# 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 generated from tetraacetylethylenediamine and sodium percarbonate

## Product-types 2, 3 and 4

(PT 2: Disinfectants and algaecides not intended for direct application to humans or animals)

(PT 3: Veterinary hygiene) (PT 4: Food and feed area) December 2016

#### Finland

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#### 1. STATEMENT OF SUBJECT MATTER AND PURPOSE

#### **Procedure followed** 1.1.

Peracetic acid generated from TAED

and sodium percarbonate

This assessment report has been established as a result of the evaluation of the active substance peracetic acid generated from tetraacetylethylenediamine and sodium percarbonate as product-types 2, 3 and 4 (PT 2: Disinfectants and algaecides not intended for direct application to humans or animals, PT 3: Veterinary hygiene, PT 4: Food and feed area), 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 producttypes 1-6 (and 11-12) including peracetic acid in aqueous solution and formed in situ from TAED and sodium percarbonate. A redefinition of the latter has been made according to the CA-March15-Doc.5.1-Final Revised on 23 June 2015 as peracetic acid generated from tetraacetylethylenediamine and sodium percarbonate ..

Commission Regulation (EC) No 1062/2014 of 4 August 2014<sup>1</sup> 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 1-6 was 31 July 2007, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 23 July 2007, Finland competent authorities received a dossier from the applicant for Peracetic acid including a dossier for in situ generation. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 23 October 2007.

On 16 January 2013, the Rapporteur Member State submitted to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The CAR has been evaluated and submitted according to the BPD with the guidance available at that time.

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 Group meetings (and Biocides Technical Meeting TMIV2013) and the competent authority report was amended accordingly.

Peracetic acid in aqueous solution and peracetic acid generated in situ has been separated to different CARs. Peracetic acid in aqueous solution in PTs 1-6 was approved in BPC-10.

<sup>&</sup>lt;sup>1</sup> COMMISSION DELEGATED REGULATION (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council. OJ L 294, 10.10.2014, p. 1

#### 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 peracetic acid generated from tetraacetylethylenediamine (TAED) and sodium percarbonate for product-types 2, 3 and 4, and, should it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available from the Agency 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

<u>Identification of the active substance</u>

CAS-No.	
CAS name	
EINECS-No.	
Other No. (CIPAC, ELINCS)	Not available
IUPAC Name	
Common name, synonyms	Common name: Peracetic acid generated from tetraacetylethylenediamine and sodium percarbonate Synonyms: -
Molecular formula	C <sub>2</sub> H <sub>4</sub> O <sub>3</sub>
Structural formula	H <sub>3</sub> C O O
Molecular weight (g/mol)	76.05 g/mol

The active substance is peracetic acid generated from tetraacetylethylenediamine and sodium percarbonate.

Once solubilized in water, sodium percarbonate (SPC) liberates hydrogen peroxide and sodium carbonate. Hydrogen peroxide reacts with tetraacetylethylenediamine (TAED), and in the reaction peracetic acid, DAED and water are produced.

TAED + 2 
$$H_2O_2$$
 (+  $Na^+$  and  $CO_3^{2-}$ )  $\rightarrow$  DAED + 2 PAA + 2  $H_2O$  + (+  $Na^+$  and  $CO_3^{2-}$ )

The specifications are set for the two precursors of peracetic acid, TAED and SPC. Minimum purity of tetraacetylethylenediamine is 99.0 % and the minimum purity of the sodium percarbonate is 85.1%. Sodium percarbonate is considered a commodity chemical. No ratio has been set for TAED and SPC in biocidal products. In the representative products variation in the ratio of SPC/TAED (as %/%) is moderate: 2.00 - 3.75. The theoretical biocidal products evaluated in this CAR are dry powders of sodium percarbonate and TAED in a mixture. Typically the granules in the powder are coated. Exhaustive lists of coatings (including a few binders) are in Confidential documents as appendices. Coformulants such as detergents also exist in products. It is also known that powders can be pressed or formulated in other physical forms such as tablets or pouches. Kits containing sodium percarbonate and TAED packed separately may also be developed.

Maximum levels were set for impurities including heavy metals and iron in precursors. No impurities or coatings of toxicological concern have been identified.

Several member companies of the applicant were identified as reference sources. Compliance with the set specification was assessed for both TAED and SPC.

Three representative theoretical products have been defined in this dossier (see Doc IIB for details of the theoretical products). Peracetic acid generated in situ is mainly used for laundry disinfection (PT2), but also for other disinfectants used in PT2, 3, and 4. From a product (powder or tablet) containing the precursors TAED and sodium percarbonate, peracetic acid is liberated upon contact with water, i.e. when the product (in the case of PT2, a biocidal detergent) is added to the washing solution in a washing machine or when the application solution is prepared (PT2, 3, 4) by mixing the product into water. The information on the kinetics of active substance formation and subsequent degradation/hydrolysis with typical realistic concentration ranges of precursors and active substance in the substance generated *in situ* are provided in Documents IIB.

Batches used for the toxicology testing cannot be confirmed to be representative of the technical specification. The testing for peracetic acid has been performed on aqueous solutions of peracetic acid. It nevertheless can be concluded that the specifications set for the precursors TAED and sodium percarbonate (from which peracetic acid and hydrogen peroxide are formed) are covered by the risk assessment performed for the active substance since the substances with main toxicological and ecotoxicological importance are peracetic acid and hydrogen peroxide. In addition, information on TAED and DAED, a hydrolytic product of TAED, has been included in the CAR.

#### **Physico-Chemical Properties**

This section covers properties of peracetic acid, as in CARs PT 1-6 and 11,12. The relevance to peracetic acid generated from TAED and SPC may depend on the endpoint.

Pure (100%) peracetic acid cannot be prepared for testing of the physico-chemical properties of pure peracetic acid according to the guidelines, because 100% does not exist and can only be isolated in a laboratory scale. Then it would be highly explosive. 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.

This paragraph is not relevant for peracetic acid generated in situ, but it is left here for information on properties of aqueous equilibrium solutions of peracetic acid. 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 according to available requirements of information including data requirements of precursors of substances generated in situ.

