value. The human NOAEC of 0.5 ppm is divided by an intraspecies dynamic factor of 3.16. In conclusion, an inhalation AEC value is set at 0.16 ppm (0.5 mg/m³). This figure is considered appropriate also for medium- and long-term

exposure because the sensory irritation symptoms, once produced at a certain concentration, are not enhanced with additional exposure time.

Reference values for hydrogen peroxide

In view of the absence of systemic effects after exposure to hydrogen peroxide, only external exposure limits are relevant to account for the potential local effects of hydrogen peroxide. Since in the intended use(s) the in-use concentration of hydrogen peroxide is below a skin irritating threshold (concentration limit for classification as skin irritating is 35 %), only the inhalation route of exposure has been identified to be relevant in the exposure and risk assessment of hydrogen peroxide.

The following AEC for inhalation exposure has been set for hydrogen peroxide: for short-term, medium-term and long-term exposure: 1.25 mg/m³ based on the NOAEC in 90-day inhalation rat study with the overall assessment factor of 8 (2.5 x 3.2).

For more details please refer to the CAR of hydrogen peroxide as a biocidal active substance.

2.2.1.3. Exposure assessment

Peracetic acid is used in industrial/professional applications in product types 11 and 12.

Description of uses

PT 11: Treatment of cooling water in open recirculating systems and once-through cooling systems, shock dosing

PT 12: Use as slimicide in the pulp and paper industry

For dermal and inhalation exposure values in different scenarios, please refer to the tables in Appendix IV.

In the absence of systemic adverse effects, the risk characterisation of peracetic acid is focused on local effects and no systemic doses are estimated. For the inhalation route the airborne exposure concentration is compared with the AEC for inhalation (0.5 mg/m³). For dermal exposure route, the concentrations in the products and in-use solutions are compared with the dermal NOAEC values to account for the potential local effects of peracetic acid (0.2 % for short/medium-term exposure and 0.1 % for long-term exposure).

Since hydrogen peroxide has been demonstrated not to exert systemic effects, the local risk characterisation approach applies also to hydrogen peroxide. Thus, for the inhalation exposure a comparison with the external exposure limit value (AEC for inhalation 1.25 mg/m³) and for dermal exposure a comparison with the skin irritation limit (35 %) have been considered to account for the potential local effects of hydrogen peroxide.

2.2.1.4. Risk characterisation

It is concluded that in the absence of (primary) systemic adverse effects the risk characterisation is focused on local effects. The systemic effects, e.g. mortality are considered to be secondary to the local irritation/corrosion. Although some NOAEL/LOAEL values have been set based on the study results, there is, however, no need to compare these internal values to any external dose descriptors in order to decide on the most critical effects.

Tables of risk characterisation for human health are presented in Appendix IV.

Aqueous peracetic acid solution used in a variety of different product types for disinfection purposes is composed of acetic acid, peracetic acid, hydrogen peroxide (25 % in both concentrated theoretical products) and water. After application of peracetic acid in the intended uses within PT 11 and PT 12, peracetic acid and hydrogen peroxide are the relevant substances which have to be considered in the human health exposure assessment and risk characterisation. For this reason, the risk characterisation was performed for both

peracetic acid and hydrogen peroxide, respectively. Since both peracetic acid and hydrogen peroxide are highly reactive and degrade rapidly at the site of first contact with organic material, assumptions made in the exposure assessment for the intended uses within PT 11 and PT 12 were identical for both substances. Only if the reference value for hydrogen peroxide is exceeded that is noted in the conclusion texts.

Primary exposure – industrial/professional use

PT 11: Disinfection of cooling water in open re-circulation systems and once-through cooling systems

The concentrated product containing 15 % of peracetic acid is used and applied during mixing and loading for the disinfection of cooling water in open re-circulating systems and once-through cooling systems. Dermal exposure is possible to 15 % peracetic acid and 25 % hydrogen peroxide during connecting/disconnecting IBC drums and transfer of the concentrate into stationary storage tanks and especially if there is manual mixing/loading in minor cases. In post-application (i.e. inspection and maintenance of cooling water systems and cooling towers) during disinfection of cooling water in open re-circulating systems dermal exposure is also possible to in-use concentrations, 0.0005 % peracetic acid and 0.00083 % hydrogen peroxide. Since the product is corrosive, chemical resistant gloves, coverall and goggles are required in mixing/loading, and also in post-application phase if exposure to concentrated product is possible. In general, the in-use concentrations are below the skin irritation values.

Inhalation exposure to aerosols and vapours during the manual mixing/loading phase was estimated to amount to 2.3 mg/m³ for peracetic acid and 2.6 mg/m³ for hydrogen peroxide. Respiratory protective equipment (RPE) is needed during manual handling of concentrated products. With RPE10 the inhalation exposure during these operations is below the inhalation AEC values of 0.5 mg/m³ for peracetic acid and 1.25 mg/m³ for hydrogen peroxide (0.23 mg/m³ and 0.26 mg/m³, respectively). For the more usual automated mixing/loading, the highest estimated value for peracetic acid is 0.25 mg/m³ with the transfer flow rate of 100-1000 l/min and medium level containment (calculations with the Advanced Reach Tool). This is 50 % of the AEC value.

In post-application the inhalation exposure to aerosols and vapours without RPE is 0.29 mg/m³ for peracetic acid (58 % of the AEC value). During inspection and maintenance of running cooling towers, wearing of RPE is also anticipated.

PT 12: Disinfection of paper slurries in the pulp and paper industry

The concentrated product containing 15 % of peracetic acid is used and applied during mixing and loading for use as a slimicide in paper pulp. Dermal exposure is possible to 15 % peracetic acid and 25 % hydrogen peroxide during connecting/disconnecting IBC drums and transfer of the concentrate into stationary storage tanks. Dermal exposure is also possible to in-use concentrations, 0.0075 % peracetic acid and 0.0125 % hydrogen peroxide, in application (i.e. process operation) and in post-application (i.e. inspection and maintenance of paper machines). Since the product is corrosive, chemical resistant gloves, coverall and goggles are required during mixing/loading, and also in the post-application phase if exposure is possible to concentrated product. In general, the in-use concentrations are below the skin irritation values.

Inhalation exposure to aerosols and vapours during the manual mixing/loading phase was estimated to amount to 2.3 mg/m³ for peracetic acid and 2.6 mg/m³ for hydrogen peroxide. Respiratory protective equipment (RPE) is needed during manual handling of concentrated products. With RPE10 the inhalation exposure during these operations is below the inhalation AEC values of 0.5 mg/m³ for peracetic acid and 1.25 mg/m³ for hydrogen peroxide (0.23 mg/m³ and 0.26 mg/m³, respectively). For the more usual automated mixing/loading, the highest estimated value for peracetic acid is 0.25 mg/m³ with the

transfer flow rate of 100-1000 l/min and medium level containment. This is 50 % of the AEC value. In application, inhalation exposure to aerosols and vapours without RPE was estimated to 0.2 mg/m³ (40% of the AEC value).

In post-application (maintenance tasks), the exposure level for the combined inhalation exposure to aerosols and vapours without RPE is 0.2 mg/m³ for peracetic acid (40% of the AEC value). During inspection and maintenance of running paper machines, wearing of RPE is also anticipated.

Conclusion for industrial uses in PT 11 and PT 12:

The exposure and accompanying risk assessments performed for industrial uses of peracetic acid as a disinfectant of cooling water in open re-circulation systems and once-through cooling systems and paper slurries in the pulp and paper industry demonstrated that for dermal exposure effective protective clothing is needed when handling concentrated products. Since the product is corrosive, chemical resistant gloves, coverall and goggles are required in mixing/loading and also in post-application phase (inspection and maintenance) if exposure to concentrated product is possible.

For inhalation exposure the AEC value of peracetic acid (0.5 mg/m³) is not reached for intended industrial uses within PT 11 and 12 except in manual mixing and loading phase where effective respiratory protection is needed during handling of concentrated products. Automated (connecting lines) and self-vented automatic systems are more generally in use for mixing and loading lowering the risk of exposure. During inspection and maintenance, wearing of RPE is anticipated as a good working practice.

Secondary exposure

Worker acute secondary inhalation exposure during maintenance/repair tasks

During the application of aqueous peracetic acid solutions for the disinfection of cooling water systems and cooling water (PT 11) and as a slimeicide in paper pulp (PT 12) an acute secondary dermal and inhalation exposure scenario does exist when immediate action is required for unscheduled maintenance and repair of dosing pumps. These tasks are considered to be of short duration and will, thus, lead to an acute secondary dermal and inhalation exposure of workers towards peracetic acid and hydrogen peroxide. Because of the high reactivity and rapid degradation of peracetic acid and hydrogen peroxide and as irritation/corrosion at the site of first contact is the primary effect of the substances, only the inhalation route of exposure has been considered to be relevant for the assessment of the acute secondary exposure of workers during maintenance and repair tasks. Effective control measures, protective clothing and gloves are in place for the handling of concentrated, corrosive peracetic acid and hydrogen peroxide formulations which provide protection from direct dermal contact.

Inhalation exposure to aerosols and vapour was estimated to amount to 2.3 mg/m³ for peracetic acid and 2.6 mg/m³ for hydrogen peroxide. The exposure is reduced to 0.23 mg/m³ and 0.26 mg/m³ with RPE10 showing inhalation exposure to peracetic acid and hydrogen peroxide during these operations to be below the inhalation AEC values. Therefore, acute secondary inhalation exposure during unscheduled maintenance and repair of dosing pumps was shown to be acceptable.

Bystander/Non-User chronic secondary inhalation exposure during disinfection of cooling water systems and cooling towers

Following application of peracetic acid solutions for the disinfection of cooling water systems and cooling water within PT 11, non-users/bystanders residing near cooling towers or passing by might be chronically exposed via the inhalation route of exposure to mist or vapours released from the cooling towers as a consequence of uncontrolled windage or

blowdown. For the disinfection of once-through cooling systems the chronic secondary exposure of non-users/bystanders via the inhalation route due to blowdown or uncontrolled windage from cooling towers is not relevant as no cooling towers are connected to this type of cooling systems. The chronic secondary inhalation exposure of non-users/bystanders to aerosols and vapours was estimated to amount to 0.0027 mg peracetic acid/m³. This corresponds to 0.5 % of the AEC value of peracetic acid (0.5 mg/m³). Although this exposure is far below the AEC value and no health risk for non-users/bystanders as a result of chronic secondary inhalation exposure could be identified, the estimated exposure is considered to represent a worst case as no degradation of the substance in air has been assumed in this estimation.

Consumer (adults/children) chronic secondary dermal and oral exposure via treated paper

In the intended uses of peracetic acid solutions as a slimicide in paper pulp, a chronic secondary dermal or oral exposure of consumers (adults/children) towards peracetic acid after dermal or oral contact with treated paper might be theoretically possible. However, peracetic acid degrades very quickly at the site of first contact and due to the high reactivity and instability of the substance, no residues are expected to which consumers/children could be exposed after dermal contact with treated paper or after chewing or licking on treated paper for instance. In view of the absence of a systemic exposure and systemic bioavailability of peracetic acid after dermal and oral contact and taking into account that the substance is rapidly degraded in blood in case penetration through the skin barrier might occur, it can therefore be concluded that a chronic secondary exposure via the dermal and oral route of exposure is not relevant in the intended industrial and professional applications of peracetic acid solutions within PT 12. Even in the unlikely case of residues on treated paper, no irritation is expected following dermal or oral contact as the in-use concentration of peracetic acid is well below the threshold of irritation.

Performing a dietary risk assessment for the active substance and the degradation products is not considered necessary in use as a slimicide in paper pulp. Peracetic acid has no systemic effects, it is ready biodegradable and expected to rapidly degrade to acetic acid in the pulp. A dietary risk assessment for acetic acid is not needed since acetic acid is also a food item and the quantities which could be taken up through migration from paper into food are irrelevant. Should peracetic acid not be completely degraded to acetic acid and should therefore traces of peracetic acid remain in the paper and migrate into food, degradation of peracetic acid to acetic acid in the food would occur. Consequently, there is no concern for residues of peracetic acid and acetic acid in food from use in PT 12.

Also for veterinary products no MRL is needed when animals are treated (directly or indirectly) with peracetic acid: see page 53 of:

http://ec.europa.eu/health/files/eudralex/vol-5/reg_2010_37/reg_2010_37_en.pdf

There is also the EFSA opinion on safety and efficacy of peroxyacetic acid solutions for reduction of pathogens on poultry carcasses and meat available. The conclusion in that opinion was that no toxicity concerns were identified with regard to residues of peroxyacids due to the high instability. Peracetic acid concentrations in the treatment solutions were 230-2000 ppm. (see

http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3599.pdf).

Combined exposure

Based on the absence of systemic effects after exposure towards peracetic acid, it is important to note in this context that the AEC value is not time-dependent and relate to the concentrations of peracetic acid in the air, which do not cause sensory irritation or corrosive effects. For this reason, only the highest inhalation exposure level is relevant and the addition of exposure levels and the calculation of a combined inhalation exposure during the different tasks are not relevant.

Combined exposure assessment and risk characterisation for the inhalation route could also be performed for peracetic acid and hydrogen peroxide as they both have local mode of action. If the exposure/AEC ratios are calculated together, safe uses are shown (Hazard Quotient <1).

Conclusion

Based on the results obtained in the risk assessment, the exposure of operators and professional users results in acceptable health risk if appropriate personal protective equipment is used. Skin protection with chemical resistant gloves, coverall, goggles and respiratory protection is needed when handling concentrated products. During inspection and maintenance, wearing of RPE is anticipated as a good working practice.

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and distribution in the environment

Abiotic decomposition is a significant degradation route for peracetic acid. Depending on environmental conditions, the abiotic decomposition can follow three different reactions: spontaneous decomposition, metal catalysed decomposition and hydrolysis. Spontaneous decomposition results in the formation of acetic acid and oxygen, while hydrolysis results in acetic acid and hydrogen peroxide. Abiotic decomposition rate increases with increasing pH and the role of hydrolysis become significant, when pH increases above 10.5. Phototransformation in water is not a significant degradation route for peracetic acid. The data for the phototransformation in air show that peracetic acid is not expected to persist in the atmosphere.

Peracetic acid degrades rapidly under conditions, where organic matter and microbial activity are present and it can be considered as readily biodegradable substance. DT50 for biodegradation of peracetic acid in the sewage sludge is 3 minutes (at 20°C) and in effluent water from a sewage treatment plant << 5 minutes. No reliable DT50 has been determined for surface waters or soil. Peracetic acid is not expected to be persistent, because organic substances and metal ions promoting the decomposition of peracetic acid are usually available in natural environments.

The adsorption of peracetic acid to aerosol particles, the volatilisation from water into air and the adsorption of peracetic acid to soil can be considered to be very low. Thus, peracetic acid mainly distributes in the aqueous phase if released into the environment.

The measured log Kow of -0.60 (at pH 7) indicates negligible potential of bioconcentration of peracetic acid in biota. Thus, peracetic acid is not expected to accumulate in organisms.

2.2.2.2. Effects assessment

In the acute aquatic tests, algae were found to be the most sensitive species with 72-h EC50 of 0.16 mg PAA/L. Fish with the lowest 96-h LC50 of 1.1 mg PAA/L and daphnia with the lowest 48-h EC50 of 0.73 mg PAA/L were less susceptible. The lowest available NOEC of 0.00069 mg PAA/L is for Zebra fish (*Danio rerio*) based on initial test concentrations, NOEC for daphnia is 0.0121 mg PAA/L. PNECaquatic is 0.069 µg PAA/L and PNECmarine 0.0069 µg PAA/L based on NOEC for fish. The assessment factors for PNECaquatic and PNECmarine are 10 and 100, respectively.

The PNEC for sewage treatment plant micro-organisms is 0.051 mg/l based on an assessment factor of 100. Acute terrestrial toxicity tests are available for earthworm, non-target plants and soil micro-organisms. PNECterrestrial is 0.282 mg PAA/kg_{wwt} based on the

seedling emergence test with non-target plants (*Brassica napus*) with an assessment factor of 1000. Birds and mammals are not anticipated to be directly exposed to peracetic acid, thus risk assessment for bird and mammals is not considered necessary.

2.2.2.3. PBT and POP assessment

Peracetic acid shows a very rapid biodegradation in sewage sludge with a DT50 of 3 minutes (at 20°C). Therefore, peracetic acid does not fulfil the criteria for a persistent compound. The measured log K_{ow} of peracetic acid is -0.60 (at pH 7) indicating negligible potential of bioconcentration in biota, thus the bioaccumulation criterion is not fulfilled. The toxic endpoint is below the trigger of < 0.01 mg/L and thus the toxic criterion is fulfilled. Peracetic is not a PBT substance, as it fulfils only one of the three criteria.

Peracetic acid does not fulfil criteria for being persistent organic pollutant (POP). In addition, peracetic does not have potential for long-range transboundary atmospheric transport. The vapour pressure of peracetic acid is above 1000 Pa (14.1 hPa, 20 °C) even though the estimated atmospheric half-life (3.9 days) is more than two days given for persistent organic pollutants (POP) as defined in the Annex D of the Stockholm Convention 2001.

2.2.2.4. Exposure assessment

Production

Emissions of peracetic acid into water are very limited, because any waste water is collected and reconditioned in a neutralising facility. Also releases into the air are negligible as nearly the whole production process is run in closed system.

Intended uses and emission routes in different PTs

PT11.01: Treatment of cooling water in once-through cooling systems - shock dosing performed with a site-specific and a generic scenario. Direct emission to marine water. In addition, direct emission to soil from cooling tower and subsequent emission to groundwater according to the generic scenario.

PT11.02: Treatment of cooling water in open recirculating cooling systems - shock dosing performed with a large and a small installation scenario. Direct emission to soil from cooling tower and subsequent emission to groundwater. Direct emission to freshwater from the large installation scenario. Emissions from the small installation scenario to surface water, soil and groundwater via STP (2000 m³/d).

PT12: Use as a slimicide in the pulp and paper industry - continuous dosing performed with a typical case and a realistic worst case scenario. In the typical scenario after primary settling emission to a local STP (5000 m³/d). Emissions to surface water, soil and groundwater via STP. In the realistic worst case scenario direct emission to freshwater after settling and mechanical/chemical treatment.