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/	1.22 g/cm³ liquid at 20°C	(OVA 2009)	
relative density			
Vapour pressure	1.3 - 2.6 kPa, at 20°C (293 K) variable	(OVA 2009, CIS 2009)	

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

	sources	
	1.9 kPa, at 25°C (298 K)	(EPIWIN 3.20 experimental
	1.41 kPa, at 20°C (293K)	database)
		Swern (1970)
Solubility in water	Miscible in water in all proportions	Swern (1970)
Henry's Law	0.217 Pa·m³/mol at 25°C	Lind & Kok (1986)
Constant H		
Dissociation	pKa= 8.24 at 25°C	Mekelburger (2007), Doc. No. 115-
constant		002, A3.6/01
Surface tension	54.0 mN/m at 20°C for the neat solution	Mekelburger (2007), Doc. No. 216-
	(5%)	002
	47.7 mN/m at 20°C (ring method) for the	Mekelburger (2007), Doc. No. 216-
	neat solution (15 %)	003
Partition coefficient	log Kow =	Byers (1998)
n-octanol/ water	-0.46 at pH 5	
	log Kow = - 0.60 at pH 7	
	log Kow = - 0.66 at pH 9	
	-0.23 (calc. neutral form)	Brachhold (2007)
Flammability	15% product "PEROXYACETIC ACID	Mekelburger (2007),
	15%": Auto-ignition temperature: 280 °C	Doc.242-005, B3.4/02
	5% product "PEROXYACETIC ACID 5%":	
	Auto-ignition temperature: 435 °C	Mekelburger (2007),
	Other information will be added.	Doc.242-004, B3.4/01
Flash-point	According to information which has not	Safety Data Sheet (combined)
	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	
Frank - in a	peracetic acid in CLP.	OTC (2000)
Explosive	The liquid itself can be made to explode.  Vapour/air explosive limit: Pure or highly	CIS (2009)
properties	concentrated stabilized PAA may form	
	explosive vapour/air mixtures above	
	40.5°C. Detailed explosive limits are	
	unknown in the literature.	
Oxidizing properties		<u> </u>
Oxidizing properties	Ondizing	
	1	

<sup>\*)</sup> 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.

For physical properties of the theoretical biodical products included in this CAR, see Documents IIB.

#### **Methods of Analysis**

The following is adapted from CARs of PAA in aqueous solution, PTs 1-6 and 11,12.

Analysis of peracetic acid or hydrogen peroxide can be performed by reactive titration or titration, respectively. Their analytical methods and validation data were acceptable for the purpose of the CAR for PTs 11,12 with minor needs for further data on validation. A validated method for determination of acetic acid had been requested at product authorisation.

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

LOQ in the **water** method is not sufficiently low in comparison to the current lowest NOEC for aquatic environment. The eCA has recently received further information on method and a sound justification for non-submission of a revised method, based on measured short half-life of peracetic acid in water. This information has not yet been included in the CAR or fed in the evaluation process.

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). Due to properties of peracetic acid, for acute toxicity, no blood method is required.

The analytical methods for determination of products, precursors and their impurities relevant for products, are in Doc IIBs and in lists in confidential documents. No formulation containing peracetic acid generated from TAED and SPC exists.

#### 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) 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 generated from tetraacetylethylenediamine (TAED) and sodium percarbonate (*in situ* PAA) has been evaluated for several uses in PT2-4. In PT2 *in situ* PAA has been evaluated for laundry disinfection in household, and in industrial and institutional use, and also for surface disinfection in industrial, public and and health care area. In PT3 *in situ* PAA has been evaluated for surface and instrument disinfection in veterinary area. In PT4 *in situ* PAA has been evaluated for surface and instrument disinfection for food and beverage industry.

*In situ* PAA exerts toxic (bactericidal, yeasticidal, etc.) rather than bacteriostatic, yeastistatic effects on target organisms. For PT2-4 applications bactericidal, yeasticidal, virucidal and sporicidal (only surface and equipment disinfection) properties are relevant.

In situ PAA products show evidence of bactericidal, yeasticidal, virucidal and sporicidal activity. However, products referred to in the CAR are theoretical products and hence efficacy data on real products appropriately simulating in-use conditions (e.g. for PT3: high level soiling and organisms representative for the application area) have to be submitted at product authorisation phase. 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 solutions generated from TAED and sodium percarbonate contain also hydrogen peroxide. Comparison of efficacy of PAA and hydrogen peroxide in the CAR of PAA PT1-6 showed that peracetic acid contributes most to the biocidal efficacy of the application solutions. In regard to the *in situ* PAA products the ratio of generated PAA and excess hydrogen peroxide released from sodium percarbonate varies depending on the initial concentrations of precursors TAED and sodium percarbonate. Synergistic effects of PAA and hydrogen peroxide in the efficacy of *in situ* PAA products cannot be excluded.

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

Peracetic acid generated from TAED	Product types	<b>Final CAR</b>	December
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#### 2.1.3. Classification and Labelling

The classification of the active substance peracetic acid is presented here as it was in the CARs of peracetic acid in aqueous solution (PT1-6, 11, 12). No classification separately for the active substance generated *in situ* is needed. In the context of *in situ* generation, precursors generating the active substance are considered as the biocidal product.

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:

acid is classified and labelled as follows:							
Hazard Class and Category							
Code(s)	Org. Perox. D ***	* H242					
222 SP 1985	Acute Tox. 4 * H	332					
	Acute Tox. 4 * H	312					
	Acute Tox. 4 * H	302					
	Skin Corr. 1A H3	14					
	Aquatic Acute 1	1400					
Hazard Statement Code(s)	H226 Flar	mmable liquid and	vapour.				
950. 1 <del>5</del> 00	H242 Hea	ating may cause a	fire.				
	H332 Har	mful if inhaled.					
	H312 Har	mful in contact wit	th skin.				
		mful if swallowed.					
	H314 Cau	ises severe skin bu	irns and eye damage	<b>.</b>			
	H400 Ver	y toxic to aquatic I	ife.				
Supplemental Hazard	-						
Statement Code(s)							
Pictogram(s) and Code(s)	GHS02	GHS05	GHS07	GHS09			
Signal Word (Code)	Danger (Dgr)						
Specific Concentration *							
Limits STOT SE 3; H335: C ≥ 1 %							
M Factors							
Notes	BD	•					

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:  $C \ge 10$  %) 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 2017 at the earliest.

According to the ECHA Classification and Labelling Inventory the precursor TAED is not classified, while sodium percarbonate is classified as Ox. Sol. 2; H272 (May intensify fire; oxidiser), Acute Tox. 4; H302 (Harmful if swallowed), Eye Dam. 1; H318 (Causes serious

eye damage) (Specific Concentration limits: Eye Dam. 1:  $C \ge 25\%$ , Eye Irrit. 2: 7.5%  $\le C < 25\%$ ).

#### 2.2. Summary of the Risk Assessment

#### 2.2.1. Human Health Risk Assessment

#### 2.2.1.1. Hazard identification

This chapter of Hazard identification is the same as for the active substance peracetic acid in aqueous solution in PT1-6 and PT11-12. No toxicity tests for the substance generated *in situ* is available, and therefore the respective data on peracetic acid in aqueous solution (containing also hydrogen peroxide and acetic acid) was used for the toxicology part regarding peracetic acid in the in-use solution.