PEC in STP

Predicted environmental concentrations (PEC) in STP ranged from 2.89E-13 µg/L to 84.9 µg/L for peracetic acid and from 2.47E-04 µg/L to 103 µg/L for hydrogen peroxide.

PEC in aquatic compartment

After degradation in the STP, residual peracetic acid and hydrogen peroxide reach surface water. Consequently, PECs in surface water (river) were assumed to be diluted 10-fold

when entering the river. The PECs after STP were 2.89E-14 - 8.49 µg/L for peracetic acid and 2.47E-09 - 10.3 µg/L for hydrogen peroxide.

The PECs from direct emissions to freshwater were 1.0E-28 - 222 µg/L for peracetic acid and 2.5E-10 - 484 µg/L for hydrogen peroxide. The maximum dilution factor was 1000.

The PECs from direct emission to marine water were 0.41 - 74.6 µg/L for peracetic acid and 125 µg/L for hydrogen peroxide. The PEC for acetic acid calculated from maximum total concentration in blow down water is 134 µg/l. The dilution factor was 100.

Peracetic acid and hydrogen peroxide in surface water do not partition to suspended matter or sediment to any relevant extent.

PEC in air

Peracetic acid and hydrogen peroxide enter the atmosphere due to volatilisation from the cooling towers and the STP. The highest PEC in air was calculated to be 2.7 µg/m³ for peracetic acid and 10 µg/m³ for hydrogen peroxide.

PEC in soil

Direct emissions to soil are expected from cooling towers. The PECs from drift ranged from 4.98E-06 to 6.9E-03 mg/kg for peracetic acid and from 1.4E-04 to 0.03 mg/kg for hydrogen peroxide.

Indirect emissions to soil are expected from STP via the application of sewage sludge and due to volatilisation from the STP. The PECs were 3.68E-19 - 1.08E-04 mg/kg for peracetic acid and 8.69E-10 - 3.62E-04 mg/kg for hydrogen peroxide.

PEC in groundwater

The concentrations of peracetic acid and hydrogen peroxide in the porewater of agricultural soil, calculated according to the TGD in the case of direct emissions from cooling towers, were 0.03 - 49 µg/l and 0.95 - 204 µg/l, respectively.

Since degradation in soil, transformation and dilution in deeper soil layers are not taken into account by TGD and EUSES 2.1.2, the calculated values overestimate the potential ground water levels of peracetic acid and hydrogen peroxide. Under real life conditions, it is very unlikely that peracetic acid or hydrogen peroxide concentrations exceed the trigger value of 0.1 µg/L in groundwater. Therefore, a refined groundwater assessment for the aerial deposition with FOCUS Pearl 4.4.4 was performed according to the report of Klein (Proposals for standard scenarios and parameter setting of the FOCUS groundwater scenarios when used in biocide exposure assessments, 2011) as the worst case. The FOCUS Pearl calculation was based on the large installation scenario. The FOCUS Pearl report is found in the Annex 2 of Doc IIB. Based on the FOCUS Pearl modelling it can be concluded that in most of the scenarios the concentrations of peracetic acid and hydrogen peroxide are below the trigger value of 0.1 µg/L as defined in directives 2006/118/EC and 98/83/EC. Thus there is enough acceptable scenarios for the active substance approval in PT11.

The concentrations of peracetic acid and hydrogen peroxide in the porewater of agricultural soil, calculated according to the TGD and EUSES 2.1.2 in the case of emissions from STP, were 4.59E-16 - 0.135 µg/l and 9.9E-07 - 0.414 µg/l, respectively. There is no unacceptable risk to groundwater from indirect emission from STP to soil in PT11. In addition, there is no risk to groundwater in PT12 when the reactivity of peracetic acid and hydrogen peroxide i.e. their total degradation in paper mills is taken into account.

2.2.2.5. Risk characterisation

Peracetic acid products contain in addition to peracetic acid also hydrogen peroxide as a second active substance. The risks of two substances were evaluated separately and the risk of the product according to the TNsG on Product Evaluation using PEC/PNEC summation of active ingredients and substances of concern ($(PEC/PNEC)_{\text{product}} = \sum(PEC/PNEC)_{\text{components}}$).

STP

There is no unacceptable risk to organisms involved in the biological processes of the sewage treatment plants from the proposed uses of theoretical product 2 in PT 11 and PT 12 except in PT12 case A.

Aquatic compartments (including sediment)

No unacceptable risk is identified in PT 11 small installation connected to the STP. For PT 11 large open recirculating cooling systems, an unacceptable risk is identified from proposed use of peracetic acid in theoretical product 2.

An unacceptable risk is identified from proposed use of peracetic acid in the theoretical product 2 in PT 12 Case A. However, no unacceptable risks are identified in other PT 12 scenarios when the reactivity of peracetic acid and hydrogen peroxide i.e. their total degradation in paper mills is taken into account.

Marine compartment (including sediment)

Unacceptable risk to marine water is identified in all evaluated once-through system scenarios for peracetic acid and hydrogen peroxide. Acceptable risk with the risk ratio of 0.67 is identified for acetic acid. This worst case quantitative approach confirms that no unacceptable risk is identified for acetic acid in PT 11 regarding direct emissions to marine or surface water.

Atmosphere

Local emissions to air in PT 11 from cooling towers during the episode is assumed to be 1 % of the blow down water rate without taking into account substance specific properties. However, during the passage of water droplets through the tower under the elevated temperatures and on the large internal surfaces of cooling towers, peracetic acid and hydrogen peroxide most probably decomposes for example when reacting with organic substances. Thus peracetic acid and hydrogen peroxide actually reaching the outside air via windage from cooling towers are probably much lower than calculated according the default assumptions of emission scenario if substance specific properties are taken into account. Indirectly peracetic acid and hydrogen peroxide might reach the air compartment by volatilisation from the sewage treatment plant regarding small open recirculating systems connected to STP (PT 11 and PT 12).

Terrestrial compartment

An unacceptable risk is identified from hydrogen peroxide of the theoretical product 2 in PT11.03 Case A. No unacceptable risk from the theoretical product 2 is identified in other PT11 and PT 12 scenarios.

Groundwater

The overall conclusion is that peracetic acid and hydrogen peroxide does not pose a risk to groundwater.

Overview table of PEC/PNEC for peracetic acid and hydrogen peroxide.

Exposure scenario	Compartment	PAA	H ₂ O ₂	Σ (PAA + H ₂ O ₂)
PT11.01 - Once-through cooling systems - shock dosing Specific plant After one event	Marine water	2173	99	2272
PT11.01 - Once-through cooling systems - shock dosing Generic scenario After one event	Marine water	Tier 1: 10811 Tier 2: 59	99	Tier 1: 10910 Tier 2: 158
	Soil (drift)	Tier 1: <0.001 Tier 2: <0.001	0.52	Tier 1: 0.52 Tier 2: 0.52
	Groundwater (drift) (TGD) ¹⁾	Tier 1: 4.6 Tier 2: 0.025	6.8	
PT11.03 - Open recirculating cooling systems Case A: Large installation	Surface water ²⁾	Tier 1: 10x 3217 200x 161 1000x 32 Tier 2: 10x 397 200x 20 1000x 4	10x 38.4 200x 1.9 1000x 0.4	Tier 1: 10x 3255 200x 163 1000x 32 Tier 2: 10x 435 200x 22 1000x 4.4
	Soil (drift)	Tier 1: 0.02 Tier 2: 0.003	16	Tier 1: 16 Tier 2: 16
	Groundwater (drift) (TGD)	Tier 1: 49 Tier 2: 6.1	204	
PT11.03 - Open recirculating cooling systems Case B: Small installation	STP	Tier 1: <0.001 Tier 2: <0.001	0.0010	Tier 1: 0.0010 Tier 2: 0.0010
	Surface water	Tier 1: 0.03 Tier 2: 0.0010	0.035	Tier 1: 0.065 Tier 2: 0.036
	Soil (drift)	Tier 1: <0.001 Tier 2: <0.001	0.07	Tier 1: 0.07 Tier 2: 0.07
	Groundwater (drift) TGD	Tier 1: 0.79 Tier 2: 0.04	0.95	
	Soil (STP) EUSES	Tier 1: <0.001 Tier 2: <0.001	0.008	Tier 1: 0.008 Tier 2: 0.008
	Groundwater (STP) EUSES	Tier 1: <0.001 Tier 2: <0.001	0.02	

PT12.01 Slimicides used in paper mills Case A: Typical case	STP	1.66	0.02	1.68
	Surface water	123	0.83	123
	Soil	<0.001	0.19	0.19
	Groundwater	0.135	0.414	
PT12.01 Slimicides used in paper mills Case B1: Typical case	STP	<0.001	<0.001	<0.001
	Surface water	<0.001	<0.001	<0.001
	Soil	<0.001	<0.001	<0.001
	Groundwater	<0.001	<0.001	
PT12.01 Slimicides used in paper mills Case B1: realistic worst case	Surface water ³⁾	all dilutions: <0.001	all dilutions: <0.001	all dilutions: <0.001

¹⁾ Please note that for the groundwater, the PEC ($\mu\text{g/l}$) calculated according to the TDG and EUSES 2.1.2 is presented. For the result of the refined groundwater assessments see the following tables.

²⁾ The dilution factors of 10, 200 and 1000 for PT11 open recirculating large systems were agreed at TM III 2011.

³⁾ The dilution factors of 5, 10, 200 and 1000 for PT12 were proposed by NL at the WG II 2014 based on the waste water production of paper mill and the flow rates of recipient rivers for PT11.

Overview of the refined groundwater assessment for the aerial deposition - large open cooling systems with FOCUS Pearl 4.4.4. as the worst case.

PAA and HP concentrations in the leachate at 1 metre soil depth (80th percentile), Tier 1

Scenario	maize		grass (= alfalfa)	
	(arable land)		(grassland)	
	PAA	HP	PAA	HP
	[$\mu\text{g.L}^{-1}$]		[$\mu\text{g.L}^{-1}$]	
CHATEAUDUN	0.000032	< 0.0001	0.000046	< 0.0001
HAMBURG	0.075110	0.1303	0.101713	0.1774
JOKIOINEN	n.a.	n.a.	19.659298	53.33
KREMSMUNSTER	0.007322	0.013349	0.005120	0.009849
OKEHAMPTON	0.006004	0.008881	0.007176	0.010589
PIACENZA	0.035812	0.072334	0.033685	0.068062
PORTO	0.000652	0.000787	0.000725	0.000881
SEVILLA	0.000971	0.000827	0.002401	0.003526
THIVA	0.000007	< 0.0001	0.000011	< 0.0001

n.a.= not available

PAA and HP concentrations in the leachate at 1 metre soil depth (80th percentile), Tier 2

Scenario	maize (arable land)		grass (= alfalfa) (grassland)	
	PAA	HP	PAA	HP
	[µg.L ⁻¹]		[µg.L ⁻¹]	
CHATEAUDUN	0.000005	< 0.0001	0.000007	< 0.0001
HAMBURG	0.017567	0.000459	0.021525	0.000636
JOKIOINEN	n.a.	n.a.	2.635316	0.195
KREMSMUNSTER	0.000962	< 0.0001	0.001065	< 0.0001
OKEHAMPTON	0.001465	< 0.0001	0.001688	< 0.0001
PIACENZA	0.005420	0.000326	0.004328	0.000305
PORTO	0.000317	< 0.0001	0.000288	< 0.0001
SEVILLA	0.000029	< 0.0001	0.000184	< 0.0001
THIVA	0.000001	< 0.0001	0.000004	< 0.0001

n.a.= not available

Potential for secondary poisoning of peracetic acid

The log Kow of -0.60 for peracetic acid and the log Kow of -1.57 for hydrogen peroxide indicate that both substances have a low potential for bioconcentration and bioaccumulation. Moreover, peracetic acid and hydrogen peroxide dissipate rapidly in the environment which is a further indication of their low accumulation potential.

Aggregated (environmental) exposure assessment for peracetic acid

According to Article 10(1) of BPD a cumulative risk assessment shall be performed where relevant. A cumulative risk assessment for peracetic acid is relevant, since there might be overlapping emissions from one or several PTs into the same environmental compartment. The cumulative assessment for PTs 1 - 6 is explained in detail in the Assessment report for PT 1-6. For hydrogen peroxide it was agreed at the WG V 2014 that aggregated risk assessment is not regarded relevant due to the high reactivity of the substance.

No possible overlapping emissions into the same STP were identified within PT 11 or PT 12. In addition, no overlapping emissions between PT 11 and PTs 1 - 6 were identified. Between PT 6 and PT 12 a potential overlapping emission might be possible, since the dry-end and wet-end operations in paper production might be discharging into the same STP (5000 m³/d). However, measurements performed in the coating colour and ultra-filtrated pigment slurries demonstrated rapid degradation of peracetic acid and hydrogen peroxide in the slurries in PT6. Therefore, there is no concern for cumulative environmental risks for peracetic acid or hydrogen peroxide when concerning PT 11 and PT12.

2.2.3. Assessment of endocrine disruptor properties

There is no evidence of any endocrine disruption potential in the human health or ecotoxicological studies presented in the dossier. In addition, peracetic acid does not meet the transitional criteria of Regulation (EU) No 528/2012. Therefore, peracetic acid shall not be considered as having endocrine-disrupting properties.

2.3. Overall conclusions

The outcome of the assessment for Peracetic acid in product-types 11 and 12 is specified in the BPC opinions following discussions at the 16th meeting of the Biocidal Products Committee (BPC). The BPC opinions are available from the ECHA website.

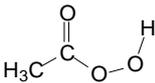
2.4. List of endpoints

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

Appendix I: List of endpoints

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

Active substance (ISO Common Name)	Peracetic acid
Product-type	PT 11: Preservatives for liquid cooling and processing systems PT 12: Slimicides
Identity	
Chemical name (IUPAC)	Peroxyethanoic acid
Chemical name (CA)	Peracetic acid
CAS No	79-21-0
EC No	201-186-8
Other substance No.	None available
Minimum purity of the active substance as manufactured (g/kg or g/l)	<p>The active substance is peracetic acid in an aqueous solution containing acetic acid and hydrogen peroxide.</p> <p>Pure peracetic acid does neither exist commercially nor is it an intermediate in the production of peracetic acid products.</p> <p>Peracetic acid is produced by reacting hydrogen peroxide (H₂O₂) with acetic acid in aqueous solution. In this process, peracetic acid is obtained as aqueous solutions containing peracetic acid, acetic acid, hydrogen peroxide. The peracetic acid content in aqueous equilibrium solutions is typically in the range of 0.1 % - 15% (w/w).</p> <p>Specifications are based on the starting materials acetic acid and hydrogen peroxide. The specification of (starting material) acetic acid is as in accordance to Regulation 231/2012. The minimum purity of acetic acid is >99.8%.</p> <p>For hydrogen peroxide the specification is 35% – 69.9%, as indicated in the approval of Hydrogen peroxide CAR in PTs 1-6.</p> <p>The risk assessment does not cover formulations containing higher than 15% PAA concentrations. For products containing peracetic acid in concentrations > 15%, further assessment shall be required for toxicological and physico-chemical risks.</p> <p>Non-equilibrium solutions. The starting materials and catalyzers for concentrated (distilled) solutions (products) of peracetic acid must comply with the specifications set for equilibrium peracetic acid. Non-equilibrium peracetic acid has not been evaluated in the CAR.</p>
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	The maximum impurities of the starting material acetic acid are in accordance to Regulation 231/2012. For the starting material hydrogen

	<p>peroxide the maximum impurities are as in the Hydrogen peroxide CAR in PTs 1-6.</p> <p>The technical active substance peracetic acid may contain also sulphuric acid (max 10 g/kg) as a catalyser. It also may contain 1-hydroxyethane-1,1-diphosphonic acid (HEDP) (max 14 g/kg) and dipicolinic acid (max 1.6 g/kg) in aqueous solution, as stabilizers.</p>
Molecular formula	C ₂ H ₄ O ₃
Molecular mass	76.05 g/mol
Structural formula	
Physical and chemical properties	
Melting point (state purity)	<p>The melting points of 5% solutions are in the range of -26°C to -30°C.</p> <p>The melting points of 15% solutions are in the range of -30°C to -50°C.</p> <p>The melting point of the representative "Peracetic acid 15%" is -73°C.</p> <p>The melting point of the pure PAA is 0°C.</p>
Boiling point (state purity)	<p>The boiling points of 5% solutions are in the range of 99°C to 105°C.</p> <p>The boiling points of 15% solutions are above 100°C.</p> <p>For neat PAA, a boiling point of 110°C at 760 mmHg was calculated.</p> <p>The boiling point of the representative "Peracetic acid 15%" is 105°C.</p>
Temperature of decomposition	<p>Decomposition of PAA can be initiated by high temperatures, high pH and contamination with metal catalysts such as copper, iron, and chromium, and incompatible organic materials. The decomposition of PAA is strongly exothermic, liberating large volume of oxygen gas.</p>
Appearance (state purity)	Clear, colorless liquid (all PAA solutions)
Relative density (state purity)	<p>D²⁰₄ = 1.1535 (15% product "PEROXYACETIC ACID 15%")</p> <p>D²⁰₄ = 1.1284 (5% product "PEROXYACETIC ACID 5%")</p>
Surface tension	<p>54.0 mN/m at 20°C (ring method, 5% product "PEROXYACETIC ACID 5%")</p> <p>47.7 mN/m at 20°C (ring method, 15% product "PEROXYACETIC ACID 15%")</p> <p>This indicates that PAA does not need to be regarded as surface active, because only substances exhibiting a surface tension < 60 mN/m <u>when tested at a concentration of 0.1%</u> are regarded as surface active.</p>
Vapour pressure (in Pa, state temperature)	p _(20°C) = 14.1 hPa

	The overall vapour pressure of the representative product "Peracetic acid 15%" is 17 hPa.
Henry's law constant (Pa m ³ mol ⁻¹)	0.217 Pa m ³ mol ⁻¹ .
Solubility in water (g/l or mg/l, state temperature)	Completely miscible with water at any ratio
Solubility in organic solvents (in g/l or mg/l, state temperature)	Solubility at 25°C (15% product "PEROXYACETIC ACID 15%"): n-Heptane: < 10 g/l p-Xylene: < 10 g/l 1,2-Dichloroethane: < 10 g/l Propan-2-ol: > 500 g/l Acetone: > 500 g/l Ethyl acetate: 20-25 g/l
Stability in organic solvents used in biocidal products including relevant breakdown products	Not applicable: Peracetic acid is not formulated with organic solvents.
Partition coefficient (log P _{ow}) (state temperature)	pH___5___: -0.46 (temperature not indicated)
	pH___7___: -0.60 (temperature not indicated)
	pH___9___: -0.66 (temperature not indicated)
	QSAR calculation: logP _{ow} = -0.23 at pH 5, -0.26 at pH 7 and -1.2 at pH 9
Hydrolytic stability (DT ₅₀) (state pH and temperature)	Determined for an initial TS concentration (C ₀) of 0.001 mol PAA/L (95 ppm):
	pH___4___: 46.7 hours (at 25°C)
	pH___7___: 31.7 hours (at 25°C)
Dissociation constant	pH___9___: 3.6 hours (at 25°C)
	pK _a = 8.2 (literature data) pK _a = 8.24 (determined using 15% product "PEROXYACETIC ACID 15%")
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	The UV-VIS spectra at pH <2, 7 and >12 showed no absorption maxima.
Photostability (DT ₅₀) (aqueous, sunlight, state pH)	No study on phototransformation of peracetic acid was conducted. Peracetic acid does not absorb light in the visible wavelength range.
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not applicable because of lack of absorption of light in the visible wavelength range
Flammability	15% product "PEROXYACETIC ACID 15%": Auto-ignition temperature: 280 °C
	5% product "PEROXYACETIC ACID 5%": Auto-ignition temperature: 435 °C
	Flash-point: According to information, which has not been confirmed, in concentrated solutions the flashpoint can be lower than 60 °C.

Explosive properties	<p>5% and 15% products ("PEROXYACETIC ACID 5% and 15%"): not explosive (no mechanical and thermal sensitivity). Pure or highly concentrated stabilized PAA may form explosive vapour/air mixtures above 40.5 °C. Detailed explosive limits are unknown in the literature. Under CLP, explosive property determination as described for the hazard class 'explosives' needs not to be conducted for organic peroxides.</p>
Classification and proposed labelling with regard to physical/chemical data	<p>Current classification of peracetic acid according to Regulation 1272/2008: Flam. Liq. 3; H226 Flammable liquid and vapour Org. Perox. D ****; H242 Heating may cause a fire <u>Pictogram:</u> GHS02</p>
with regard to toxicological data	<p>Current classification of peracetic acid according to Regulation 1272/2008: Acute Tox. 4 *; H332 Harmful if inhaled Acute Tox. 4 *; H312 Harmful in contact with skin Acute Tox. 4 *; H302 Harmful if swallowed Skin Corr. 1A; H314 Causes severe skin burns and eye damage STOT SE 3; H335 May cause respiratory irritation <u>Specific Concentration Limits:</u> STOT SE 3; H335: C ≥ 1% <u>Pictograms:</u> GHS05, GHS07 <u>Signal Word Code:</u> Danger</p>
with regard to fate and behaviour data	No classification
with regard to ecotoxicological data	<p>Current classification of peracetic acid according to Regulation 1272/2008: Aquatic Acute 1; H400 Very toxic to aquatic life <u>Pictogram:</u> GHS09</p>

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)

Peracetic acid and hydrogen peroxide: Titration method. Peracetic acid: The sample is diluted in a solution of potassium iodide and an organic solvent at -10 °C. The liberated iodine is titrated with a sodium thiosulphate solution. Using these conditions, the hydrogen peroxide reacts very slowly with the iodide. If the titration is performed quickly, no significant interference from hydrogen peroxide occurs. Validation data such as linearity and recovery should be submitted in product authorization, or a justification for non-submission of data.

Hydrogen peroxide: The sample is dissolved in

	<p>diluted sulphuric acid and cooled with ice. The hydrogen peroxide is titrated with ceric sulphate solution using ferroin as indicator. Validation data such as linearity and recovery should be submitted in product authorization or a justification for non-submission of data.</p>
<p>Impurities in technical active substance (principle of method)</p>	<p>Acetic acid: Titration method. The sample to be analyzed is dissolved in deionized water and potentiometrically titrated with sodium hydroxide. The potential change is detected with the help of a single-rod pH electrode. A validated method for determination will be requested at product authorisation.</p> <p>Sulphuric acid: Ion chromatography: The sample is diluted with Millipore water and fed into the chromatographic system. By means of an anion exchanger, the sulfate is separated from the matrix components and detected <i>via</i> its conductivity. Quantification is based on the method of external standard calibration. The method is only for information and no new method was requested. 1-Hydroxyethane-1,1-diphosphonic acid</p> <p>(HEDP): Ion chromatography. By means of an anion exchange column, HEDP is separated from other components. After the separation, the phosphonates are oxidized in a first reaction step to orthophosphate. In a second step, the reagent vanadate-molybdate is added. As a reaction result, yellow phosphovanadomolybdic acid forms which is detected at 410 nm in the UV-VIS range. Quantification is based on the method of external standard calibration.</p> <p>Full validation of stabilizers will be required. Validated methods for determination for stabilizers will be required at product authorisation. For HEDP, an existing method is acceptable for the purpose of risk assessment, but is with a need for a further validation at product level. For the other allowed stabilizer, a method has not yet been submitted, and will be requested at product authorization.</p>
<p>Analytical methods for residues</p>	
<p>Soil (principle of method and LOQ)</p>	<p>Applicant's justification for non-submission of data for analytical method for soil is acceptable, because absorption to sediment is not likely to occur due to the physico-chemical properties of peracetic acid and rapid degradation in contact with organic material</p>
<p>Air (principle of method and LOQ)</p>	<p>Reverse-phase HPLC with UV detection .</p> <p>A special sampling device was developed for the simultaneous sampling of peracetic acid and hydrogen peroxide in air. The device consists of a set of quartz fibre filters impregnated with titanium oxysulfate, to sample hydrogen peroxide (cassette) and a tube filled with basic silica gel impregnated with MTSO. Air samples are first directed through the titanium oxysulfate</p>

	<p>impregnated filters and then through the MTSO impregnated silica gel.</p> <p>The filters impregnated with titanium oxysulfate sample hydrogen peroxide. The flow rate has to be chosen high enough so that the PAA could pass the titanium oxysulfate soaked filter without reaction. PAA is sampled by the MTSO impregnated silica gel under formation of MTSO. Immediately after sampling, the cassettes are desorbed with 5 – 10 mL of molar sulphuric acid. The solution is made up to 10 mL and analysed by reverse-phase column and UV-detection at 224 nm. Hydrogen peroxide is quantified <i>via</i> the titanium peroxy sulfate by molecular absorption spectrometry.</p> <p>LOQ: 0.00072 mg/L (0.23 ppm) (peracetic acid), 0.32 ppm (hydrogen peroxide)</p>
Water (principle of method and LOQ)	<p>Reverse-phase HPLC with UV detection . The amount of PAA is determined by oxidation of methyl-p-tolyl-sulfide (MTS) to methyl-p-tolyl-sulfoxide (MTSO), which is stable in a solution for several days. The amount of MTS in a solution must be at least twice as much as the expected PAA amount to ensure a quantitative reaction. MTSO is determined by reversed phase HPLC with UV detection.</p> <p>H2O2 is enzymatically reduced with peroxidase in the presence of 4-amino-antipyrine and phenol. Under these conditions 4-(benzoquinone-mono-imino)-phenoxon is formed, a red complex molecule which is quantified photometrically at 505 nm. For preparation of test solutions dilutions were made in purified water which was prepared according to methods of European Pharmacopoeia and the USP Purified Water.</p> <p>LOQ: 0.02 ppm (peracetic acid)</p> <p>The analytical method for detection and identification of PAA in water by HPLC-UV is acceptable for the purpose of the evaluation. The LOQ is not sufficiently low in comparison to the current lowest NOEC for aquatic environment. The conclusion of WG-V-2014 APCP for surface water was that LOQ might be necessary to be revised accordingly depending on the outcome of WG ENV. As a result, in product authorization the method should demonstrate sufficient specificity and a sufficient LOQ in comparison to the lowest relevant NOEC for aquatic environment available, or a justification for non-submission of an updated method should be presented. After the peer review process the applicant has submitted to RMS information on degradation of peracetic acid in water as well as information on methodologies, but those need to be evaluated.</p>
Body fluids and tissues (principle of method and LOQ)	This method is not required.

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Applicant's justification for non-submission of data for analytical method for residues in/on food or feedstuffs and other products where relevant is acceptable due to the properties of peracetic acid (highly unstable and rapid degradation upon contact with organic matter).
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Applicant's justification for non-submission of data for analytical method for residues in/on food or feedstuffs and other products where relevant is acceptable due to the properties of peracetic acid (highly unstable and rapid degradation upon contact with organic matter).

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Not determined, 100% as a default.
Rate and extent of dermal absorption for the active substance:	Not determined, 100% as a default.
Rate and extent of dermal absorption for the representative product(s):	Not determined, 100% as a default.
Distribution:	20 % of radio-activity tissue-bound with highest levels found in liver, gastro-intestinal tract and exposed skin
Potential for accumulation:	No evidence for bioaccumulation
Rate and extent of excretion:	<ul style="list-style-type: none"> - approx. 30 – 60 % of the applied dose recovered as CO₂ after 72 hours with the majority formed after 24 hours; an initial lag phase of approx. 1 hour evident - about 17 % of given radioactivity excreted via the urine after 72 hours; majority of urinary excretion occurred after 24 hours - about 4 - 5 % of given radioactivity excreted via the faeces and 17 % via urine after 72 hours; majority of faecal excretion occurred after 24 hours
Toxicologically significant metabolite(s)	None

Acute toxicity

Rat LD ₅₀ oral	<p>1020 mg/kg; (Acute Tox. 4 *, H302; Xn, R22) corresponding to 153 mg/kg (100% PAA) (Acute Tox. 3; H301)</p> <p>1700 mg/kg (Acute Tox. 4 *, H3012; Xn, R22) corresponding to 85 mg/kg (100% PAA) (Acute Tox. 3; H301)</p>
Rabbit LD ₅₀ dermal	1147 mg/kg; (Acute Tox. 4 *, H312; Xn, R21) corresponding to 56.1 mg/kg (100% PAA) (Acute Tox. 2; H310)
Rat LC ₅₀ inhalation	1 mg/L ≤ LC ₅₀ ≤ 5 mg/L; (Acute Tox.4 *, H332; Xn, R20)

	LC50 0.204 mg/l (100% PAA) (Acute Tox. 2; H330)
Skin corrosion/irritation	Corrosive; (Skin Corr. 1A, H314; C, R35)
Eye irritation	Corrosive (severe damage to the eyes) ; (Skin Corr. 1A H314; Xi, R41)
Skin sensitization (test method used and result)	Non-sensitising (GPMT)
Repeated dose toxicity	
Species/ target / critical effect	Rat (oral): local irritation in stomach/gastro-intestinal-tract, no systemic effects
Lowest relevant oral NOAEL / LOAEL	90-days gavage study in rats NOAEL 15 mg/kg bw/day corresponding to 0.055% PAA
Lowest relevant dermal NOAEL / LOAEL	Not established
Lowest relevant inhalation NOAEL / LOAEL	No study required for this endpoint for animal welfare reasons and owing to the intrinsic properties of PAA (primary local irritation/corrosion at the site of first contact and absence of systemic effects/systemic availability)
Genotoxicity	<p><i>In vitro</i>: Positive results in <i>in vitro</i> cytogenetic assay (chromosome aberrations) in human lymphocytes. Negative results in Ames test, gene mutation assay in mammalian cells, negative/equivocal <i>in vitro</i> chromosome aberration assay with Chinese hamster lung fibroblasts</p> <p><i>In vivo</i>: Equivocal in three micronucleus tests and <i>in vivo</i> UDS. The biological meaning of any result from the <i>in vivo</i> studies is questionable in view of uncertainty of the availability of the test substance in the target organ.</p> <p>Weight of evidence indicates no concern of mutagenic / genotoxic potential</p>
Carcinogenicity	
Species/type of tumour	<p>No study required for this endpoint for animal welfare reasons and owing to the intrinsic properties of PAA (primary local irritation/corrosion at the site of first contact and absence of systemic effects/systemic availability)</p> <p>No concern of mutagenic / genotoxic potential.</p> <p>Site of contact carcinogenicity not tested.</p>
lowest dose with tumours	n.a.
Reproductive toxicity	
Species/ Reproduction target / critical effect	<p>No indication of reproductive toxicity in 90-days oral and continuous breeding studies</p> <p>In the absence of both teratogenic effect and findings on reproductive organs in repeated dose toxicity studies, no study is required for this</p>

	particular endpoint for animal welfare reasons and owing to the intrinsic properties of PAA (primary local irritation/corrosion at the site of first contact and absence of systemic effects/systemic availability)
Lowest relevant reproductive NOAEL / LOAEL	n.a.
Species/Developmental target / critical effect	Rat: maternal effects: reductions in body weight, body weight gain developmental effects: impairment of ossification (bones missing or poor/hypertrophic ossification)
Developmental toxicity	
Lowest relevant developmental NOAEL / LOAEL	Maternal: 12.5 mg PAA/kg bw/d Developmental: 12.5 mg PAA/kg bw/d
Neurotoxicity / Delayed neurotoxicity	
Species/ target/critical effect	No indicative signs from acute and repeated dose studies; no structural alerts
Lowest relevant developmental NOAEL / LOAEL.	n.a.
Other toxicological studies	
Toxic effects on livestock and pets	<p>Not required since the mode of action of PAA is known, i.e. the primary toxicological effect (local irritation/corrosion) which is not specific to any particular mammalian species or organ/tissue but is limited to the site of first contact.</p> <p>PAA is not systemically available in the body beyond the site of first contact due to rapid breakdown to the physiological metabolites hydrogen peroxide, water, oxygen and acetic acid</p> <p>The toxicity of Peracetic acid has been investigated and it has been shown not to be mutagenic or teratogenic.</p> <p>In the summary report of the Committee for Veterinary Medicinal Products (CVMP) on Peracetic acid (EMA/MRL/060/96-FINAL, Doc. No. 983-001), PAA is admitted for use in livestock animals and that there is no need to establish an MRL for PAA.</p>

Studies related to the exposure of the a.s. to humans	<p>Not required since the mode of action of PAA is known, i.e. the primary toxicological effect (local irritation/corrosion) which is not specific to any particular mammalian species or organ/tissue but is limited to the site of first contact.</p> <p>PAA is not systemically available in the body beyond the site of first contact due to rapid breakdown to the physiological metabolites hydrogen peroxide, water, oxygen and acetic acid. These degradation products will form in any species and no other pathways of degradation occur.</p> <p>No degradation pathways other than those known from animal studies are expected to occur. Thus, PAA will not be transformed to further substances which were not observed and assessed in the available mammalian toxicity studies.</p>
Food and feeding stuffs	<p>Peracetic acid (PAA) is not intended to be used in or on food or feeding stuff. In uses, however, where residues on food stuff packaging material cannot be excluded, no safety concern for does exist since PAA is rapidly degraded to the physiological metabolites hydrogen peroxide, oxygen and acetic acid.</p> <p>Based on the evaluation of and the conclusions made by the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food, possible residues of PAA on food and feeding stuff are not considered to be associated with a safety concern.</p>
Other tests related to exposure of the a.s. to human considered to be necessary	<p>No other tests related to the exposure of the active substance to humans for the purpose of performing reliable human health risk assessments studies necessary. The proposed biocidal products are sufficiently covered by the aforementioned tests. There are no endpoints of concern which would require further testing.</p>
Tests to assess toxic effects from metabolites of treated plants	<p>Peracetic acid is not used in products for action against plants.</p> <p>Therefore, no tests to assess toxic effects of metabolites from treated plants are required.</p>

Mechanistic studies

Based upon the known mode of action of peracetic acid, no mechanistic studies are required. The toxicity of PAA is due to its locally irritating properties, i.e. decomposition to hydrogen peroxide, oxygen and acetic acid. After contact with organs and tissues, hydrogen peroxide will undergo decomposition into water and oxygen.

The primary toxicological effect (local irritation) is not specific to any particular mammalian species or organ/tissue but is limited to the site of first contact.

PAA is not systemically available in the body beyond the site of first contact due to rapid breakdown to the physiological metabolites hydrogen peroxide, water, oxygen and acetic acid. Acetic acid is introduced in the C2-pool or further metabolised via physiological pathways to carbon dioxide and water. All occurring metabolites are rapidly eliminated and do not bioaccumulate.

Further human health related studies

In view of the known mode of action and considering results of available mammalian toxicity studies, no further human health-related studies are required.

Medical data

Medical surveillance data on manufacturing plant personnel

No data available

Direct observations, e.g. clinical cases, poisoning incidents

1: The cytotoxic and irritating potential of peracetic acid in humans used as a disinfectant for hand washing procedures applied by surgeons was investigated. Three of 15 surgeons developed immediately erythema and 6 of 15 surgeons developed dermatosis of the hands after 7 days following daily soaping, brushing and disinfection of skin with PAA at a concentration of 0.5 %. PAA applied as Wofasteril caused dermal irritation reactions in a third of health care workers.

2: Several recommendations were made to allow a safe handling with concentrated PAA solutions:

- wearing protective gloves and protective glasses for diluting concentrated PAA
- dilutions should be made in a ventilated room
- for spray application of dilutions for disinfection purposes a respirator should be used.

3: Effects of diluted PAA solutions used as an aerosol (0.8 % PAA) as a disinfectant for human skin (0.08 or 0.2 % PAA) and for the treatment of a recurrent, pruritic epidermitis (0.1 % PAA):

- irritation of the respiratory tract, lachrimation, salivation, increased nasal discharge and partly temporal loss of olfactory senses (0.8 % PAA)
- slight skin desquamation after 1 or 2 days without hypersensitivity (0.2 % PAA)
- daily skin disinfection for 3 years using solutions of 0.2 % PAA mixed with alcohol did not cause any adverse effects
- temporarily reduced skin roughness after 1 day.

The hands appeared slippery when wet, smooth and well-manicured (0.2 % PAA)

- treatment of a recurrent, pruritic epidermitis using a 0.1 % PAA successful

- Concentrations of 0.2 % peracetic acid can be considered as non to only slightly irritating to skin.