#### 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 LD $_{50}$  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 LD $_{50}$  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 LC $_{50}$  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 RD $_{50}$  value for peracetic acid of approx. 15 mg/m $^3$  (5 ppm) in mice vs. clinical signs of irritation in an acute toxicity study at 87 mg/m $^3$  (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 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  $H_2O_2$ ) 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

The active substance peracetic acid is generated *in situ* from biocidal product containing the precursors tetra-acetylethylenediamine (TAED) and sodium percarbonate. When the solid product gets into contact with water (e.g. within the washing machine or in mixing of the disinfection solution), sodium percarbonate dissociates to sodium carbonate and hydrogen

peroxide. In the presence of hydrogen peroxide, TAED rapidly undergoes perhydrolysis to form DAED (diacetylethylenediamine) and the active substance *in situ* peracetic acid. All these ingredients contribute to the human health effects and the subsequent risks, and have to be taken into account in the overall risk characterisation. No toxicity tests for the substance generated *in situ* is available, and therefore the respective data on peracetic acid in aqueous solution (containing also hydrogen peroxide and acetic acid) was used for the toxicology part of the in-use solution. For the precursors and DAED limited toxicological data was available to derive the reference values. The data package for the precursors was considered sufficient in TM IV 2013. At the time of product authorisation the need for further data on precursors should be considered taken into account the agreed data requirements.

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.

The exposure and risks were assessed for the precursors TAED and sodium percarbonate in the mixing and loading scenario. For the application of the in use solution the exposure and risks to peracetic acid, hydrogen peroxide, TAED and its degradation product DAED were separately assessed including primary and secondary exposure.

#### Dermal reference values for peracetic acid

<u>Corrosive effects:</u> 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.

<u>Serious eye damage/eye irritation:</u> 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. RD<sub>50</sub> 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 RD<sub>10</sub> 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 "nodiscomfort" 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**  $mg/m^3$  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.

#### Precursors of in situ generated peracetic acid

Regarding the human health effects of the precursor TAED and its degradation product DAED and the other precursor sodium percarbonate the information in the report of HERA (2002) (Human & environmental risk assessment on ingredients of European household cleaning products – Tetraacetylethylenediamine (TAED)/Sodium percarbonate) supplied by the applicant was used for the risk assessment. Information on the purity of the precursors tested in the studies was not available in the report. At product authorisation there may be a need for further data based on the agreed data requirements for precursors.

TAED as well as its hydrolysis product DAED are of low acute toxicity and only slightly or non-irritating. TAED and DAED have no classification. They are not potential sensitizers. The available data does not raise concern of mutagenic or genotoxic potential. In the repeated dose studies, TAED caused, inter alia, reduced body weight gain as well as increased weight and reversible centrilobular hypertrophy of liver. No fertility studies are available with either TAED or DAED. In the available 90-day study with TAED in rats, no adverse effects on the reproductive organs have been observed and no adverse effects on reproduction parameters were reported in the teratology study conducted with TAED in rats.

The study considered to be most relevant for the deduction of an acceptable systemic exposure level of TAED is the 90-day oral study in rats. Using an uncertainty factor of 100, the acceptable systemic exposure level for TAED is derived at 0.9 mg/kg bw/day. For the exposure and risk assessment of TAED, a default value of 25% is used for estimating dermal absorption of TAED from the concentrated product and 75% from the diluted solutions, disinfected laundry during wearing of clothing and from disinfected surfaces.

Toxicity data on DAED, the main metabolite of TAED, is sparse. A NOEL of 5700 mg/kg bw/ day in a 13-week rat feeding study has been reported. The low toxicity is plausible in view of the toxicokinetics of TAED and DAED. Using an uncertainty factor of 100, the acceptable systemic exposure level for DAED is derived at 57 mg/kg bw/day. For DAED, a default value of 75% is used for estimating dermal absorption of DAED from the diluted washing solutions, disinfected laundry during wearing of clothing and from disinfected surfaces.

The second precursor, sodium percarbonate, dissociates into sodium, carbonate and hydrogen peroxide and only hydrogen peroxide is considered to be a toxicologically relevant substance in the exposure assessment and risk characterisation for sodium percarbonate. It should be noted that during mixing and loading tasks, hydrogen peroxide is not yet released from solid sodium percarbonate, and as a consequence, risk assessment of local dermal and inhalation effects during this task has to be performed on sodium percarbonate instead of hydrogen peroxide.

It is worth noting that in the context of REACH, several DNELs have been set for the local effects percarbonate (http://echa.europa.eu/web/quest/information-onchemicals/registered-substances). The dermal DNEL for local effects of sodium percarbonate is set at 6.4 mg/cm<sup>2</sup> for general population. For local effects of sodium percarbonate via the inhalation route, only a local long-term inhalation DNEL of 5 mg/m<sup>3</sup> for workers has been derived. In accordance with the procedure chosen for the derivation of the long-term DNEL for local effects in workers and general population, an additional safety factor of 2 was applied on the local long-term inhalation DNEL for workers to correct for differences in the general population. This results in a proposed long-term local inhalation DNEL of 2.5 mg/m³ for sodium percarbonate in general population. These reference values are used as a qualitative/semi-quantitative way in the filling/mixing and loading tasks where external dermal and inhalation exposure to sodium percarbonate is possible. However, a qualitative risk assessment for local effects would be considered sufficient according to the guidance for local risk characterisation.

This CAR includes three theoretical in situ products containing different amounts of precursors. Regarding product 1 there is 15% TAED and 40% sodium percarbonate. Product 2 contains 4% TAED and 15% sodium percarbonate and product 3 contains 25% TAED and 50% sodium percarbonate.

The precursor TAED has no classification. Sodium percarbonate is classified for health effects as Acute Tox. 4; H302 and Eye Dam. 1; H318 (Eye Dam. 1: C ≥ 25%, Eye Irrit. 2  $7.5\% \le C < 25\%$ , ECHA C&L inventory, joint entry).

Based on the classification of the components, the theoretical products can be classified as follows:

- Product 1: Acute Tox. 4 (H302), Skin Irrit. 2 (H315), Eye Dam. 1 (H318), STOT SE 3 (H335)
- Product 2: Skin Corr. 1 (H314), Eye Dam. 1 (H318)
- Product 3: Acute Tox. 4 (H302), Eye Dam. 1 (H318)

The classification of theoretical products 1 and 3 for Acute Tox. 4 and Eye Dam. 1 are based on sodium percarbonate. In addition for product 1, the classification as Skin Irrit. 2 and STOT SE 3 are derived from a coformulant. Also for product 2 the more severe classification is based on the coformulant (Eye Irrit. 2 if based only on sodium percarbonate).

#### 2.2.1.3. Exposure assessment

Peracetic acid generated *in situ* is mainly used in industrial/professional applications. Non-professional use is applicable in laundry disinfection in households (PT2) with *in situ* product 1.

#### **Description of uses**

PT2

- Laundry disinfection in closed washing machines: The product is automatically dosed into the washing machine (product 1 and 2). Soaking or hand-washing of laundry in households (product 1).
- Disinfection of surfaces in industrial, public and health care areas: The product is applied by wiping of hard surfaces with flat mops or cleaning cloths (product 3).

PT3

- Disinfection of animal houses by low-pressure manual spraying: Floors and walls of animal houses are disinfected by low pressure spraying with a hand held spray wand (product 3).
- Disinfection of equipment by dipping: Equipment is dipped into a bath with contains the treatment solution (product 3).

PT4

- Disinfection of surfaces and equipment by low pressure manual spraying and wiping:
  Floor and walls of buildings, machines and equipment (e.g. milking equipment) is
  disinfected by low pressure spraying with a hand-held spray wand or by wiping with
  flat mops and cleaning cloths (product 3).
- Disinfection of equipment in the food and beverage industry by dipping and immersion: Equipment in the food and beverage industry (including milking equipment) is disinfected by dipping (product 3).

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

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 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.

For the first precursor of *in situ* peracetic acid, i.e. TAED as well as for the hydrolysis product DAED, a systemic approach is used for assessing exposure by the dermal and inhalation route. The second precursor, sodium percarbonate, dissociates into sodium, carbonate and hydrogen peroxide and only hydrogen peroxide is considered to be a toxicologically relevant substance in the exposure assessment for sodium percarbonate except during filling/mixing and loading tasks when external dermal and inhalation exposure to sodium percarbonate is possible. For these tasks the external dermal and inhalation

exposure is estimated and qualitatively/semi-quantitatively compared to dermal and inhalation DNELs of sodium percarbonate for local effects, i.e. 6.4 mg/cm<sup>2</sup> and 2.5 mg/m<sup>3</sup>, respectively.

#### 2.2.1.4. Risk characterisation

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

The exposure models primarily used for the estimation of inhalation exposure (TNsG models) do not take into account the volatility of the substance. The inhalation exposure to vapour of peracetic acid in addition to aerosols during use of solutions (e.g. soaking or hand-washing of laundry, wiping, spraying, dipping) has to be calculated and taken into account at product authorisation. Sufficient ventilation and other organisational risk mitigation measures should be in use to avoid vapour formation and exposure to values higher than the AEC for inhalation.

#### Conclusion for non-professional users in PT2 (Product 1)

The exposure assessment and accompanying risk characterisation performed for the application of in situ generated peracetic acid as a laundry disinfectant in washing machines and hand-washing in PT2 by non-professionals demonstrated that the in-use concentrations of peracetic acid and hydrogen peroxide are below the skin irritation thresholds. The inhalation AEC values of peracetic acid and hydrogen peroxide are not exceeded in laundry disinfection and post-application. Also the reference values of sodium percarbonate for local effects on the skin and via the inhalation route are not exceeded during mixing and loading. In addition, no exceeding of the acceptable systemic reference dose is demonstrated for TAED or DAED during mixing and loading, application and post-application of in situ peracetic acid disinfectants for laundry. However, in view of intrinsic properties of the theoretical biocidal product (classification for serious eye damage and skin irritation), safe practices in handling the product during dosing are essential. Contact with eyes and skin for any reason should be avoided. However, the likelihood of eye and skin exposure is considered to be low as the product typically is a non-dusty powder with inert coating, and it is loaded with a dosing cup with no direct hand contact. It is also used with low frequency for short duration and with low amount per event by non-professionals. Labelling, instructions for use, product formulation and packaging eliminating exposure should be in use for products authorized for non-professional use.

#### Conclusion for professional users in PT2 (Product 2)

The exposure assessment and accompanying risk characterisation performed for the application of *in situ* generated peracetic acid as a <u>laundry disinfectant in washing machines</u> in PT2 by professionals demonstrated that the reference values of sodium percarbonate for local effects on the skin and *via* the inhalation route are not exceeded during filling of washing machines. No exceeding of the acceptable systemic reference dose was demonstrated for TAED or DAED during application of *in situ* peracetic acid disinfectants. However in view of intrinsic properties of the theoretical biocidal product (classification for severe skin burns and eye damage), safe practices in handling the product during dosing are essential. Contact with eyes and skin for any reason should be avoided with use of gloves and eye protection.

#### Conclusion for professional users in PT2, 3 and 4 (Product 3)

The exposure assessments and accompanying risk characterisation performed for the application of *in situ* generated peracetic acid in the intended uses within PT2, PT3 and PT4 demonstrated that the in-use concentrations of peracetic acid (0.25%) exceed the dermal NOAEC (0.1% in long-term exposure and 0.2% in short/medium-term exposure) indicating

the need for skin protection during all tasks. The inhalation AEC value of 0.5 mg/m³ of peracetic acid is not exceeded except in spraying applications where RPE is needed (due to exposure to vapour). No exceeding of the acceptable systemic reference doses are derived for TAED and DAED. During preparation of the disinfection solutions, local dermal and inhalation exposure was below the DNELs derived for local effects for sodium percarbonate.

In mixing and loading tasks goggles are needed due to the classification of the theoretical product for serious eye damage. In application phases peracetic acid concentrations are above the reference values and therefore gloves are needed and in spraying applications protective clothing and RPE in addition. At product authorisation the inhalation exposure to vapour has to be calculated in all scenarios to be able to determine the need for other organisational RMM and RPE.

#### Conclusion for secondary exposure

Product 1 in PT2: The acute secondary exposure to peracetic acid, hydrogen peroxide, sodium percarbonate, TAED and DAED *via* the inhalation route of exposure during manual disinfection of laundry and subsequent draining of the disinfection solution after use are demonstrated to be at acceptable level. Secondary dermal exposure during wearing of clothes which have been disinfected with *in situ* generated peracetic acid is relevant only for the precursor TAED and its hydrolysis product DAED and this is at acceptable level. Secondary oral exposure of infants licking/sucking on disinfected laundry is considered to be at acceptable level.

Product 2 in PT2: During loading of washing machines, acute secondary inhalation exposure towards sodium percarbonate and TAED was well below the indicative inhalation DNEL for sodium percarbonate as well as the systemic reference dose for TAED. Chronic secondary dermal exposure during wearing of clothes and oral exposure of infants licking/sucking on disinfected laundry are acceptable for product 2 as well.