4: After a Patch test with dilutions of 1:33 (1500 mg/L PAA), 1:20 (2500 mg/L PAA) and 1:15 (3500 mg/L according to publication, correct value should be 3300 mg/L) it was concluded that up to 2500 mg/L PAA (corresponding to an about 0.25 % solution) is non-irritant. At 3300 mg/L PAA (corresponding to an about 0.33 % solution) is a mild irritant.

Health records, both from industry and any other sources

The Persteril dilution containing 0.2 % PAA was well tolerated by the 20 volunteers. The concentration of 0.2 % PAA is sufficient for eradication of pyogenic staphylococci and 97 % reduction of residual flora on the hand within 3 minutes. PAA does not have a residual effect. Solutions of PAA with concentrations of 0.2 % do not damage the skin.

Epidemiological studies on the general population

No data available

Diagnosis of poisoning including specific signs of poisoning and clinical tests

No data available

Sensitization/allergenicity observations

The cases of two subjects who developed cough wheezing and shortness of breath after being exposed to PAA-hydrogen peroxide (PAA-HP) vapours are investigated. The main symptoms observed were rhinorrhoea, conjunctivitis, continuous cough, breathlessness and chest tightness appeared after several hours of exposure to PAA-HP vapours and improved after removal from exposure. It was concluded that symptoms in these subjects were generated by an irritant mechanism and occupational prolonged exposure to vapours of PAA-HP mixtures caused symptoms which were the consequence of a sustained irritation process rather than a real asthmatic reaction.

Specific treatment in case of an accident or poisoning: first aid measures and medical treatment

Basic aid: decontamination and symptomatic treatment is warranted. No specific antidote is known.
Eyes: In case of contact with eyes rinse thoroughly with water. Contact a physician immediately.
Skin: Remove contaminated clothes. Wash affected body areas carefully with plenty of water and soap.
Ingestion: Rinse out mouth and give plenty of water to drink. Do not induce vomiting.
Inhalation: Ensure supply of fresh air. Contact a physician as necessary.

Prognosis following poisoning

Depending on severity of effects

Summary

Peracetic acid:

ADI (acceptable daily intake, external long-term reference dose)

AEL short-term/medium-term/long-term

NOAEC dermal

NOAEC oral

AEC inhalation

ARfD (acute reference dose)

Reference value for inhalation (proposed OEL)

Reference value for dermal absorption

Value	Study	Safety factor
n.a.; PAA does not cause systemic effects	-	-
n.a.; PAA does not cause systemic effects	-	-
0.2% for short/medium term	Human volunteer study	-
0.1% for long-term	rabbit one year study	2
0.055%	90 day rat	
0.5 mg/m ³ (0.16 ppm)	Human data (NOAEC 0.5 ppm)	3.16
n.a.; PAA does not cause systemic effects	-	-
-	-	-
100% as a	-	-

concerning the active substance:	default		
Reference value for dermal absorption concerning the representative product(s) ⁴ :	100% as a default	-	-

Hydrogen peroxide:

Skin irritating threshold	35%	classification limit for irritation	-
AEC inhalation	1.25 mg/m ³	NOAEC in 90-day inhalation rat study	8

Acceptable exposure scenarios (for method of calculation, please refer to Appendix IV)

Industrial and professional users:	
Production of active substance:	No risk characterisation is made.
Formulation of biocidal product	No risk characterisation is made.
Intended uses	PT11 Disinfection of cooling water in open re-circulating systems and once-through cooling systems: PPE in mixing & loading, inspection and maintenance (goggles + skin protection + RPE) PT12 Slimicide in the pulp and paper industry: PPE in mixing & loading, inspection and maintenance (goggles + skin protection + RPE)
Secondary exposure	PT11/12: Acute bystander/non-user secondary dermal and inhalation exposure during unscheduled maintenance and repair tasks PT11: Chronic bystander/non-user secondary inhalation exposure to spray drift (uncontrolled windage or blowdown) PT12: Chronic consumer secondary dermal and oral exposure via coated paper PT12: Chronic consumer secondary oral exposure via food
Non-professional users:	
Intended uses	no non-professional exposure
Indirect exposure as a result of use	-

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)	Determined for an initial TS concentration (C ₀) of 0.001 mol PAA/L (95 ppm): pH__5__: 46.7 hours (at 25°C) pH__7__: 31.7 hours (at 25°C) pH__9__: 3.6 hours (at 25°C)
Photolytic / photo-oxidative degradation of active substance and resulting relevant	No study on phototransformation of peracetic acid was conducted. Peracetic acid does not absorb

metabolites	<p>light in the visible wavelength range.</p> <p>According to an Atkinson calculation, PAA degrades in the atmosphere with a DT50 of 3.969 days (based on a 24-hour day), corresponding to 95.26 hours. As the molecule does not contain olefin carbon-carbon double or acetylic triple bonds, peracetic acid is not expected to react with ozone.</p>
Readily biodegradable (yes/no)	yes
Biodegradation in seawater	50% degradation within 2 minutes
Non-extractable residues	Not formed
Distribution in water / sediment systems (active substance)	Peracetic acid is expected to partition mainly into the aquatic compartment (96.9% mass amount), while only 0.132% is expected to partition to soil, 2.99 % to the air and only 0.00001 % into sediment (fugacity level III calculation according to Mackay using EPIWIN v. 3.20).
Distribution in water / sediment systems (metabolites)	<p>Peracetic acid remains mainly in the water phase due to its high solubility in water and low K_{oc}. Any amount coming in contact with the sediment is rapidly decomposed.</p> <p>According to a fugacity level III calculation, peracetic acid only partitions into the sediment at very low rates (see above).</p>
Route and rate of degradation in soil	
Mineralization (aerobic)	
Laboratory studies (range or median, with number of measurements, with regression coefficient)	<p>Peracetic acid degrades rapidly when in contact with organic matter. This has been shown in the activated sludge test. Thus, peracetic acid is not expected to be persistent in soil.</p> <p>It was agreed in the BPC WG ENV II-2016 to use the DT₅₀ from hydrogen peroxide of 12 hrs in the absence of a DT₅₀ for PAA.</p> <p>DT_{50lab} (20°C, aerobic): No reliable data available</p> <p>DT_{90lab} (20°C, aerobic): No reliable data available</p> <p>DT_{50lab} (10°C, aerobic): No reliable data available</p> <p>DT_{50lab} (20°C, anaerobic): not data</p> <p>Degradation in the saturated zone: no data.</p>
Field studies (state location, range or median with number of measurements)	<p>DT_{50f}: no data from field studies available</p> <p>DT_{90f}: no data from field studies available</p>
Anaerobic degradation	<p>Peracetic acid degrades rapidly when in contact with organic matter. This has been shown in the activated sludge test. Though the degradation of peracetic acid is mediated by micro-organisms, the main pathway is through decomposition in contact with organic matter. The latter process is independent of the oxidative status (aerobic/ anaerobic conditions) of the environment. Further, peracetic acid itself liberates oxygen upon decomposition.</p>

Soil photolysis	Not expected to contribute to the degradation of peracetic acid because peracetic acid does not absorb light in the visible wavelength range.
Non-extractable residues	None formed
Relevant metabolites - name and/or code, % of applied active ingredient (range and maximum)	Peracetic acid is degraded to acetic acid, hydrogen peroxide and finally to CO ₂ , water and oxygen.
Soil accumulation and plateau concentration	No accumulation due to rapid and complete degradation to CO ₂ , water and oxygen.

Adsorption/desorption

K _a , K _d	<p>The adsorption coefficient was calculated applying QSAR (according to page 26 of TGD) for soil and sediment.</p> <p>The calculated K_{oc} is 1.46 l/kg.</p> <p>Consequently, peracetic acid is to be considered as mobile in soil and sediment.</p>
K _{aoc} , K _{doc}	
pH dependence (yes / no) (if yes type of dependence)	

Fate and behaviour in air

Direct photolysis in air	Not applicable: no absorption of light in the visible wavelength range
Quantum yield of direct photolysis	Not applicable: no absorption of light
Photo-oxidative degradation in air	According to an Atkinson calculation of the atmospheric residence time, peracetic acid degrades in the atmosphere with a DT ₅₀ of 3.969 days (based on a 24-hour day), corresponding to 95.26 hours. As the molecule does not contain olefin carbon-carbon double or acetylic triple bonds, peracetic acid is not expected to react with ozone.
Volatilization	The measured Henry's Law constant of 0.217 Pa m³ mol⁻¹ indicates that volatilisation from surface water is not expected to be an important process.

Monitoring data, if available

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	No data available
Ground water (indicate location and type of study)	No data available
Air (indicate location and type of study)	No data available

Chapter 5: Effects on Non-target Species

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

Species	Time-scale	Endpoint	Toxicity
Fish			

<i>Lepomis macrochirus</i> (bluegill sunfish)	96 hours	Mortality	LC ₅₀ = 1.1 mg/L
<i>Danio rerio</i> (zebra fish)	33 days	Post hatch success / Overall survival	NOEC = 0.00069 mg/L
Invertebrates			
<i>Daphnia magna</i>	48 hours	Immobility	EC ₅₀ = 0.73 mg/L
<i>Daphnia magna</i>	21 days	Reproduction	NOEC = 0.0121 mg/L
Algae			
<i>Selenastrum capricornutum</i>	72 hours	Growth inhibition	EC ₅₀ = 0.16 mg/L NOEC = 0.061 mg/L
Microorganisms			
Activated sludge	3 hours	Respiration rate	EC ₅₀ = 5.1 mg/L

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms

14-day LC₅₀: > 1000 mg/kg dry soil equals > 885 mg/kg wet soil.

Reproductive toxicity to

No data available

Effects on soil micro-organisms

Nitrogen mineralization

28-day EC₅₀: > 933.6 mg/kg dry soil equals 826.2 mg/kg wet soil

Carbon mineralization

28-day EC₅₀: > 933.6 mg/kg dry soil equals 826.2 mg/kg wet soil

Effects on terrestrial plants

21-day EC₅₀: 320 mg/kg dry soil equals 282 mg/kg wet soil (*Brassica napus*), based on seedling emergence reduction

Effects on terrestrial vertebrates

Acute toxicity to mammals

No data available and no data required

Acute toxicity to birds

No data available and no data required

Dietary toxicity to birds

No data available and no data required

Reproductive toxicity to birds

No data available and no data required

Effects on honeybees

Acute oral toxicity

No data available and no data required

Acute contact toxicity

No data available and no data required

Effects on other beneficial arthropods

Acute oral toxicity

No data available and no data required

Acute contact toxicity

No data available and no data required

Acute toxicity

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Bioconcentration

Bioconcentration factor (BCF)

The low $\log P_{ow}$ ($\ll 3$, see above) indicates that peracetic acid has a low potential for bioconcentration and bioaccumulation (according to guideline OECD 117, $\log P_{ow}$ values below 3 are regarded to be indicators of low accumulation potential). Moreover, peracetic acid dissipates rapidly in the environment. This is a further indication of low accumulation potential.

Not experimentally determined

Depuration time (DT₅₀)
(DT₉₀)

Not applicable: no test performed

Uptake of peracetic acid into the organism of fish can be excluded due the instantaneous degradation of peracetic acid in contact with organic material.

Level of metabolites (%) in organisms accounting for > 10 % of residues

Not applicable: no test performed

Chapter 6: Other End Points

Appendix II: List of Intended Uses

Object and/or situation	Product Name*	Organisms controlled	Formulation		Application method, kind number and interval between applications (min), if relevant	Applied amount per treatment	Remarks: Efficacy data to support the use
			Type	Conc. of as			
PT 11: Treatment of cooling water in open recirculating systems, shock dosing; industrial / professional use	PAA 5% / PAA 15%	Bacteria, fungi, algae	Aqueous solution		From IBC containers (1100 kg) or from stationary storage tanks, the product is automatically pumped by special self-priming dosing pumps as shock dose once per day into the cooling water stream.	The in-use concentration for the disinfection of cooling water is 5 mg/L peracetic acid during shock dosing. 5 mg/L peracetic acid correspond to <ul style="list-style-type: none"> • 100 mg/L of Theoretical product 1 – PAA5% • 33.3 mg/l of Theoretical product 2 – PAA15% 	Minimal bactericidal concentration (MBC) of PAA (15% PAA product, Interlox Chemicals Ltd) was 3 mg/l PAA for <i>Escherichia coli</i> , <i>Staphylococcus aureus</i> , and <i>Pseudomonas aeruginosa</i> water strains and culture collection strains, 1 h contact time. Test temperature: 37 °C.
PT 11: Treatment of cooling water in once-through cooling systems, shock dosing	PAA 5% / PAA 15%	Bacteria, fungi, algae	Aqueous solution		From IBC containers (1100 kg) or from stationary storage tanks, the product is automatically pumped by special self-priming dosing pumps as shock dose once per day into the cooling water stream.	The in-use concentration for the disinfection of cooling water is 7.5 mg/L peracetic acid during shock dosing. 7.5 mg/L peracetic acid correspond to <ul style="list-style-type: none"> • 150 mg/L of Theoretical product 1 – PAA5% • 50 mg/l of Theoretical product 2 – PAA15% 	Minimal bactericidal concentration (MBC) of PAA (15% PAA product, Interlox Chemicals Ltd) was 3 mg/l PAA for <i>Escherichia coli</i> , <i>Staphylococcus aureus</i> , and <i>Pseudomonas aeruginosa</i> water strains and culture collection strains, 1 h contact time. Test temperature: 37 °C.

PT 12: Use as a slimicide in the pulp and paper industry; industrial / professional use	PAA 5% / PAA 15%	Bacteria and fungi	Aqueous solution		The product is transferred from IBC containers (in this case no intermediate storage in storage tanks) or from storage tanks by an electronic dosing pump to the injection points, where it is automatically dosed into the short circulation of the paper mill.	The in-use concentration is 5 - 75 mg/L peracetic acid, corresponding to an application rate of 0.048 - 0.15 kg peracetic acid per ton of paper. 5 - 75 mg/L peracetic acid correspond to <ul style="list-style-type: none"> • 100 - 1500 mg/L of Theoretical product 1 - PAA5% • 33 - 500 mg/L of Theoretical product 2 - PAA15% 	Product Fennosan PAA (12-17% peracetic acid, 13-16% hydrogen peroxide, 21-26% acetic acid) was effective in killing aerobic bacteria at concentration of 300 mg/L (1h and 24h), test temperature: 45 °C.
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*Theoretical product 1 (PAA 5%) and theoretical product 2 (PAA 15%) are referred to in the table as PAA 5% and PAA 15%; respectively.

Appendix III: List of studies

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

Reference list Doc IIIA by Section Points:

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 2.10/01	Rowbottom, K.	1996	SOLVAY MEMO - ATMOSPHERIC MONITORING DURING FILLING OF IBC'S WITH PERACETIC ACID AT ELLIS AND EVERARD ON THE 27TH MARCH 1996 Source: SOLVAY PHARMACEUTICALS, NL Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 574-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 2.10/04	Lebert Weitzel	1990	ARBEITSPLATZMESSUNGEN AUF PERESSIGSÄURE IN DER RAUMLUFT Source: Degussa AG, Hanau, Germany Report No.: U 288/901 Not GLP; (unpublished) Doc. No.: 574-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 2.10/07	Rowbottom, K.	1996	SOLVAY MEMO - ATMOSPHERIC MONITORING AT NORTH DEVON DISTRICT HOSPITAL IN BARNSTAPLE - 2ND DECEMBER 1996 Source: SOLVAY PHARMACEUTICALS, NL Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 574-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 2.10/08	McDonagh, J.	1997	ATMOSPHERIC MONITORING OF PERACETIC ACID ON THE EXISTING CAPROLACTONE PLANT DISTILLATION HOUSES A & B - ASSESSMENT OF RESULTS Source: SOLVAY PHARMACEUTICALS, NL Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 574-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 2.10/09	Fraser, J.A.L. Thorbinson, A.	1986	FOGGING TRIALS WITH TENNECO ORGANICS LIMITED (30TH JUNE, 1986) AT COLLARDS FARM Source: Not indicated Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 575-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 2.10/10	Guiver, R.	1999	A REPORT OF 16 VISITS ADDRESSING OCCUPATIONAL EXPOSURE ARISING FROM DIPPING ACTIVITIES WITH BIOCIDES AND NON AGRICULTURAL PESTICIDES Source: Health and Safety Executive, UK Report No.: 3830/R51.169 Not GLP; (unpublished) Doc. No.: 575-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 3.1.1/01	Anonymous	2001	ECETOC - PERACETIC ACID (CAS NO. 79-21-0) AND ITS EQUILIBRIUM SOLUTIONS Source: European Centre for Ecotoxicology and Toxicology of Chemicals,(2001) , pp. 152, ISSN: 0733-6339-40 Report No.: 40 Not GLP; (published) Doc. No.: 092-003	No	N.R.
A3.1.1/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE MELTING POINT AND BOILING POINT OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.1 GLP; (unpublished) Doc. No.: 112-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 3.1.2/01	Mücke, H. Sprössig, M.	1969	DIE EIGENSCHAFTEN DER PERESSIGSÄURE Source: Wissenschaftliche Zeitschrift der Humboldt-Universität zu Berlin, Math.-Nat. R XVIII, 1969, Vol. 6, pp. 1167-1170 Report No.: Not applicable Not GLP; (published)	No	N.R.
A 3.1.2/02	Swern, D.	1970	ORGANIC PEROXIDES VOLUME 1 Source: Fels Research Institute and Department of Chemistry Temple University, Philadelphia, Pennsylvania Report No.: Not applicable Not GLP; (published) Doc. No.: 192-003	No	N.R.
A3.2/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE VAPOUR PRESSURE OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.3 0649 82474 GLP; (unpublished) Doc. No.: 115-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 3.2.1/01	Lind, J.A. Kok, G.L.	1986	HENRY 'S LAW DETERMINATIONS FOR AQUEOUS SOLUTIONS OF HYDROGEN PEROXIDE, METHYLHYDROPEROXIDE, AND PEROXYACETIC ACID Source: Journal of Geophysical Research, Vol. 91, No. D7, pp. 7889-7895 Report No.: Not applicable Not GLP; (published) Doc. No.: 192-005	No	N.R.
A3.4/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE UV/VIS SPECTRUM OF PEROXYACETIC ACID 15% Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.4 GLP; (unpublished) Doc. No.: 217-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 3.4/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE IR SPECTRUM OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.6 GLP; (unpublished) Doc. No.: 217-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A3.4/03	Mekelburger, H.-B.	2007	DETERMINATION OF THE 1H-NMR SPECTRUM OF PEROXYACETIC ACID 15% Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.5 GLP; (unpublished) Doc. No.: 217-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A3.6/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE DISSOCIATION CONSTANTS IN WATER OF PEROXYACETIC ACID 15 % (INCLUDING AMENDMENT) Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.7 GLP; (unpublished) Doc. No.: 115-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 3.7/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE SOLUBILITY IN ORGANIC SOLVENTS OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.8 GLP; (unpublished) Doc. No.: 215-007	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 3.9/01	Byers, L.	1998	CORRESPONDENCE BETWEEN CAROPRESO AND BYERS (FMC) - OCTANOL-WATER PARTITION COEFFICIENT FOR PERACETIC ACID AND HYDROGEN PEROXIDE Source: Not applicable Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 114-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 3.9/02	Thus, J.	1994	FAX COMMUNICATION ON CALCULATION OF THE OCTANOL/WATER PARTITION COEFFICIENT OF PERACETIC ACID Source: SOLVAY PHARMACEUTICALS, NL Report No.: JLGT/ybz/56835/cor/94-179 Not GLP; (unpublished) Doc. No.: 114-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 3.9/03	Brachhold, H.	2007	ESTIMATION OF THE PARTITION COEFFICIENT (N-OCTANOL/WATER) OF PERACETIC ACID Source: Degussa AG, Hanau, Germany Report No.: 2007-0094-DKB Not GLP; (unpublished) Doc. No.: 154-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A3.10/01 Post-submission	Schrieber, M.	2000	BESTIMMUNG SICHERHEITSTECHNISCHER KENNGRÖSSEN FÜR [REDACTED] UND [REDACTED] Henkel Analytik, Düsseldorf Report No.: 00-10286 Not GLP, unpublished Doc. No.: 241-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ECOLAB
A3.15/01 Post-submission	Kratz, W.	1977	DIE BILDUNG EXPLOSIVER DÄMPFE ÜBER GLEICHGEWICHTSPERESSIGSÄUREN Degussa AG, Hanau, Germany Report No.: 261 Not GLP, unpublished Doc. No.: 241-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Evonik Industries
A 4.1/01	Görg, J.	2005	ROUND ROBIN TEST - STATISTICAL EVALUATION OF THE TEST RESULTS FOR PERACETIC ACID AND HYDROGEN PEROXIDE IN A DISINFECTANTS Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 834-004 Not GLP; (unpublished) Doc. No.: 411-018	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 4.1/02	Richarz, J.	2007	BESTIMMUNG VON ESSIGSÄUREN IN [REDACTED] DURCH POTENTIOMETRISCHE TITRATION MIT NATRONLAUGE Source: Henkel KGaA Report No.: VTA32X07002.01 Not GLP; (unpublished) Doc. No.: 412-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 4.1/03	Richarz, J.	2007	IONENCHROMATOGRAPHISCHE BESTIMMUNG VON SULFAT IN [REDACTED] Source: Henkel KGaA Report No.: VTA23X07001.01 Not GLP; (unpublished) Doc. No.: 412-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 4.1/04	Richarz, J.	2007	IONENCHROMATOGRAPHISCHE BESTIMMUNG VON HYDROXYETHAN-1,1-DIPHOSPHONSÄURE IN [REDACTED] Source: Henkel KGaA Report No.: VTA23X07002.01 Not GLP; (unpublished) Doc. No.: 412-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 4.2b/01	Hecht, G. Héry, M. Hubert, G. Subra, I.	2004	SIMULTANEOUS SAMPLING OF PEROXYACETIC ACID AND HYDROGEN PEROXIDE IN WORKPLACE ATMOSPHERES Source: Ann. Occup. Hyg., Vol. 48, pp. 715-721, 2004, © 2004 British Occupational Hygiene Society, Published for Oxford University Press Report No.: Not applicable Not GLP; (published) Doc. No.: 436-003	No	N.R.
A 4.2c/01	van Egdrom, T.R.	2007	EVALUATION OF THE DEGRADATION OF PERACETIC ACID AND HYDROGEN PEROXIDE IN EFFLUENT FROM A WASTE WATER TREATMENT PLANT Source: SOLVAY PHARMACEUTICALS, NL Report No.: E.SOL.S.025 GLP; (unpublished) Doc. No.: 714-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 4.2d/01	[REDACTED]	2005	DEGRADATION OF PERACETIC ACID IN DILUTED RAT BLOOD (HPLC METHOD) Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 593-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 5.3/01	Alasri, A. Roques, C. Michel, G.	1992	BACTERICIDAL PROPERTIES OF PERACETIC ACID AND HYDROGEN PEROXIDE, ALONE AND IN COMBINATION, AND CHLORINE AND FORMALDEHYDE AGAINST BACTERIAL WATER STRAINS Source: Can. J. Microbiol, 1992, 38, 635-642 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-041	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/02	Alasri, A. et al.	1993	SPOROCIDAL PROPERTIES OF PERACETIC ACID AND HYDROGEN PEROXIDE, ALONE AND IN COMBINATION, IN COMPARISON WITH CHLORINE AND FORMALDEHYDE FOR ULTRAFILTRATION MEMBRANE DISINFECTION Source: Can. J. Microbiol, 1993, 39, 52-60 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-042	No	N.R.
A 5.3/03	Mourcel, P.	2007	TEST CERTIFICATE N° 294 - ██████████ Source: Laboratoire de Microbiologie et d'Hygiene, Dinard Cedex, France Report No.: FM 064G -2 Not GLP; (unpublished) Doc. No.: 321-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 5.3/04	Anonymous	2007	TEST CERTIFICATE N° 1014 - ██████████ Source: Laboratoire de Microbiologie et d'Hygiene, Dinard Cedex, France Report No.: FM 064G -2 Not GLP; (unpublished) Doc. No.: 321-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 5.3/05	Schröder, W.	1982	PERESSIGSÄURE (PES) ALS DESINFEKTIONSWIRKSTOFF FÜR DIE LEBENSMITTELINDUSTRIE Source: Confrocia, Bd. 26 (9182) Nr. 5, pp. 139-147 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-009	No	N.R.
A 5.3/06	Sagripanti, J.-L. Bonifacino, A.	1996	COMPARATIVE SPORICIDAL EFFECTS OF LIQUID CHEMICAL AGENTS Source: Applied and Environmental Microbiology, Feb. 1996, 62, 2, 545-551 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-056	No	N.R.
A 5.3/07	Baldry, M.G.	1983	THE BACTERICIDAL, FUNGICIDAL AND SPORICIDAL PROPERTIES OF HYDROGEN PEROXIDE AND PERACETIC ACID Source: Journal of Applied Bacteriology 1983, 54, 417-423 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-044	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/09	Kretzschmar, C. Agerth, R. Bauch, R. Friedrich, D.	1971	PERESSIGSÄURE - NUR EIN DESINFEKTIONSMITTEL? Source: Monatsheft, Veterinär Medizin, 27, pp. 324-332 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-003	No	N.R.
A 5.3/15	Fraser, J.A.L.	1986	PEROXYGENS IN ENVIRONMENTAL PROTECTION Source: Effluent and Water Treatment Journal, June 1986, pp. 186-199 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-011	No	N.R.
A 5.3/16	Baldry, M.G.C. Fraser, J.A.L.	N.I.	DISINFECTION WITH PEROXYGENS Source: Industrial Biocides, Wiley, 91- 116 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-061	No	N.R.
A 5.3/20	Cords, B.R. Dychdala, G.R.	1993	SANITIZERS: HALOGENS, SURFACE- ACTIVE AGENTS, AND PEROXIDES Source: Name of Journal not indicated, pp. 469-537 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-016	No	N.R.
A 5.3/28	Antonelli, M. et al.	2006	SECONDARY EFFLUENT DISINFECTION: PAA LONG TERM EFFICIENCY Source: Environ. Sci. Technol., 2206, 40, 4771-4775 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-037	No	N.R.
A 5.3/29	Gilbert, P. et al.	2001	ASSESSMENT OF RESISTANCE TOWARDS BIOCIDES FOLLOWING THE ATTACHMENT OF MICRO-ORGANISMS TO, AND GROWTH ON, SURFACES Source: Journal of Applied Microbiology, 2001, 91, 248-254 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-038	No	N.R.
A 5.3/31	Clapp, P.A. et al.	1994	THE BACTERICIDAL ACTION OF PEROXIDES - AN E.P.R. SPIN- TRAPPING STUDY Source: Free Rad. Res. 1994, 21 (3), 147-167 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-045	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/32	Marquis, R.E. et.al.	1995	SPORICIDAL ACTION OF PERACETIC ACID AND PROTECTIVE EFFECTS OF TRANSITION METAL IONS Source: Journal of Industrial Microbiology, 1995, 15, 486-492 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-054	No	N.R.
A 5.3/33	Block, S.	2001	DISINFECTION, STERILLISATION AND PRESERVATION Source: Lippincott Williams and Wilkins, 2001, (5), 191-200 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-040	No	N.R.
A 5.3/34	Taylor, D.M.	1991	RESISTANCE OF THE ME7 SCRAPIE AGENT TO PERACETIC ACID Source: Verterinary Microbiology, 1991, 27, 19-24 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-058	No	N.R.
A 5.3/35	Antloga, K. et.al.	2000	PRION DISEASE AND MEDICAL DEVICES Source: Asaio Journal 2000, 46 (6), 69-72 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-043	No	N.R.
A 5.3/36	Ercken, D. et al.	2003	EFFECTS OF PERACETIC ACID AND MONOCHLORAMINE ON THE INACTIVATION OF NAEGLERIA LOVANIENSIS Source: Water Science and Technology, 2003, 47, 3, 167-171 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-066	No	N.R.
A 5.3/37	Sagripanti, J.-L. Bonifacino, A.	1996	COMPARATIVE SPORICIDAL EFFECTS OF LIQUID CHEMICAL AGENTS Source: Applied and Environmental Microbiology, Feb. 1996, 62, 2, 545-551 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-056	No	N.R.
A 5.3/38	Hussaini, S.N. Ruby, K.R.	1976	SPORICIDAL ACTIVITY OF PERACETIC ACID AGAINST B ANTHRACIS SPORES Source: Veterinary Record 1976, 98, 257-259 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-049	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/39	Lensing, H.H. Oei, H.L.	1984	EEN ONDERZOEK NAAR DE WERKZAAMHEID VAN ONTSMETTINGSMIDDELEN TEN OPZICHTE VAN MILTVUURSPOREN - A STUDY ON THE EFFICACY OF DISINFECTANTS AGAINST ANTHRAX SPORES Source: Tijdschr. Diergeneeskd. 1984, 109, 557-563 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-052	No	N.R.
A 5.3/40	Lensing, H.H. Oei, H.L.	1985	INVESTIGATIONS ON THE SPORICIDAL AND FUNGICIDAL ACTIVITY OF DISINFECTANTS Source: Zbl. Bakt. Hyg., I.Abt. Orig. B. 1985, 181, 487-495 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-053	No	N.R.
A 5.3/41	Coates, D.	1996	SPORICIDAL ACTIVITY OF SODIUM DICHLOROISOCYANURATE, PEROXYGEN AND GLUTARALDEHYDE DISINFECTANTS AGAINST BACILLUS SUBTILIS Source: Journal of Hospital Infection, 1996, 32, 283-294 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-046	No	N.R.
A 5.3/42	Ossia-Ongagnia, Y. Sabatier, R.	1993	COMPARAISON DE L'ACTIVITÉ IN VITRO DE SIX DÉSINFECTANTS SUR DES BACTÉRIES DE CONTAMINATION DES EAUX D'HÉMODIALYSE Source: J. Pharm. Belg., 1993, 48, 5, 341-351 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-055	No	N.R.
A 5.3/43	Griffiths, P.A. Babb, J.R. Fraise, A.P.	1999	MYCOBACTERICIDAL ACTIVITY OF SELECTED DISINFECTANTS USING A QUANTITATIVE SUSPENSION TEST Source: Journal of Hospital Infection, 1999, 41, 111-121 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-047	No	N.R.
A 5.3/44	Holton, J. Nye, P. McDonald, V.	1994	EFFICACY OF SELECTED DISINFECTANTS AGAINST MYCOBACTERIA AND CRYPTOSPORIDIA Source: Journal of Hospital Infection, 1994, 27, 105-115 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-048	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/45	Jursch, C.A.	2002	MOLECULAR APPROACHES TO VALIDATE DISINFECTANTS AGAINST HUMAN HEPATITIS B VIRUS Source: Med Microbiol Immunol 2002, 190, 189-197 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-050	No	N.R.
A 5.3/46	Thamlikitkul, V. et al.	2001	MICROBIAL KILLING ACTIVITY OF PERACETIC ACID Source: J Med Assoc Thai, October 2001, 1375-1382 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-060	No	N.R.
A 5.3/47	Anonymous	2003	CONTROL OF POND ALGAE UTILIZING PERACETIC ACID CITY OF MODESTO, CA Source: Enviro Tech Chemcials, Inc, 2003, 1-6 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-067	No	N.R.
A 5.3/48	Anonymous	2002	DECONTAMINATION OF ENDOSCOPES Source: Device Bulletin DB 2002(05) Report No.: Not applicable Not GLP; (published) Doc. No.: 392-064	No	N.R.
A 5.3/49	Bernet, C. Garcia, V.	2005	ACIDE PERACÉTIQUE - ACTIVITÉS ET USAGES EN ÉTABLISSEMENTS DE SANTÉ Source: Centre de Coordination de la Lutte contre les Infections Nosocomiales de l'inter-région Sud-Est, 2005 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-063	No	N.R.
A 5.3/50	Mazzola, P.G. Martins, A.M. Penna, T.C.	2006	CHEMICAL RESISTANCE OF THE GRAM-NEGATIVE BACTERIA TO DIFFERENT SANITIZERS IN A WATER PURIFICATION SYSTEM Source: BMC Infectious Diseases 2006, 6, 131 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-078	No	N.R.
A 5.3/51	Landsrud, S. Sundheim, G. Borgmann-Strahsen, R.	2003	INTRINSIC AND ACQUIRED RESISTANCE TO QUATERNARY AMMONIUM COMPOUNDS IN FOOD-RELATED PSEUDOMONAS SPP. Source: Journal of Applied Microbiology, 2003, 95, 874-882 Report No.: Not indicated Not GLP; (published) Doc. No.: 392-077	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/52	Ernst, C. et al.	2006	EFFICACY OF AMPHOTERIC SURFACTANT - AND PERACETIC ACID - BASED DISINFECTANTS ON SPORES OF BACILLUS CEREUS IN VITRO AND ON FOOD PREMISES OF THE GERMAN ARMED FORCES Source: Journal of Food Protection, 2006, 69, 7, 1605-1610 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-080	No	N.R.
A 5.3/53	Block, C.	2004	THE EFFECT OF PERASAFE AND SODIUM DICHOROISOCYNURATE (NADCC) AGAINST SPORES OF CLOSTRIDIUM DIFFICILE AND BACILLUS ATROPHAEUS ON STAINLESS STEEL AND POLYVINYL CHLORIDE SURFACES Source: Journal of Hospital Infection, 2004, 57, 144-148 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-081	No	N.R.
A 5.3/54	Natterman, H. et al.	2005	EFFIZIENTE ABTÖTUNG VON MILZBRANDSPOREN DURCH WÄSSRIGE UND ALKOHOLISCHE PERESSIGSÄURE-LÖSUNGEN Source: Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz, 2005, 8, 939-950 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-082	No	N.R.
A 5.3/55	Penney, N. et al.	2007	EFFICACY OF A PEROXYACETIC ACID FORMULATION AS AN ANTIMICROBIAL INTERVENTION TO REDUCE LEVELS OF INOCULATED ESCHERICHIA COLI O157;H7 ON EXTERNAL CARCASS SURFACES OF HOT-BONED BEEF AND VEAL Source: Journal of Food Protection, 2007, 70, 1, 200-203 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-086	No	N.R.
A 5.3/56	Kasková, A. et al.	2007	APPLICATION OF PERACETIC ACID AND QUARternary AMMONIUM DISINFECTANTS AS PART OF SANITARY TREATMENT IN A POULTRY HOUSE AND POULTRY PROCESSING PLANT Source: Zoonoses Public Health, 2007, 54, 125-130 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-087	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/57	Lagacé, L. et al.	2006	BIOFILM FORMATION AND BIOCIDES SENSITIVITY OF PSEUDOMONAS MARGINALIS ISOLATED FROM A MAPLE SAP COLLECTION SYSTEM Source: Journal of Food Protection, 2006, 69, 10, 2411-2416 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-089	No	N.R.
A 5.3/58	Stampi, S. De Luca, G. Zanetti, F.	2001	EVALUATION OF THE EFFICIENCY OF PERACETIC ACID IN THE DISINFECTION OF SEWAGE EFFLUENTS Source: Journal of Applied Microbiology, 2001, 91, 833-838 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-072	No	N.R.
A 5.3/59	Brinez, W.J. et al.	2006	BACTERICIDAL EFFICACY OF PERACETIC ACID IN COMBINATION WITH HYDROGEN PEROXIDE AGAINST PATHOGENIC AND NON PATHOGENIC STRAINS OF STAPHYLOCOCCUS SPP., LISTERIA SPP., AND ESCHERICHIA COLI Source: Food Control, 2006, 17, 516-521 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-071	No	N.R.
A 5.3/60	Maillard, J.-Y. et al.	1994	EFFECT OF BIOCIDES ON MS2 AND K COLIPHAGES Source: Applied and Environmental Microbiology, June 1994, 60, 6, 2205-2206 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-073	No	N.R.
A 5.3/61	Ryu, J.-H. Beuchat, L.R.	2005	BIOFILM FORMATION AND SPORULATION BY BACILLUS CEREUS ON A STAINLESS STEEL SURFACE AND SUBSEQUENT RESISTANCE OF VEGETATIVE CELLS AND SPORES TO CHLORINE, CHLORINE DIOXIDE, AND A PEROXYACETIC ACID-BASED SANITIZER Source: Journal of Food Protection, 2005, 68, 12, 2614-2622 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-084	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/62	Bore, E. Langsrud, S.	2005	CHARACTERIZATION OF MICRO-ORGANISMS ISOLATED FROM DAIRY INDUSTRY AFTER CLEANING AND FOGGING DISINFECTION WITH ALKYL AMINE AND PERACETIC ACID Source: Journal of Applied Microbiology, 2005, 98, 96-105 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-092	No	N.R.
A 5.3/67	Krapu, S.	2006	PRESERVATION TEST - STORA ENSO OY, PANKAKOSKI Source: Kemira Oyi, Vaasa / Finland Report No.: Not indicated Not GLP; (unpublished)	Yes (Data on existing a.s. submitted for the first time for entry into Annex	Kemira
A5.3/68	Mathieu, L. et al.	1990	EFFET DE L'ACIDE PERACETIQUE SUR DES BACTERIES EN SUSPENSION ET FIXEES Journal Francais d'Hydrologie, 1990, Fasc. 1, 101-111 Report No.: Not applicable Not GLP, published Doc. No.: 392-122	No	N.R.
A5.3/69	Marques, S.C. et al.	2007	FORMATION OF BIOFILMS BY STAPHYLOCOCCUS AUREUS ON STAINLESS STEEL AND GLASS SURFACE AND ITS RESISTANCE TO SOME SELECTED CHEMICAL SANITIZERS Brazilian Journal of Microbiology, 2007, 38, 538-543, ISSN 1517-8382 Report No.: Not applicable Not GLP, published Doc. No.: 392-109	No	N.R.
A5.3/70	Alasri, A.	1992	EFFETS DE DIFFÉRENTS BIOCIDES SUR UN BIOFILM MIXTE RÉALISÉ SUR TUBES TYGON ET SUR MEMBRANES D'ULTRAFILTRATION Spectra 2000, Octobre 1992, 168, 21-24 Report No.: Not applicable Not GLP, published Doc. No.: 392-128	No	N.R.
A5.3/71	Gebel, J.	N.I.	WIRKSAMKEITSPRÜFUNG BIOZIDER WIRKSTOFFE IN BIOFILMKONTAMINIERTEN SYSTEMEN UNTER PRAXISNAHEN BEDINGUNGEN Institut für Hygiene und Öffentliche Gesundheit der Universität Bonn Report No.: Not applicable Not GLP, published Doc. No.: 392-131	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A5.3/72	Flemming, H.-C.	2003	WIRKSAMKEIT VON WASSERSTOFFPEROXID GEGENÜBER BIOFILMEN Fakultät für Naturwissenschaften der Universität Duisburg-Essen Report No.: Not applicable Not GLP, published Doc. No.: 392-130	No	N.R.
*A5.3/73	Cristiani, P.	2005	SOLUTIONS TO FOULING IN POWER STATION CONDENSERS Applied Thermal Engineering, 2005, 25, 2630-2640 Report No.: Not applicable Not GLP, published Doc. No.: 392-110	No	N.R.
*A5.3/74	Duan, Y. Hu, Y. Duan, Q. Yu, L.	2005	DISINFECTION OF CIRCULATION COOLING WATER SYSTEMS WITH PEROXYACETIC ACID - CHINESE PUBLICATION INCLUDING ENGLISH TRANSLATION Chemical Industry and Engineering Progress, 2005, 24 Report No.: Not applicable Not GLP, published Doc. No.: 392-111	No	N.R.
*A5.3/75	Eguia, E. et al.	2007	OPTIMISATION OF BIOCIDES DOSE AS A FUNCTION OF RESIDUAL BIOCIDES IN A HEAT EXCHANGER PILOT PLANT EFFLUENT Biofouling, 2007, 23, 3/4, 231-247 Report No.: Not applicable Not GLP, published Doc. No.: 392-103	No	N.R.
*A5.3/76 (Study summary B5.10/17)	Sreenivasan, P.K. Chorny, R.C.	1999	THE EFFECTS OF DISINFECTANT FOAM ON MICROBIAL BIOFILMS Biofouling, 2005, 21, 2, 141-149 Report No.: Not applicable Not GLP, published Doc. No.: 392-133	No	N.R.
*A5.3/77	Schwab, H. Kaschke, W.	1975	SCHLEIM- UND GERUCHSBEKÄMPFUNG VON FABRIKATIONSWÄSSERN IN DER PAPIERINDUSTRIE Papier (Bingen, Germany), 1975, 29, 10A, 43-51. CODEN: PAERAY. ISSN: 0031-1340. Report No.: Not applicable Not GLP, published Doc. No.: 392-117	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
*A5.3/78 (Study summary B5.10/16)	Conkey, J.H.	1981	SPORICIDAL ACTIVITIES OF CHLORINE, CHLORINE DIOXIDE AND PERACETIC ACID IN A SIMULATED PAPERMAKING FURNISH TAPPI Papermakers Conference [Proceedings], 1981, 7-11, CODEN: TPCPDY; ISSN: 0197-5153 Report No.: Not applicable Not GLP, published Doc. No.: 392-116	No	N.R.
*A5.3/79	Rantakokko, J. Maunuksela, J. Malone, J.	1994	EINSATZ VON PEROXYESSIGSÄURE ANSTELLE VON BIOZIDEN - ERFOLGREICHER VERSUCH ZUR SCHLEIMBEKÄMPFUNG IN EINER PAPIERFABRIK - INCLUDING ENGLISH TRANSLATION: SUCCESSFUL PAPERMILL TRIAL FOR SLIME CONTROL, REPLACING ORGANIC BIOCIDES WITH PERACETIC ACID Papier (Bingen, Germany), 1994, 48, 11, 681, 684-686 CODEN: PAERAY; ISSN: 0031-1340 Report No.: Not applicable Not GLP, published Doc. No.: 392-115	No	N.R.
*A5.3/80	Bhattacharjee, S. Farr, R.	1997	A LOW RESIDUAL TOXICITY MICROBIOLOGICAL CONTROL PROGRAM Tappi Journal, 1997, 80, 12, 43-46, CODEN: TAJODT. ISSN: 0734-1415. Report No.: Not applicable Not GLP, published Doc. No.: 392-113	No	N.R.
A5.3/81	Jäkärä, J. et al.	2000	THE EFFECT OF PERACETIC ACID IN FINE PAPER PRODUCTION Appita Annual Conference Proceedings, 2000, 54, 1, 169-174 CODEN: AACPFS; ISSN: 1443-5454 Report No.: Not applicable Not GLP, published Doc. No.: 392-112	No	N.R.
*A5.3/82	Anonymous	2006	KILLING TEST - SC PAPER MACHINE Not applicable Report No.: Not applicable Not GLP, unpublished Doc. No.: 336-1202	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	N.R.
*A5.3/83	Anonymous	2005	KILLING TEST - NEWSPAPER MACHINE Not applicable Report No.: Not applicable Not GLP, unpublished Doc. No.: 336-1201	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
*A5.3/84	Anonymous	2006	KILLING TEST - SACK PAPER AND KRAFTLINER MACHINE Not applicable Report No.: Not applicable Not GLP, unpublished Doc. No.: 336-1203	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	N.R.
A 6.1.1/01	[REDACTED]	1998	PERACETIC ACID 5 % - ACUTE ORAL TOXICITY STUDY IN RATS Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 521-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.1/02	[REDACTED]	1985	ACUTE ORAL TOXICITY TO RATS OF 5% PEROXYACETIC ACID Source: [REDACTED] Report No.: [REDACTED] Not GLP; (unpublished) Doc. No.: 521-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.1/03	[REDACTED]	1982	BERICHT - ÜBER DIE TOXIKOLOGISCHE PRÜFUNG VON PERESSIGSÄURE 15% NACH EINMALIGER ORALER GABE AN DER RATTE Source: [REDACTED] Report No.: [REDACTED] Not GLP; (unpublished)	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.1/04	[REDACTED]	1995	ACUTE ORAL TOXICITY IN RATS - MEDIAN LETHAL DOSAGE DETERMINATION OF: [REDACTED] Source: [REDACTED] Report No.: [REDACTED] [REDACTED] GLP; (unpublished) Doc. No.: 526-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.2/01	[REDACTED]	1996	[REDACTED] - ACUTE DERMAL TOXICITY STUDY IN RABBITS Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 527-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.2/02	[REDACTED]	1996	[REDACTED] - ACUTE DERMAL TOXICITY STUDY IN RABBITS Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 527-007	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.1.3/01	[REDACTED]	1994	ACUTE INHALATION TOXICITY STUDY WITH [REDACTED] IN MALE AND FEMALE RATS Source: [REDACTED] Report No. [REDACTED] GLP; (unpublished) Doc. No.: 528-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.3/02	[REDACTED]	1985	INHALATION APPROXIMATE LETHAL CONCENTRATION (ALC) OF PEROXYACETIC ACID Source: [REDACTED] Report No. [REDACTED] GLP; (unpublished) Doc. No.: 523-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.3/03	Gagnaire, F. Marignac, B. Hecht, G. Hery, M.	2002	SENSORY IRRITATION OF ACETIC ACID, HYDROGEN PEROXIDE, PEROXYACETIC ACID AND THEIR MIXTURE IN MICE Source: © British Occupational Hygiene Society, Ann. Eurcup. Hyg., Vol. 46, No. 1, pp. 97-102, 2002 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-048	No	N.R.
A 6.1.4/01	[REDACTED]	1987	PRIMARY IRRITATION STUDY OF [REDACTED] TO THE SKIN OF THE MALE RABBIT Source: [REDACTED] Report No. [REDACTED] GLP; (unpublished) Doc. No.: 565-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.4/02	[REDACTED]	1988	PEROXYACETIC ACID 5% - ACUTE TOXICITY - TESTING THE PRIMARY IRRITANCY AFTER SINGLE APPLICATION TO THE SKIN OF THE RABBIT (PATCH TEST) Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 565-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.1.4/03	[REDACTED]	1982	BERICHT ÜBER DIE PRÜFUNG DER LOKALEN REIZWIRKUNG VON PERESSIGSÄURE 15% NACH EINMALIGER APPLIKATION AN DER HAUT DES KANINCHENS (PATCH- TEST) Source: [REDACTED] Report No.: [REDACTED] Not GLP; (unpublished) Doc. No.: 565-011	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.4/04	[REDACTED]	1991	PERACETIC ACID 0.15% USE DILUTION - PRIMARY EYE IRRITATION STUDY IN RABBITS Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 566-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.4/05	[REDACTED]	1983	PRIMARY EYE IRRITATION STUDY OF DILUTE PERACETIC ACID IN RABBITS Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 566-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.5/01	[REDACTED]	2000	UNTERSUCHUNGEN ZUR SENSIBILISIERUNG DER HAUT DURCH [REDACTED] IM MEERSCHWEINCHEN- MAXIMIERUNGSTEST Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 567-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.2/01	[REDACTED]	1994	PHARMACOKINETIC STUDIES ON PEROXYACETIC ACID AS A COMPONENT OF [REDACTED] IN THE RAT Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 511-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.2/02	[REDACTED]	2005	DEGRADATION OF PERACETIC ACID IN DILUTED RAT BLOOD (HPLC METHOD) Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 593-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.2/03	[REDACTED]	2003	DEGRADATION OF PERACETIC ACID AND HYDROGEN PEROXIDE IN RAT BLOOD Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 514-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.2/04	Krüger, S. Jancke, S.	1976	ZUR PROBLEMATIK DER TIERVERTRÄGLICHKEIT VON PERESSIGSÄURE - 2. MITT.: QUALITÄTS- UND RÜCKSTANDSUNTERSUCHUNGEN AN FLEISCH NACH APPLIKATIONEN VON PERESSIGSÄUREHALTIGEN LÖSUNGEN AUF DIE HAUT VON SCHWEINEN Source: Monatsheft, Veter., Med., 31(2), pp. 65-68 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-006	No	N.R.
A 6.2/05	Anonymous	2001	ECETOC - PERACETIC ACID (CAS NO. 79-21-0) AND ITS EQUILIBRIUM SOLUTIONS Source: European Centre for Ecotoxicology and Toxicology of Chemicals,(2001) , pp. 152, ISSN: 0733-6339-40 Report No.: 40 Not GLP; (published) Doc. No.: 092-003	No	N.R.
A 6.3.1/01	Juhr, N.-C. Klomburg, S. Haas, A.	1978	TRÄNKWASSERSTERILISATION MIT PERESSIGSÄURE Source: Z. Versuchstierk., Bd. 20, pp. 63-72 (1978) Report No.: Not applicable Not GLP; (published) Doc. No.: 392-006	No	N.R.
A 6.3.1/02	[REDACTED]	2004	PALATABILITY STUDY OF PERACETIC ACID BY REPEATED ORAL ADMINISTRATION VIA THE DRINKING WATER TO CD RATS Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 568-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.3.1/03	Veger, J. Svihovcová, P. Benesová, O. Nejedlý, K.	1977	TOXICITE SUB-CHRONIQUE DU PERSTERIL PAR VOIE BUCCALE DU PERSTERIL Source: Journal "Ceskoslovenská Hygenia", N°22, 1977, C 2 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-011	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.3.2/01	Kramer, A. et al.	1982	SUBAKUTE UND SUBCHRONISCHE PERCUTANE VERTRÄGLICHKEITSPRÜFUNG IM 28- UND 90-TAGE-TEST VON DESINFEKTIONSMITTELN BEI EPICUTANER APPLIKATION, DARGESTELLT AM BEISPIEL VON PEROXYETHANSÄURE Source: Pharmazie 37, H. 1,1982 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-019	No	N.R.
A 6.3.3/01	Heinze, W. Werner, E. Fischer, A.R.	1981	WIRKUNG UND WIRKUNGSWEISE VON PERESSIGSÄURE-AEROSOLEN AUF DEN TIERISCHEN ORGANISMUS Source: Mh. Vet.-Med. 36, 1981, pp. 343-349 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-016	No	N.R.
A 6.3.3/02	Heinze, W. Hahn, T. Wrensch, G. Fischer, A.R.	1982	WIRKUNGSWEISE UND GRENZEN DER SCHADWIRKUNG VON PERESSIGSÄURE- (PES-), MILCHSÄURE- UND ESSIGSÄURE-AEROSOLEN SOWIE DEN PERESSIGSÄURE- UND SCHWEFELDIOXID-GASEN BEI SÄUGETIEREN Source: Wissenschaftliche Zeitschrift der Humboldt-Universität zu Berlin, Math.-Nat. 1982, pp. 549-555 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-020	No	N.R.
A 6.3.3/03	Heinze, W. Werner, E. Krüger, S. Wilsdorf, G.	1979	ZUR TIERVERTRÄGLICHKEIT VON PERESSIGSÄURE-AEROSOLEN UNTER BESONDERER BERÜCKSICHTIGUNG DER BEEINTRÄCHTIGUNG DER ABWEHRLEISTUNG Source: Mh. Vet.-Med., Volume 34, 1979, pp. 212-217 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-012	No	N.R.
A 6.4.1/01	██████████	2003	13-WEEK TOXICITY STUDY BY ORAL ROUTE (GAVAGE) IN RATS Source: ██████████ Report No.: ██████████ GLP; (unpublished) Doc. No.: 533-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.4.2/01	Kramer, A. et al.	1982	SUBAKUTE UND SUBCHRONISCHE PERCUTANE VERTRÄGLICHKEITSPRÜFUNG IM 28- UND 90-TAGE-TEST VON DESINFEKTIONSMITTELN BEI EPICUTANER APPLIKATION, DARGESTELLT AM BEISPIEL VON PEROXYETHANSÄURE Source: Pharmazie 37, H. 1,1982 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-019	No	N.R.
A 6.4.3/01	Heinze, W. Natterman, H.	1984	PERESSIGSÄURE-AEROSOL-WIRKUNG BEI LANGZEITANWENDUNG NIEDRIGER KEIMWIRKSAMER KONZENTRATION AUF VERSUCHSTIERE Source: Wissenschaftliche Zeitschrift der Humboldt-Universität zu Berlin, Math.-Nat. R. XXXIII, 1984 Report No.: 6075 Not GLP; (published) Doc. No.: 592-057	No	N.R.
A 6.5/01	Müller, P. Raabe, G. Hörold, J. Juretzek, U.	1988	ACTION OF CHRONIC PERACETIC ACID (WOFASTERIL) ADMINISTRATION ON THE RABBIT ORAL MUCOSA, VAGINAL MUCOSA, AND SKIN Source: Epx. Pathol. 1988, Volume 34, pp. 223-228 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-028	No	N.R.
A 6.6.1/01	Wallat	1984	██████████ - PRÜFUNG AUF MUTAGENITÄT IM AMES-TEST Source: Henkel KGaA Report No.: 840154 Not GLP; (unpublished) Doc. No.: 557-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.1/02	Zeiger, E. Anderson, B. Hawort, S. Lawlor, T. Mortelmans, K.	1988	SALMONELLA MUTAGENICITY TESTS: IV. RESULTS FROM THE TESTING OF 300 CHEMICALS Source: Environmental and Molecular Mutagenesis Volume 11, Supplement 12, pp. 1-158, 1988 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-029	No	N.R.
A 6.6.2/01	Phillips, B.J.	1994	THE EFFECTS OF ██████████ ON THE CHROMOSOMES OF CULTURED HUMAN LYMPHOCYTES Source: BIBRA Toxicology International Report No.: 1295/1/3/94 1295/1 GLP; (unpublished) Doc. No.: 557-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.6.2/02	██████████	2002	CHROMOSOME ABERRATION TEST IN CHINESE HAMSTER V79 CELLS IN VITRO WITH ██████████ Source: ██████████ Report No.: ██████████ GLP; (unpublished) Doc. No.: 557-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.3/01	██████████	2002	GENE MUTATION TEST IN CHINESE HAMSTER V79 CELLS IN VITRO WITH ██████████ (HPRT-TEST) Source: ██████████ Report No.: ██████████ GLP; (unpublished) Doc. No.: 557-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.3/02	Coppinger, W.J. Wong, T.K. Thompson, E.D.	1983	UNSCHEDULED DNA SYNTHESIS AND DNA REPAIR STUDIES OF PEROXYACETIC AND MONOPEROXYDECANOIC ACIDS Source: Environmental Mutagenesis 5: pp. 177-192,1983 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-023	No	N.R.
A 6.6.3/03	Buschini, A. Carboni, P. Furlini, M. Poli, P. Rossi, C.	2004	SODIUM HYPOCHLORITE-, CHLORINE DIOXIDE- AND PERACETIC ACID-INDUCED GENOTOXICITY DETECTED BY THE COMET ASSAY AND SACCHAROMYCES CEREVISIAE D7 TESTS Source: Mutagenesis, Vol. 19, No. 2, pp. 157-162 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-053	No	N.R.
A 6.6.4/01	██████████	1984	██████████ - PRÜFUNG AUF MUTAGENITÄT IM MIKROKERN-TEST IN VIVO Source: ██████████ Report No.: ██████████ Not GLP; (unpublished) Doc. No.: 557-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.4/02	██████████	1994	A MICRONUCLEUS TEST WITH ██████████ Source: ██████████ Report No.: ██████████ ██████████ GLP; (unpublished) Doc. No.: 557-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.4/03	██████████	2001	Maus-Mikrokerntest mit ██████████ nach oraler Applikation Source: ██████████ ██████████ Report No.: ██████████ Doc. No.: 557-013 (unpublished)	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.6.4/04	[REDACTED]	2003	Bone Marrow Micronucleus Test by Oral Route in Mice Source: [REDACTED] Report No.: [REDACTED] Doc. No.: 557-009 (unpublished)	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.5/01	[REDACTED]	2002	MEASUREMENT OF UNSCHEDULED DNA SYNTHESIS (UDS) IN RAT HEPATOCYTES USING AN IN VIVO PROCEDURE WITH ACIDE PERACETIQUE 5 % Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 557-007	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.5/02	[REDACTED]	1994	AN IN VIVO UNSCHEDULED DNA SYNTHESIS ASSAY WITH [REDACTED] Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 557-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.7/01a	Monarca, S. et al.	2001	MUTAGENICITY AND DISINFECTION BY-PRODUCTS IN SURFACE DRINKING WATER DISINFECTED WITH PERACETIC ACID Source: Environmental Toxicology and Chemistry, Vol. 21, No. 2, pp. 309-318, 2002 Report No.: Not applicable Not GLP; (published) Doc. No.: 792-018	No	N.R.
A 6.6.7/01b	Crebelli, R. et al.	2003	EFFETTI GENOTOSSICI ED ECOTOSSICOLOGICI DI ACQUE REFLUE URBANE SOTTOPOSTE A DISINFEZIONE CON IPOCLORITO DI SODIO O ACIDO PERACETICO Source: Ann IG 2003, 15, 277-302 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-097	No	N.R.
A 6.6.7/01c	Monarca, S. Zani, C. Richardson, S.D. Thruston, A.D. Moretti, M. Feretti, D.	2004	A NEW APPROACH TO EVALUATION THE TOXICTY AND GENOTOXICITY OF DISINFECTED DRINKING WATER Source: Water Research 38, 2004, pp. 3809 - 3819 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-052	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.6.7/01d	Guzzella, L. et al.	2004	IN VITRO POTENTIAL GENOTOXIC EFFECTS OF SURFACE DRINKING WATER TREATED WITH CHLORINE AND ALTERNATIVE DISINFECTANTS Source: Mutation Research 564, 2004, 179-193 Report No.: not applicable Not GLP; (published) Doc. No.: 592-099	No	N.R.
A 6.6.7/01e	Marabini, L. et al.	2006	TOXICITY EVALUATION OF SURFACE WATER TREATED WITH DIFFERENT DISINFECTANTS IN HEPG2 CELLS Source: Water Research, 40, 2006, pp.267-272 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-111	No	N.R.
A 6.6.7/01f	Crebelli, R. et al.	2005	GENOTOXICITY OF THE DISINFECTION BY-PRODUCTS RESULTING FROM PERACETIC ACID-OR HYPOCHLORITE-DISINFECTED SEWAGE WASTEWATER Source: Water Research 39, 2005, pp. 1105-1113 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-055	No	N.R.
A 6.6.7/01g	Maffei, F. et al.	2005	USE OF THE COMET TEST AND MICRONUCLEUS ASSAY ON HUMAN WHITE BLOOD CELLS FOR IN VITRO ASSESSMENT OF GENOTOXICITY INDUCED BY DIFFERENT DRINKING WATER DISINFECTION PROTOCOLS Source: Environmental and Molecular Mutagenesis 2005, 46, 116-125 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-100	No	N.R.
A 6.6.7/01h	Feretti, D. et al.	2003	VALUTAZIONE DELLA GENOTOSSICITÀ DI IPOCLORITO DI SODIO, BIOSSIDO DI CLORO E ACIDO PERACETICO MEDIANTE VEGETALI Source: Ann Ig 2003, 15, 959-963 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-098	No	N.R.
A 6.6.7/01i	Anonymous	2003	VALUTAZIONE DELLA GENOTOSSICITÀ DI ACQUE SUPERFICIALI TRATTATE CON DIVERSI DISINFETTANTI MEDIANTE TEST SU VEGETALI Source: Ann IG 2003, 15, 953-957 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-096	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.6.7/01j	Monarca, S. et al.	2003	GENOTOXICITY OF SURFACE WATER TREATED WITH DIFFERENT DISINFECTANTS USING IN SITU PLANT TESTS Source: Environmental and Molecular Mutagenesis, 2003, 41, 353-359 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-093	No	N.R.
A 6.6.7/01k	Monarca, S. et al.	2005	GENOTOXICITY OF DRINKING WATER DISINFECTANTS IN PLANT BIOASSAYS Source: Environmental and Molecular Mutagenesis, 2005, 46, 96-103 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-092	No	N.R.
A 6.6.7/01l	Bolognesi, C. et al.	2004	COMET AND MICRONUCLEUS ASSAYS IN ZEBRA MUSSEL CELLS FOR GENOTOXICITY ASSESSMENT OF SURFACE DRINKING WATER TREATED WITH THREE DIFFERENT DISINFECTANTS Source: Science of the Total Environment 333, 2004, pp. 127-136 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-054	No	N.R.
A 6.6.7/01m	Buschini, A. et al.	2004	COMET ASSAY AND MICRONUCLEUS TEST IN CIRCULATING ERYTHROCYTES OF CYPRINUS CARPIO SPECIMENS EXPOSED IN SITU TO LAKE WATERS TREATED WITH DISINFECTANTS FOR POTABILIZATION Source: Mutation Research 2004, 119-129 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-095	No	N.R.
A 6.6.7/01n	Gustavino, B. et al.	2005	MODULATING EFFECTS OF HUMIC ACIDS ON GENOTOXICITY INDUCED BY WATER DISINFECTANTS IN CYPRINUS CARPIO Source: Mutation Research 2007, 587, 103-113 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-101	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.6.7/01o	Ferraris, M. et al.	2005	STUDY OF POTENTIAL TOXIC EFFECTS ON RAINBOW TROUT HEPATOCYTES OF SURFACE WATER TREATED WITH CHLORINE OR ALTERNATIVE DISINFECTANTS Source: Chemosphere, 2005, 60, 65-73 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-105	No	N.R.
A 6.6.7/01p	Monarca, S.	2002	STUDIES ON MUTAGENICITY AND DISINFECTION BY-PRODUCTS IN RIVER DRINKING WATER DISINFECTED WITH PERACETIC ACID OR SODIUM HYPOCHLORITE Source: Water Science and Technology: Water Supply. Vol. 2, No. 3, pp. 199-204 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-050	No	N.R.
A 6.6.7/01q	Sapone, A. et.al.	2007	PERTURBATION OF CYTOCHROME P450, GENERATION OF OXIDATIVE STRESS AND INDUCTION OF DNA DAMAGE IN CYPRINUS CARPIO EXPOSED IN SITU TO POTABLE SURFACE WATER Source: Mutation Research, 2007, 626, 143-154 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-112	No	N.R.
A 6.6.7/01r	Kitis, M.	2004	DISINFECTION OF WASTEWATER WITH PERACETIC ACID: A REVIEW Source: Environment International, 2004, 30, 47-55 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-093	No	N.R.
A 6.7/01	Bock, F.G. Myers, H.K. Fox, H.W.	1975	COCARCINOGENIC ACTIVITY OF PEROXY COMPOUNDS Source: Journal of the National Cancer Institute, Vol. 55, No. 6, December 1975, pp. 1359-1361 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-007	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.8.1/01	[REDACTED]	2005	PRENATAL DEVELOPMENT TOXICITY STUDY WITH [REDACTED] IN THE RAT USING ORAL (DRINKING WATER) ADMINISTRATION Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 551-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
6.8.1/01	[REDACTED]	2007	PRENATAL DEVELOPMENT TOXICITY STUDY WITH [REDACTED] IN THE RAT USING ORAL (DRINKING WATER) ADMINISTRATION ([REDACTED]) - Peer Review and Re-Evaluation of Discoloration in Fetal Liver Preparations; Source: [REDACTED] Report No. [REDACTED] Not GLP (unpublished) Doc. No. 581-010	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
6.8.1/03	[REDACTED]	2010	PRENATAL DEVELOPMENT TOXICITY STUDY WITH [REDACTED] IN THE RAT USING ORAL (DRINKING WATER) ADMINISTRATION ([REDACTED]) - 2 nd Peer Review and Re-Evaluation of Discoloration in Fetal Liver Preparations; Source: [REDACTED] Report No. [REDACTED] GLP (unpublished) Doc. No. 581-014	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.11/01	[REDACTED]	1983	PRÜFUNG DER AKUTEN INTRAVENÖSEN TOXIZITÄT VON [REDACTED] IM VERGLEICH ZU FORMALIN Source: [REDACTED] Report No.: [REDACTED] Not GLP; (unpublished) Doc. No.: 524-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.12.2/01	Kramer, A. Weuffen, W. Adrian, V.	1987	TOXISCHE RISIKEN BEI DER ANWENDUNG VON DESINFEKTIONSMITTELN AUF DER HAUT Source: Hyg. + Med. 12,1987,pp. 134-142 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-027	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.12.2/02	Mücke, H. Sprössig, M.	1969	DIE EIGENSCHAFTEN DER PERESSIGSÄURE Source: Wissenschaftliche Zeitschrift der Humboldt-Universität zu Berlin, Math.-Nat. R XVIII, 1969, Vol. 6, pp. 1167-1170 Report No.: Not applicable Not GLP; (published) Doc. No.: 192-002	No	N.R.
A 6.12.2/03	Kretzschmar, C. Agerth, R. Bauch, R. Friedrich, D.	1971	PERESSIGSÄURE - NUR EIN DESINFEKTIONSMITTEL? Source: Monatsheft, Veterinär Medizin, 27, pp. 324-332 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-003	No	N.R.
A 6.12.2/04	Schröder, W.	1982	PERESSIGSÄURE (PES) ALS DESINFEKTIONSWIRKSTOFF FÜR DIE LEBENSMITTELINDUSTRIE Source: Confrocia, Bd. 26 (9182) Nr. 5, pp. 139-147 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-009	No	N.R.
A 6.12.2/05	French, M.S.	1993	SOLVAY INTERNAL MEMO - IRRITANCY TESTING OF PERACETIC ACID TO SKIN Source: SOLVAY PHARMACEUTICALS, NL Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 572-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.12.3/01	Pazdiora, A. Kubicek, V.	1967	RAPID PRE-OPERATIVE PREPARATION OF THE HAND WITH PERSTERIL Source: Vojenské Zdravotnické Listy, 1967, 36, (3), pp. 116-117 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-002	No	N.R.
A 6.12.6/01	Cristofari- Marquand, E. et al.	2007	ASTHMA CAUSED BY PERACETIC ACID-HYDROGEN PEROXIDE MIXTURE Source: J. Occup. Health 2007, 49, 155-158 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-094	No	N.R.
A 7.1.1.1.1/0 1a	Gamet, J.- C. et al.	2000	REPORT ABOUT ABIOTIC DEGRADATION OF PERACETIC ACID: HYDROLYSIS VERSUS ph Source: Bioxal Report No.: 04/00 MPP/DB Not GLP; (unpublished) Doc. No.: 711-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 7.1.1.1.1/0 1b	Klein, C. Goossens, S.	2007	RECALCULATION OF DT50 AND DT70 FOR THE ABIOTIC DEGRADATION OF PERACETIC ACID ON THE BASIS OF RESULTS GAMET, J. C. ET AL. (2000), DOC.-NO. 711-005 Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 834-008 Not GLP; (unpublished) Doc. No.: 781-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.1.1.1.1/0 2a	Yuan, Z. Ni, Y. van Heiningen, A.R.P.	1997	KINETICS OF PERACETIC ACID DECOMPOSITION - PART I: SPONTANEOUS DECOMPOSITION AT TYPICAL PULP BLEACHING CONDITIONS Source: The Canadian Journal of Chemical Engineering, Volume 75, February 1997, pp. 37-41 Report No.: Not applicable Not GLP; (published) Doc. No.: 792-012	No	N.R.
A 7.1.1.1.1/0 b	Yuan, Z. Ni, Y. van Heiningen, A.R.P.	1997	KINETICS OF THE PERACETIC ACID DECOMPOSITION PART II: pH EFFECT AND ALKALINE HYDROLYSIS Source: The Canadian Journal of Chemical Engineering, Volume 75, February 1997, pp. 42-47 Report No.: Not applicable Not GLP; (published) Doc. No.: 792-013	No	N.R.
A 7.1.1.2.1/0 1a	Richterich Gode	1986	ABBAUPRÜFUNG TOXISCHER STOFFE: VERMEIDUNG STÖRENDER TOXISCHER SELBSTHEMMUNG DURCH GESTUFTE PRÜFMUSTERZUGABE Source: Not applicable Report No.: 1986/2418 Not GLP; (unpublished) Doc. No.: 713-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	N.R.
A 7.1.1.2.1/0 1b	Steber, J. Berger, H.	2002	AEROBIC BIODEGRADATION: MODIFIED OECD SCREENING TEST Source: Henkel KGaA Report No.: 5947 458 Not GLP; (unpublished) Doc. No.: 713-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.1.1.2.1/0 2	L'Haridon, J.	2003	DETERMINATION OF READY BIODEGRADABILITY CLOSED BOTTLE TEST Source: Centre International de Toxicologie, France Report No.: 23246 ECS GLP; (unpublished) Doc. No.: 713-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 7.1.1.2.3/01	Kuhn, F.	2000	DECOMPOSITION OF PERACETIC ACID IN SYNTHETIC SEAWATER Source: Degussa AG, Hanau, Germany Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 711-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.1.2.1.1/01	van Egdorn, T.R.	2007	EVALUATION OF THE DEGRADATION OF PERACETIC ACID AND HYDROGEN PEROXIDE IN EFFLUENT FROM A WASTE WATER TREATMENT PLANT SOLVAY PHARMACEUTICALS, NL Report No.: E.SOL.S.025 GLP, unpublished Doc. No.: 714-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.2.1/01	Howarth, J.	2003	THE ENVIRONMENTAL FATE AND IMPACT OF [REDACTED] AND [REDACTED] (EQUILIBRIUM MIXTURES OF PEROXYACETIC ACID AND HYDROGEN PEROXIDE) IN SOIL Source: Not indicated Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 721-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.3.1/01	Görg, J. Glöckner, T.	2007	ESTIMATION OF THE ATMOSPHERIC RESIDENCE TIME OF PERACETIC ACID USING THE ATKINSON METHOD Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 743-001 Atkinson 834-008 Not GLP; (unpublished) Doc. No.: 743-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.4.1.1/01	[REDACTED]	2003	ACUTE TOXICITY IN THE RAINBOW TROUT UNDER SEMI-STATIC CONDITIONS Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 821-010	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.4.1.1/02	[REDACTED]	1996	STATIC RENEWAL ACUTE TOXICITY OF 5% PERACETIC ACID ([REDACTED]) TO BLUEGILL (LEPOMIS MACROCHIRUS) Source: [REDACTED] Report No.: [REDACTED] GLP; (unpublished) Doc. No.: 821-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A7.4.1.1/03	[REDACTED]	1987	THE ACUTE TOXICITY OF [REDACTED] TO PLAICE PLEURONECTES PLATESSA UNDER SEMI-STATIC CONDITIONS [REDACTED] Report No.: [REDACTED] Not GLP, unpublished Doc. No.: 821-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.4.1.1/04/05	[REDACTED]	2005	PACIFIC HERRING TOXICITY TESTING USING [REDACTED] [REDACTED] Report No. :not assigned Not GLP; unpublished	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Evonik Industries AG
A7.4.1.1/06 A7.4.1.2/05 /06	[REDACTED]	2005	TOXICOLOGICAL EVALUATIONS OF PERACETIC ACID (15%) [REDACTED] Report No. :not assigned Not GLP; unpublished	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Evonik Industries AG
A7.4.1.2/01	Gardner, C. Bucksath, J.D.	1996	STATIC ACUTE TOXICITY OF 5% PERACETIC ACID ([REDACTED]) TO DAPHNIA MAGNA Source: ABC Laboratories, USA Report No.: I95-2021 42349 GLP; (unpublished) Doc. No.: 822-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.4.1.2/02	Fairhurst, F.	1987	DETERMINATION OF THE 48 HOUR MEDIAN EFFECT CONCENTRATION (EC50) OF [REDACTED] TO THE COMMON MUSSEL, MYTILUS EDULIS, IN TERMS OF LARVAL SURVIVAL AND DEVELOPMENT WRc plc, Buckinghamshire, United Kingdom Report No.: CO 1644-M/EV 8687 Not GLP, unpublished Doc. No.: 824-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.4.1.2/03	Butler, R.	1987	DETERMINATION OF THE 48 HOUR MEDIAN EFFECT CONCENTRATION (EC50) OF [REDACTED] TO THE PACIFIC OYSTER, CRASSOSTREA GIGAS IN TERMS OF LARVAL SURVIVAL AND DEVELOPMENT WRc plc, Buckinghamshire, United Kingdom Report No.: CO 1643-M/EV 8687 Not GLP, unpublished Doc. No.: 825-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A7.4.1.2/04	Tinsley, D. Sims, I.	1987	THE ACUTE TOXICITY OF ██████████ TO BROWN SHRIMP CRANGON UNDER SEMI-STATIC CONDITIONS WRc plc, Buckinghamshire, United Kingdom Report No.: CO 1649-M/EV 8687 Not GLP, unpublished Doc. No.: 825-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.4.1.3/01	Hicks, S.L.	1996	ACUTE TOXICITY OF 5% PERACETIC ACID (██████████) TO SELENASTRUM CAPRICORNUTUM PRINTZ Source: ABC Laboratories, USA Report No.: 42866 I95-2027 GLP; (unpublished) Doc. No.: 823-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.4.1.3/02/03	Anonymous	2005	ALGAL TOXICITY TESTING USING ██████████ Nautilus Environmental LLC, Tacoma, WA, USA Report No. :not assigned Not GLP; unpublished	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Evonik Industries AG
A7.4.1.4/01	Hanstveit, A.O. Schoonmade, J.A. van Asten, J.G.	1999	SCREENING OF THE EFFECT OF ██████████ ON THE RESPIRATION RATE OF ACTIVATED SLUDGE Source: TNO, Department of Environmental Toxicology, Delft, Netherlands Report No.: IMW-98-0044-02 40862.01.01 GLP; (unpublished) Doc. No.: 842-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.4.1.4/02	de Groot, W.A.	2001	ACTIVATED SLUDGE, RESPIRATION INHIBITION TEST WITH PERACETIC ACID Source: SOLVAY PHARMACEUTICALS, NL Report No.: A.SOL.S.024 8320/38/01 GLP; (unpublished) Doc. No.: 842-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.4.3.2/01	Scheerbau m, D.	2007	PERACETIC ACID 15 % - EARLY-LIFE STAGE TOXICITY TEST WITH ZEBRAFISH (DANIO RERIO) UNDER FLOW-THROUGH CONDITIONS (INCLUDING EXPERT STATEMENT) Noack-Laboratorium für angewandte Biologie, Sarstedt Report No.: 051111 DM FSZ109021 2005-0338-DGO GLP, unpublished Doc. No.: 826-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 7.4.3.4/01	Wetton, P. M. Mullee, D.M.	2000	██████████ PAA: DAPHNIA MAGNA REPRODUCTION TEST Source: Safepharm Laboratories Limited, Derby Report No.: 663/007 GLP; (unpublished) Doc. No.: 827-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.5.1.1/0 1	Scheerbau m, D.	2008	PERACETIC ACID 15 % - SOIL MICROORGANISMS - CARBON TRANSFORMATION TEST Dr. Noack Laboratorium für angewandte Biologie, Hildesheim, Germany Report No.: 070425PB TBC117061 TBC11706- GLP, unpublished Doc. No.: 841-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.5.1.1/0 2	Scheerbau m, D.	2008	PERACETIC ACID 15 % - SOIL MICRO- ORGANISMS - NITROGEN TRANSFORMATION TEST Dr. Noack Laboratorium für angewandte Biologie, Hildesheim, Germany Report No.: 070425PB TBN117061 TBN11706- GLP, unpublished Doc. No.: 841-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.5.1.2/0 1	Winkelman n, G.	2007	PERACETIC ACID 15 % - EARTHWORM (EISENIA FETIDA), ACUTE TOXICITY TEST IN ARTIFICIAL SOIL - LIMIT-TEST Noack-Laboratorium für angewandte Biologie, Sarstedt Report No.: 070425PB RRA114062 GLP, unpublished Doc. No.: 833-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.5.1.3/0 1	Fiebig, S.	2007	PERACETIC ACID 15 % - TERRESTRIAL PLANT TEST, SEEDLING EMERGENCE AND GROWTH TEST Noack-Laboratorium für angewandte Biologie, Sarstedt Report No.: 070425PB TNC117061 GLP, unpublished Doc. No.: 851-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Reference list Doc IIIB by Section Points:

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
B3.2/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE EXPLOSION PROPERTIES OF PEROXYACETIC ACID 5 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.6 GLP; (unpublished) Doc. No.: 241-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.2/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE EXPLOSION PROPERTIES OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.14 GLP; (unpublished) Doc. No.: 241-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.3/01	Nims, R.W.	1996	CORROSITEX CONTINUOUS TIME MONITOR ASSAY - ██████████ Source: Microbiological Associated, Inc. Report No.: A95BO06.520004 I95-2035 A001267 GLP; (unpublished) Doc. No.: 246-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	FMC Corporation
B3.4/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE AUTO-IGNITION TEMPERATURE OF PEROXYACETIC ACID 5% Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.3 GLP; (unpublished) Doc. No.: 242-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.4/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE AUTO-IGNITION TEMPERATURE OF PEROXYACETIC ACID 15% Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.11 GLP; (unpublished) Doc. No.: 242-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B3.5/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE ACIDITY / ALKALINITY OF PEROXYACETIC ACID 5 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.8 0649 82473 GLP; (unpublished) Doc. No.: 215-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
B3.5/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE PH VALUE (1 % IN WATER) OF PEROXYACETIC ACID 5 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.7 GLP; (unpublished) Doc. No.: 215-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.5/03	Mekelburger, H.-B.	2007	DETERMINATION OF THE ACIDITY / ALKALINITY OF PEROXYACETIC ACID 15% Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.16 GLP; (unpublished) Doc. No.: 215-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.5/04	Mekelburger, H.-B.	2007	DETERMINATION OF THE PH VALUE (1 % IN WATER) OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.15 GLP; (unpublished) Doc. No.: 215-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B3.6/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE RELATIVE DENSITY OF PEROXYACETIC ACID 5 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.1 GLP; (unpublished) Doc. No.: 213-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.6/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE RELATIVE DENSITY OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.2 GLP; (unpublished) Doc. No.: 213-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B3.10/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE SURFACE TENSION OF AQUEOUS SOLUTIONS OF PEROXYACETIC ACID 5 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.4 GLP; (unpublished) Doc. No.: 216-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.10/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE SURFACE TENSION OF AQUEOUS SOLUTIONS OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.12 GLP; (unpublished) Doc. No.: 216-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
B3.11/01	Mekelburger, H.-B.	2007	DETERMINATION OF THE KINEMATIC VISCOSITY OF PEROXYACETIC ACID 5 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.5 GLP; (unpublished) Doc. No.: 214-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.11/02	Mekelburger, H.-B.	2007	DETERMINATION OF THE KINEMATIC VISCOSITY OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.13 GLP; (unpublished) Doc. No.: 214-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 5.10/01	Werner, H.-P. Naujox, K.	2002	██████████ - QUANTITATIVE SUSPENSION TEST FOR EVALUATION OF BACTERIAL ACTIVITY (PHASE 2/STEP 1) Source: HygCen GmbH, Schwerin, Germany Report No.: SN-2270.1 Not GLP; (unpublished) Doc. No.: 336-0201	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Solvay
B 5.10/02	Naujox, K. Werner, H.-P.	2002	██████████ - QUANTITATIVE SUSPENSION TEST FOR EVALUATION OF FUNGICIDAL ACTIVITY (PHASE 2/STEP 1) Source: HygCen GmbH, Schwerin, Germany Report No.: SN-2270.1 Not GLP; (unpublished) Doc. No.: 336-0202	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Solvay
B 5.10/03	Anonymous	2005	THE EVALUATION OF DISINFECTANT PRODUCTS BY SUSPENSION TESTING AND SURFACE TESTING Source: MGS Laboratories Limited Report No.: 063 Not GLP; (unpublished) Doc. No.: 336-0303	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Solvay
B 5.10/04	Debevere, J.	2005	REPORTS - EVALUATION OF THE BACTERICIDAL ACTIVITY OF ██████████ Source: State University of Gent, Belgium Report No.: 05-P180-1 Not GLP; (unpublished) Doc. No.: 336-0101	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Christeyns