Product 3 in PT2, 3 and 4: Estimated exposures to peracetic acid, hydrogen peroxide, TAED and DAED are at acceptable level for a non-user when present during manual disinfection procedures performed by wiping and mopping. Systemic exposure to TAED and DAED resulting from dermal contact with treated surfaces or objects are well below the acceptable systemic reference doses of both substances. Systemic exposure resulting from oral uptake of residues of TAED and DAED on treated surfaces or objects is well below the acceptable systemic reference doses of both substances. The premises disinfected by spraying have to be well-ventilated before re-entry.

After application *in situ* generated peracetic acid solutions, secondary exposure of humans upon dermal or oral contact with treated surfaces or equipment is considered to be non-relevant regarding peracetic acid because in-use dilutions are low in concentrations and peracetic acid is highly unstable and will rapidly degrade at the site of first contact. Additionally, in applications as a disinfectant in veterinary hygiene (PT3) and food and feeding areas (PT4), treated equipment, pipework or installations are rinsed with water or left to dry prior to further operations. Rinsing step was not used in the assessment and it is not a requirement for safe use. Therefore, secondary human exposure to peracetic acid and hydrogen peroxide *via* food etc. is not considered to be relevant as both peracetic acid and hydrogen peroxide degrade rapidly following application and no residues are expected in foodstuffs. Subsequently, no MRL setting is required as peracetic acid is not persistent, no systemic effects are observed and because of its high reactivity. No information related to the residues on precursors is available.

Peracetic acid generated from TAED	Product types	Final CAR	December
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#### **Combined exposure**

Based on the absence of systemic effects after exposure towards peracetic acid (hydrogen peroxide and sodium percarbonate), only the highest inhalation exposure level is relevant. For TAED and DAED, combined exposure calculations showed acceptable risks.

#### Conclusion

Based on the outcome of the risk assessment, the exposure of professionals, non-professionals, non-users/bystanders and the general public results in no unacceptable health risk due to *in situ* generated peracetic acid. However, in view of intrinsic locally irritating properties of the theoretical biocidal products, attention should be paid to safe and appropriate practices in handling the product during mixing and loading tasks. The same applies to tasks where in-use solutions exceeding the dermal NOAEC of peracetic acid are handled. For professionals appropriate personal protective equipment including gloves, goggles and protective clothing and in addition RPE during spraying applications is needed.

The secondary exposure of non-users/bystanders and the general public was shown to be acceptable.

#### 2.2.2. Environmental Risk Assessment

The hazard assessment of peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate is based on the respective assessment on aqueous peracetic acid described below and in the CARs for PT1-6 and PT 11-12, since no fate or ecotoxicological data for the substance generated *in situ* is available. For hydrogen peroxide the hazard assessment is described in the CAR of hydrogen peroxide for PT1-6.

#### 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. At the WG II 2016 it was agreed to use DT50 of hydrogen peroxide of 12 hrs in the absence of reliable DT50 for peracetic acid. 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  $\mu$ g PAA/L and PNECmarine 0.0069  $\mu$ g 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/kgwwt 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.

#### In situ products

The evaluated theoretical *in situ* products 1, 2 and 3 do not contain the active substance peracetic acid (PAA) itself, but only the two precursor substances; sodium percarbonate and tetra-acetylethylenediamine (TAED). *In situ* products are always diluted in water before their use and in aqueous solutions sodium percarbonate dissociates to sodium (Na), carbonate ( $CO_3^{2-}$ ) and hydrogen peroxide, the latter reacting by perhydrolysis with TAED to form DAED (diacetylethylenediamine) and peracetic acid (*in situ* PAA).

TAED + 2 H<sub>2</sub>O<sub>2</sub> (+ Na and CO<sub>3</sub><sup>2-</sup>) 
$$\rightarrow$$
 DAED + 2 PAA

The dissociation products of precursor substance sodium percarbonate, sodium and carbonate, are not considered in environmental release estimations and the risk assessment. Third dissociation product of sodium percarbonate, hydrogen peroxide, is taken into account in the environmental exposure and the risk assessment, but only the remaining amount of hydrogen peroxide which is not consumed in reaction with TAED. The environmental hazard assessment of hydrogen peroxide is presented in the hydrogen peroxide CAR.

The information regarding the fate and behaviour of the precursor substance TAED and its degradation product DAED described in the report of HERA (A voluntary industry programme to carry out Human and Environmental Risk Assessments on ingredients of household cleaning products) were used for the preliminary risk assessment. Following data is used for TAED and DAED: they are both very soluble, have low vapour pressure, readily biodegradable substances with low log Kow –values (-0.08 for TAED, -1.03 for DAED) and low measured Koc-values (80 for TAED, 25 for DAED). The PNECs are as follows; PNECwater 500µg/L and PNECstp 10 mg/L for both TAED and DAED, and PNECsoil calculated by equilibrium partitioning method 0.765 mg/kg for TAED and 0.279 mg/kg for DAED.

#### 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 Kow 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

- PT 2: Disinfection of surfaces in industrial premises, institutional and health care areas. Emission estimation is based on the consumption and the release is to the sewage system.
- PT 2: Laundry disinfection in closed washing machines by professionals. Emissions to the sewage system based on consumption are evaluated from the 'washing streets' use in medical sector and in households in closed washing machines and by soaking / handwashing. The emission estimation for the use in washing machines covers the use at soaking/hand-washing. The emissions are to the waste water and via sewage treatment plant to surface water and further with sewage sludge application to soil. Tonnage-based scenario was used.
- PT 3: Animal house disinfection by spraying. The application rates were used as a basis for the emission estimation via application of liquid manure/ slurry to agricultural land.
- PT 3: Disinfection of equipment by dipping. Emission was assumed to be similar to PT3, as in both uses similar sized vats are used and the content is assumed to be emptied into to the STP or manure/slurry storage tank.
- PT 4: Disinfection of equipment in the food and beverage industry by dipping and immersion Emission was assumed to be similar to disinfection of medical equipment by dipping and therefore a PT2 scenario designed for disinfection of medical equipment (e.g. endoscopes) by dipping was used.
- PT4: Disinfection of surfaces and equipment by low pressure manual spraying/manual application of foam in industrial kitchens and meat processing industry. Emission estimation is based on consumption and the assumption that disinfectants are released to the facility drain with rinsing water.

#### PEC in STP and aquatic compartment

Assessment of potential routes of entry into the environment shows that emission to sewage system is the relevant route for the intended biocidal uses in PT2 and PT4. Direct emissions of peracetic acid to surface water do not occur in any of the biocidal uses evaluated.

PECs in STP effluent were between 0.0016 - 0.71  $\mu$ g/L for peracetic acid, 0.048 - 25.4  $\mu$ g/L for hydrogen peroxide, 0.03 - 50.7  $\mu$ g/L for TAED and 1.95 - 3180  $\mu$ g/L for DAED. After degradation in the STP, residual acetic acid and hydrogen peroxide may reach surface water. Consequently, PECs in surface water (river) were assumed to be diluted 10-fold. Peracetic acid and hydrogen peroxide in surface water do not partition to suspended matter

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

or sediment to any relevant extent, calculated PECs in sediment ranged 5.8 x  $10^{-7}$  - 5.7 x  $10^{-5}$  mg/kg for peracetic acid, 3.9 x  $10^{-6}$  - 2.1 x  $10^{-3}$  mg/kg for hydrogen peroxide, 8 x  $10^{-6}$  - 0.0128 mg/kg for TAED and 2.6 x  $10^{-4}$  - 0.42 mg/kg for DAED.

#### **PEC** in air

Peracetic acid and hydrogen peroxide might enter the atmosphere due to volatilisation from the STP and from disinfection of animal feet. The highest PEC in air was calculated to be 9.0 x  $10^{-9}$  mg/m³ for peracetic acid and  $3.4 \times 10^{-9}$  mg/m³ for hydrogen peroxide. Emissions of TAED and DAED to air from evaluated *in situ* products uses are negligible due to very low vapour pressure.

#### **PEC in soil**

No direct emissions to soil are expected following the biocidal uses of evaluated theoretical peracetic acid products. Indirect emissions are in principle possible from disinfection in animal housing (PT 3), where residual peracetic acid and hydrogen peroxide might be spread to soil with manure. However, low amounts of peracetic acid and hydrogen peroxide are expected to remain in manure when spread to soil, due to the very rapid degradation in manure with high microbial populations and organic-matter content and the long storage times of manure before spreading to soil. Indirect emissions to soil are also possible from uses in PT2 and PT4 via the application of sewage sludge from the STP. Calculated PECs in soil ranged from 9.2 x  $10^{-9}$  to 1.12 x  $10^{-5}$  mg/kg for peracetic acid and from 6.6 x  $10^{-6}$  to 8.9 x  $10^{-5}$  mg/kg for hydrogen peroxide, 4.8 x  $10^{-5}$  - 0.0032 mg/kg for TAED and 9.5 x  $10^{-4}$  - 0.196 mg/kg for DAED.

#### 2.2.2.5. Risk characterisation

In situ peracetic acid products contain precursor TAED and in situ formed peracetic acid, hydrogen peroxide and DAED. The risks of all these 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)<sub>product</sub> =  $\Sigma$ (PEC/PNEC)<sub>components</sub>).

#### STP

The PEC/PNEC ratios are below 1 indicating that there is no unacceptable risk to microorganisms involved in the biological processes of the sewage treatment plants from peracetic acid formed during the use of theoretical *in situ* product 1, 2 and 3 in PT2, PT3 and PT4.

#### Aquatic compartments (including sediment)

The PEC/PNEC ratios for aquatic compartment are below 1 indicating that there is no unacceptable risk to organisms in the water column or sediment from *in situ* peracetic acid, hydrogen peroxide, TAED and DAED except in PT2 "Laundry disinfection in closed washing machines in households.

#### **Atmosphere**

The exposure assessment showed that the emission to air is negligible. Consequently, air is not an environmental compartment of concern.

#### Terrestrial compartment

All the individual PEC/PNEC ratios for *in situ* peracetic acid, hydrogen peroxide, TAED and DAED and also  $\Sigma(\text{PEC/PNEC})_{\text{components}}$  are below 1 indicating no unacceptable risk to soil organisms from the theoretical *in situ* products 1, 2 and 3 in PT2, PT3 and PT4.

#### Groundwater

Evaluated pore water concentrations were 6.8 x  $10^{-5}$  - 0.0184  $\mu g/L$  for peracetic acid and 7.5 x  $10^{-3}$ - 0.1  $\mu g/L$  for hydrogen peroxide. Concentrations of TAED in the groundwater using PELMO modelling were < 0.001  $\mu g/L$ . Thus, the risks for groundwater contamination by peracetic acid, hydrogen peroxide and TAED can be regarded low.

Concentrations of degradation product of the precursor, DAED, in the groundwater modelled with PELMO using substance specific parameters taken from HERA –report were 0.001 –  $10.17~\mu g/L$ . Although in some situations DAED concentrations exceed the trigger value of 0.1  $\mu g/L$  (defined in directives 2006/118/EC and 98/83/EC), in each PT there are PELMO-scenarios where trigger value is not exceeded. In the following table only the worst case modelling results with maximum application rate (kg/ha) of TAED and DAED is presented. Please note, that the conclusion of the  $47^{th}$  CA meeting in July 2012 was that for active substance approval one safe use is acceptable as for the PPP area. During product authorisation phase, however, when real in situ PAA products are evaluated the possibility of groundwater emission by DAED should be considered.

Overview table of PEC/PNEC for PAA, hydrogen peroxide, TAED and DAED (in situ products). For the groundwater a PEC ( $\mu$ g/I) is presented, since the use of PEC/trigger value -ratio is unconvential for groundwater.

Exposure scenario	Compartment	In situ PAA	TAED	DAED	H <sub>2</sub> O <sub>2</sub>	Σ (PAA + H <sub>2</sub> O <sub>2</sub> )
PT2 - Laundry	Surface water	1.03	0.0042	0.264	0.20	1.23
disinfection in	STP	0.01	0.0021	0.132	0.0055	0.016
closed washing	Soil	3.97x10 <sup>-5</sup>	0.004	0.24	0.049	0.049
machines in households	Groundwater (EUSES)	0.0184	0.69	35	0.1	
PT2 -Laundry	Surface water	0.10	0.010	0.64	0.015	0.115
disinfection in	STP	0.0001	0.005	0.318	4.08x10 <sup>-4</sup>	0.0005
closed washing	Soil	4.04x10 <sup>-7</sup>	0.010	0.55	0.0037	0.0037
machines by professionals	Groundwater (EUSES)	1.88x10 <sup>-4</sup>	1.67	84.9	7.52x10 <sup>-3</sup>	
	Groundwater		< 0.001	0.768	Châteaudun	
	(PELMO) max. application rate *TAED 0.038 kg/ha *DAED		< 0.001	6.462	Hamburg	
			< 0.001	5.971	Jokioinen	
			< 0.001	2.018	Kremsmünst	er
			< 0.001	7.484	Okehampton	
			< 0.001	10.165	Piacenza	
	0.75 kg/ha		< 0.001	0.137	Porto	
	<b>,</b>		< 0.001	0.024	Sevilla	
			< 0.001	0.236	Thiva	
PT2 - Disinfection	Surface water	0.023	6.0x10 <sup>-5</sup>	0.0039	0.0038	0.03
of surfaces in	STP	0.00031	3.0x10 <sup>-5</sup>	0.00196	0.0001	0.0004
industrial, public	Soil	8.9x10 <sup>-7</sup>	6.3x10 <sup>-5</sup>	0.0034	0.00094	0.00094
and health care areas (covers also PT 4 use)	Groundwater (EUSES)	4.15x10 <sup>-4</sup>	0.00997	0.52	0.0019	
PT3 -	Soil 1)	3.3x10 <sup>-8</sup>	4.2x10 <sup>-3</sup>	0.70	6.1x10 <sup>-5</sup>	6.1x10 <sup>-5</sup>