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
B 5.10/05	Debevere, J.	2006	REPORT - EVALUATION OF THE BACTERICIDAL ACTIVITY OF ██████████ Source: State University of Gent, Belgium Report No.: 06-P253-1 Not GLP; (unpublished) Doc. No.: 336-0105	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Christeyns
B 5.10/06	Debevere, J.	2006	REPORT - EVALUATION OF THE FUNGICIDAL ACTIVITY OF ██████████ Source: State University of Gent, Belgium Report No.: 06-P253-1 Not GLP; (unpublished) Doc. No.: 336-0104	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Christeyns
B 5.10/07	Debevere, J.	2005	REPORTS - EVALUATION OF THE SPORICIDAL ACTIVITY OF ██████████ Source: State University of Gent, Belgium Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0401	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Christeyns
B 5.10/08	Kaleta, E.F.	2003	GUTACHTEN ÜBER DIE VIRUZIDE WIRKSAMKEIT DES CHEMISCHEN DESINFEKTIONSMITTELS - ██████████ Source: Justus Liebig University Giessen Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0305	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Bactria/Stockm eier
B 5.10/09	Martin, J.M.R.	2004	DETERMINATION DE LA ACTIVIDAD BACTERICIDA FRENTE A LEGIONELLA PNEUMOPHILA - ██████████ 5% Source: Laboratorio de Diagnostico General, Barcelona Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0501	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	FMC Corporation
B 5.10/10	Martin, J.M.R.	2004	DETERMINACION DE LA ACITIVIDAD BACTERICIDA FRENTE A LEGIONELLA PNEUMOPHILA - ██████████ 15% Source: Laboratorio de Diagnostico General, Barcelona Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0502	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	FMC Corporation