Peracetic acid generated from TAED and sodium percarbonate	Product types 2, 3 and 4	Final CAR	December 2016
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Disinfection of animal houses by spraying <sup>2)</sup>	Groundwater (EUSES)	6.8x10 <sup>-5</sup>	1.88	354	0.00075	
PT3 -	Surface water	0.0023	6.3x10 <sup>-6</sup>	3.9x10 <sup>-4</sup>	3.8 x 10 <sup>-4</sup>	0.003
Disinfection of	STP	3.1x10 <sup>-5</sup>	3.2x10 <sup>-5</sup>	1.9x10 <sup>-4</sup>	1.0x10 <sup>-5</sup>	4.1x10 <sup>-5</sup>
equipment in	Soil 1)	2.1x10 <sup>-8</sup>	0.0026	0.46	3.6 x 10 <sup>-5</sup>	3.6x10 <sup>-5</sup>
animal houses by dipping	Groundwater (EUSES)	0.000045	1.17	230	0.0004	
PT4 - Disinfection	Surface water	0.028	0.00018	0.011	0.0087	0.04
of equipment by	STP	3.7 x 10 <sup>-4</sup>	8.8x10 <sup>-5</sup>	0.0054	2.4 x 10 <sup>-4</sup>	0.0006
dipping	Soil	1.0 x 10 <sup>-6</sup>	1.8x10 <sup>-4</sup>	0.0094	0.0022	0.0022
	Groundwater (EUSES)	0.00050	0.0291	1.44	0.0046	

<sup>1)</sup> Worst case value was chosen for the risk characterisation, i.e. the risk characterisation covers manure application on both grassland and arable land.

#### 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.

At the moment there is no regulatory interpretation how an identified unacceptable cumulative risk should be taken into account when approving active substances, since for approval one safe use is sufficient. Thus, approval of an active substance could not base on the outcome of the aggregated risk assessment. However, it is important to bring out if a potential cumulative risk is identified.

Aggregated environmental exposure assessment was performed for peracetic acid taking into account the emissions from both aqueous products (equilibrium solution; PTs 1-6 and PT 11-12 assessed in their separate CARs) and *in situ* -products (PTs 2, 3 and 4 assessed in this CAR). 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.

For cumulative assessment between PTs emissions from disinfectant uses in PT1 and PT 2 to STP are added up, since they are representing wide dispersive use pattern. These scenarios are marked with "a" in the following table. In addition, there are possible overlapping combinations of emissions to a same STP from wide dispersive uses and industrial, non-dispersive uses. These non-dispersive scenarios are marked with "(a)". For the aggregated assessment, a combination of wide dispersive uses and one industrial use at a time could be selected, since it is unlikely that all possible industries are located in the same catchment area. However, only a worst case Elocal of PT4 (0.025 kg/d) was used in this assessment. In addition, no possible overlapping emissions into the same STP were identified between PTs 1-5 and PT6, because the capacity of STP in PT 1-5 scenarios is 2000 m³/d and in PT6 scenarios 5000 m³/d. Between PT 6 and PT 12 a potential overlapping emission is possible, since the dry-end and wet-end operations in paper production might be discharging into the same STP (5000 m³/d). However, the measurements performed in the coating colour and

<sup>2)</sup> Only scenario "Disinfection of animal houses by spraying - pigs fattening" was assessed.

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

ultra-filtrated pigment slurries demonstrated degradation of peracetic acid and hydrogen peroxide in PT6. Therefore, there is no concern for cumulative environmental risks for peracetic acid or hydrogen peroxide when concerning PT 6 and PT12.

Summary of local emissions of peracetic acid and their relevance for cumulative risk assessment within PT and between PTs:

Product Type/Scenario	Elocal (kg/d) considering degradation in the sewer system	Relevance within PT	Relevance between PTs
PT1	-		
Hand disinfection - aqueous products	0.0008 kg/d		a
PT 2			
Laundry disinfection in closed washing machines (professional use) - aqueous products - in situ -products	0.010 kg/d 0.0014 kg/d	x	a
Laundry disinfection in closed washing machine (private use) 1) - in situ -products	0.137 kg/d	x	а
Disinfection of surfaces in industrial, public and health care areas - aqueous products - in situ -products	0.00192 kg/d 0.0031 kg/d	x	a
CIP in the pharmaceutical and cosmetic industry - aqueous products	0.011 kg/d	х	
PT 3			
Disinfection of boots - aqueous products	6.2 x 10 <sup>-5</sup> kg	x	
Disinfection of animal's feet - aqueous products	0.016 kg/d	x	
Disinfection of equipment - aqueous products - in situ -products	6.2 x 10 <sup>-5</sup> kg/d 0.00031 kg/d	×	
PT 4			
Disinfection of equipment by dipping - aqueous products - in situ -products	0.016 kg/d 0.0037 kg/d	x	
Automated spraying in closed systems Disinfection of equipment by dipping and immersion CIP and disinfection of ion exchangers - aqueous products	0.011 kg/d	x	(a)
Low pressure manual spraying Manual application of foam - aqueous products	0.025 kg/d	x	(a)
Disinfection of milking equipment - aqueous products	0.0005 kg/d	х	(a)

<sup>1)</sup> Unacceptable use.

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

Summary of PECs for aggregated assessment within PTs (PT2, PT3 and PT4) and between PTs (wide dispersive uses from PT1 and PT2 and the worst case from PT4):

	Elocal kg/d	PEC <sub>STP</sub> μg/l	PEC <sub>aquatic</sub>	PEC <sub>soll</sub> mg/kg	PEC <sub>gw</sub> μg/l
Within PTs					
PT 2	0.154 <sup>2)</sup> 0.017 <sup>3)</sup>	0.796 0.088	0.090 0.009	1.26 x 10 <sup>-5</sup> 1.39 x 10 <sup>-6</sup>	0.021 0.002
PT 3	0.016	0.083	0.008	1.31 x 10 <sup>-6</sup>	0.002
PT 4	0.056	0.289	0.029	4.58 x 10 <sup>-6</sup>	0.008
Between PTs	70-			-04	
PT1, PT2, PT4	0.180 <sup>2)</sup> 0.043 <sup>3)</sup>	0.930 0.222	0.093 0.022	1.47 x 10 <sup>-5</sup> 3.51 x 10 <sup>-6</sup>	0.024 0.006

<sup>&</sup>lt;sup>2)</sup>Unacceptable use (Laundry disinfection in closed washing machine in households) was taken into account.