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
Not indicated *B 5.10/11	Salzburger, W.	1996	MICROBIAALLY INFLUENCED CORROSION OF MATERIALS - SCIENTIFIC AND ENGINEERING ASPECTS: 30 PAPER AND ADDITIVES Springer-Verlag Berlin Heidelberg 1996, 415-427 Report No.: Not applicable Not GLP, published Doc. No.: 392-135	No	N.R.
*Not indicated *B 5.10/12	Kolari, M.	2003	ATTACHMENT MECHANISMS AND PROPERTIES OF BACTERIAL BIOFILMS ON NON-LIVING SURFACES Electronic publication available at http://ethesis.helsinki.fi ISBN 952-10-0345-6 (pdf) Report No.: Not applicable Not GLP, published Doc. No.: 392-134	No	N.R.
*B 5.10/13 ok	Brill, H. et al.	2010	MIKROBIZIDE WIRKUNG VON 15% PERESSIGSÄURE BEI EINSATZ IN KÜHLWASSERSYSTEMEN (ASTM E645-07) Dr. Brill + Partner GmbH, Labor für Hygiene und Mikrobiologie, Hamburg, Germany Report No.: L 09/115.1 Not GLP, unpublished Doc. No.: 336-1101	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
*B 5.10/14 ok	Brill, H. et al.	2010	ALGIZIDE WIRKUNG VON 15% PERESSIGSÄURE BEI EINSATZ IN KÜHLWASSERSYSTEMEN (ASTM E645-07) Dr. Brill + Partner GmbH, Labor für Hygiene und Mikrobiologie, Hamburg, Germany Report No.: L 09/115.2 Not GLP, unpublished Doc. No.: 336-1102	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
*B 6.4	Maas, W.	2007	PREPARATION OF RADIOLABEL FOR STUDY 6913 TNO, Nutrition and Food Research, Zeist, The Netherlands Report No.: Not indicated Not GLP, unpublished Doc. No.: 511-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 5.10/12	Carre, A. Strohl, P.	2009	RAPPORT D'ESSAI N° 292/0709 CHRIOX SAFE – ESSAI: NF EN 1500 (SEPTEMBRE 1997) Source: Institut de Recherche Microbiologique, Mitry-Mory, France Report No.: 292/0709 Not GLP; (unpublished) Doc. No.: 336-0106	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Christeys

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
B 6.4/01	Maas, W.	2007	LETTER REPORT OF THE PILOT STUDY ON SKIN MEMBRANE DAMAGING PROPERTIES OF PAA SOLUTIONS Source: TNO, Nutrition and Food Research, Zeist, The Netherlands Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 511-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B7.1/01	Van de Velde, A.	2005	DEGRADATION STUDY OF PERACETIC ACID AND HYDROGEN PEROXIDE IN LAUNDRY APPLICATION Source: University Twente Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 752-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B7.1/02	Hölzgen, U. Wirth, K.	2005	ECOLAB INTERNAL - PERACETIC ACID DETERMINATION IN WASTE WATER Source: ECOLAB GmbH & Co. OHG, Düsseldorf, Germany Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 752-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3 AA/02	Hazardous Substance Data Bank (HSDB)	2007	HAZARDOUS SUBSTANCES DATA BANK - ACETIC ACID (HSDB) [(CASRN: 64-19-7)] Source: Hazardous Substances Database Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 581-007	No	N.R.
B 3 AA/03	Anonymous	2007	LITERATURE SEARCH - ACETIC ACID Source: NIST, National Institute of Standards and Technology Report No.: Not applicable Not GLP; (published) Doc. No.: 191-001	No	N.R.
B 3 AA/04	Anonymous	2003	EG-SICHERHEITSDATENBLATT - ESSIGSÄURE >=90% Source: Celanese Report No.: 5 / CH Not GLP; (unpublished) Doc. No.: 955-035	No	N.R.
B 3 AA/05	Glöckner, T. Görg, J.	2007	STATEMENT RELATED TO THE OXIDISING PROPERTIES OF ACETIC ACID Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 834-008 Not GLP; (unpublished) Doc. No.: 143-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Appendix IV: Tables of Risk Characterisation for Human Health

Table Appendix IV-1 Primary exposure industrial use

Exposure scenario		Local risk characterisation for dermal exposure			Local risk characterisation for inhalation exposure			PPE	Model used		
		Dermal exposure Concentration [%]	Dermal NOAEC value [%]	Comparing to dermal NOAEC	Inhalation exposure [mg/m ³] (RPE10=10% penetration)	Inhalation AEC value [mg/m ³]	Comparing to inhalation AEC				
PT 11: Preservatives for liquid-cooling and processing systems Disinfection of cooling water in open re-circulating systems and once-through cooling systems	Mixing/ Loading ¹ : manual ² : automated (daily 15 min)	PAA: 15	PAA: 0.2 (short/medium-term)	PAA: higher; skin protection needed	PAA ¹ : 2.3 0.23 (RPE10) PAA ² : 0.25	PAA: 0.5	PAA ¹ : higher (no RPE) lower (46%, RPE10) PAA ² : lower (50%)	RPE in manual mixing/loading, gloves, coverall, goggles and boots	ART-Tool for inhalation exposure ("Transfer of liquid products/falling liquids: splash loading for manual ¹ and submerged loading for automated ² scenarios")		
		HP: 25		HP: higher; skin protection needed	HP ¹ : 2.6 0.26 (RPE10) HP ² : 0.29	HP: 1.25	HP ¹ : higher (no RPE) lower (21%, RPE10) HP ² : lower (23%)				
	Post-application (daily 30 min)	PAA: 0.0005	PAA: 0.1 (long-term)	PAA: lower	PAA: 0.29	PAA: 0.5	PAA: lower (58%)			*	ART-Tool for inhalation exposure ("Spraying of liquids in a space, large scale space spraying")
		HP: 0.00083		HP: lower	HP: 0.079	HP: 1.25	HP: lower (6%)				

PT 12: Slimicides Use as slimicide in the pulp and paper industry	Mixing/ Loading ¹ : manual ² : automated (daily 15 min)	PAA: 15	PAA: 0.2 (short/medium-term)	PAA: higher; skin protection needed	PAA ¹ : 2.3 0.23 (RPE10)	PAA: 0.5	PAA ¹ : higher (no RPE) lower (46%, RPE10)	RPE in manual mixing/loading, gloves, coverall, goggles and boots	ART-Tool for inhalation exposure ("Transfer of liquid products/falling liquids: splash loading for manual ¹ and submerged loading for automated ² scenarios")
					PAA ² : 0.25		PAA ² : lower (50%)		
		HP: 25		HP: higher; skin protection needed	HP ¹ : 2.6 0.26 (RPE10)	HP: 1.25	HP ¹ : higher (no RPE) lower (21%, RPE10)		
					HP ² : 0.29		HP ² : lower (23%)		
	Application (daily 4 h)	PAA: 0.0075	PAA: 0.1 (long-term)	PAA: lower	PAA: 0.2	PAA: 0.5	PAA: lower (40%)	*	ART-Tool for inhalation exposure ("Spraying of liquids in a space, small scale space spraying")
		HP: 0.0125		HP: lower	HP: 0.054	HP: 1.25	HP: lower (4%)		
	Post-application (daily 2 h)	PAA: 0.0075	PAA: 0.1 (long-term)	PAA: lower	PAA: 0.2	PAA: 0.5	PAA: lower (40%)	*	ART-Tool for inhalation exposure ("Spraying of liquids in a space, small scale space spraying")
		HP: 0.0125		HP: lower	HP: 0.054	HP: 1.25	HP: lower (4%)		

¹: ART: falling liquids with splash loading for manual mixing/loading

²: ART: falling liquids with submerged loading for automated mixing/loading

*: if exposure to concentrated product is possible: RPE, gloves, coverall, goggles and boots

Table Appendix IV-2 Secondary exposure – short term (acute)

Exposure scenario	Exposure route	Person	In-use concentration [%]	Inhalation exposure [mg/m ³]	% AEC ²
PT 11/12: Workers - Maintenance and repair of dosing systems	dermal/ inhalation	adult	PAA: 15 HP: 25	PAA ¹ : 2.3 0.23 (RPE10*)	PAA ¹ : higher (no RPE) lower (46 %, RPE10)
				HP ¹ : 2.6 0.26 (RPE10)	HP ¹ : higher (no RPE) lower (21 %, RPE10)

¹: ART: falling liquids with splash loading for manual mixing/loading

²: inhalation AEC values for peracetic acid = 0.5 mg/m³ and for hydrogen peroxide = 1.25 mg/m³

*: RPE = respiratory protection (10 % penetration)

Table Appendix IV-3 Secondary exposure – long term (chronic)

Exposure scenario	Exposure route	Person	In-use concentration [%]	Inhalation exposure [mg/m ³]	% AEC ¹
PT11: Non-users/bystanders - Uncontrolled windage and blowdown from cooling towers	inhalation	adult/child	PAA: 0.0005 HP: 0.00083	PAA: 0.0027 HP: 0.01	PAA: 0.5 % HP: 0.8 %

¹: inhalation AEC values for peracetic acid = 0.5 mg/m³ and for hydrogen peroxide = 1.25 mg/m³