Summary of PEC/PNECs for aggregated assessment within PTs (PT2, PT3 and PT4) and between PTs (wide dispersive uses from PT1 and PT2 and the worst case from PT4):

	Elocal (kg/d)	PEC/PNEC <sub>STP</sub>	PEC/PNEC <sub>aquatic</sub>	PEC/PNEC <sub>soll</sub>
Within PTs				
PT 2	0.154 <sup>2)</sup> 0.017 <sup>3)</sup>	0.015 0.002	1.30 0.13	4.5 x 10 <sup>-5</sup> 4.9 x 10 <sup>-6</sup>
PT 3	0.016	0.002	0.12	4.6 x 10 <sup>-6</sup>
PT 4	0.056	0.006	0.42	1.6 x 10 <sup>-5</sup>
Between PTs		12	M DRD	
PT1, PT2, PT4	0.180 <sup>2)</sup> 0.043 <sup>3)</sup>	0.018 0.004	1.34 0.32	5.2 x 10 <sup>-5</sup> 1.2 x 10 <sup>-5</sup>

<sup>&</sup>lt;sup>2)</sup>Unacceptable use (Laundry disinfection in closed washing machine in households) was taken into account.

Highest PEC/PNEC values are found in aquatic compartment (see table above), but the risks ratio values are very low, thus there is no high concerns for cumulative environmental risks for peracetic acid.

#### 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 generated from TAED and sodium percarbonate in product-types 2, 3 and 4 is specified in the BPC opinions following discussions at the 18<sup>th</sup> 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  $\frac{\text{Appendix I}}{\text{Appendix I}}$ .

<sup>&</sup>lt;sup>3)</sup>Unacceptable use (see above) was not taken into account.

<sup>&</sup>lt;sup>3)</sup>Unacceptable use (see above) was not taken into account.

#### Appendix I: List of endpoints

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

Active substance (ISO Common Name)

Peracetic acid generated from tetraacetylethylenediamine (TAED) and sodium percarbonate

Product-type

PT 2: Disinfectants and algaecides not intended for direct application to humans or animals

PT 3: Veterinary hygiene PT 4: Food and feed area

#### **Identity**

Chemical name (IUPAC)

Chemical name (CA)

CAS No

EC No

Other substance No.

Minimum purity of the active substance as manufactured (g/kg or g/l)

None available

Peracetic acid is generated by reacting TAED (tetraacetylethylenediamine) with SPC (sodium percarbonate). From a product (powder or tablet) containing the precursors TAED and SPC, peracetic acid is liberated upon contact with water. TAED + 2  $H_2O_2 \rightarrow DAED$  + 2 PAA + 2  $H_2O$  Specifications are set for the precursors TAED and SPC. The min purity of tetraacetylethylenediamine, based on 5-batch analyses, is 99.0 % and the min purity of the sodium percarbonate, based on QC data, is 85.1%, derived from Active oxygen content of 13.0%. No ratio was defined for TAED and SPC in biocidal products.

Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)

Because the pure active substance is not available, the impurities and additives are not applicable for the active substance peracetic acid. Specifications are based on the precursors TAED and SPC. Max concentrations for impurities were set for impurities including heavy metals and iron for both precursors. For the impurities and exhaustive lists of coatings, see the Confidential folder.

Molecular formula

Molecular mass

Structural formula

 $C_2H_4O_3$ 

76.05 g/mol

#### Physical and chemical properties

Melting point (state purity)

The physical and chemical properties listed refer to peracetic acid as in CARs PT1-6 and

11, 12. Hence this section covers properties of aqueous solutions of peracetic acid and, for some endpoints, properties calculated or extrapolated to pure peracetic acid, as in CARs PT1-6 and 11,12. The relevance to peracetic acid generated from TAED and SPC may depend on the endpoint.

The melting points of 5% solutions are in the range of -26°C to -30°C.

The melting points of 15% solutions are in the range of -30°C to -50°C.

The melting point of the representative "Peracetic acid 15%" is -73°C.

The melting point of the pure PAA is 0°C.

Boiling point (state purity)

The boiling points of 5% solutions are in the range of  $99^{\circ}\text{C}$  to  $105^{\circ}\text{C}$ .

The boiling points of 15% solutions are above 100°C.

For neat PAA, a boiling point of 110°C at 760 mmHg was calculated.

The boiling point of the representative "Peracetic acid 15%" is 105°C.

Temperature of decomposition

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.

Appearance (state purity)

Relative density (state purity)

Clear, colorless liquid (all PAA solutions)

 $D^{20}_4 = 1.1535$  (15% product "PEROXYACETIC ACID 15%")

 $D^{20}_4 = 1.1284$  (5% product "PEROXYACETIC ACID 5%")

Surface tension

54.0 mN/m at 20°C (ring method, 5% product "PEROXYACETIC ACID 5%")

47.7 mN/m at 20°C (ring method, 15% product "PEROXYACETIC ACID 15%")

This indicates that PAA does not need to be regarded as surface active, because only substances exhibiting a surface tension < 60 mN/m when tested at a concentration of 0.1% are regarded as surface active.

Vapour pressure (in Pa, state temperature)

 $p_{(20^{\circ}C)} = 14.1 \text{ hPa}$ 

The overall vapour pressure of the representative product "Peracetic acid 15%" is 17 hPa.

Henry's law constant (Pa m<sup>3</sup> mol -1)

0.217 Pa m3mol-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,

Solubility at 25°C (15% product "PEROXYACETIC ACID 15%"):

Peracetic acid generated from TAED and sodium percarbonate	Product types Final CAR December 2, 3 and 4 2016
state temperature)	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 biocic products including relevant breakdorproducts	
Partition coefficient (log $P_{\text{ow}}$ ) (statemperature)	te pH5: -0.46 (temperature not indicated)
	pH7: -0.60 (temperature not indicated)
	pH9: -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 a temperature)	Determined for an initial TS concentration (C <sub>0</sub> ) of 0.001 mol PAA/L (95 ppm):
	pH4: 46.7 hours (at 25°C)
	pH7: 31.7 hours (at 25°C)
	pH9: 3.6 hours (at 25°C)
Dissociation constant	$pK_a = 8.2$ (literature data) $pK_a = 8.24$ (determined using 15% product "PEROXYACETIC ACID 15%")
UV/VIS absorption (max.) (if absorption 290 nm state $\epsilon$ at wavelength)	> The UV-VIS spectra at pH <2, 7 and >12 showed no absorption maxima.
Photostability ( $DT_{50}$ ) (aqueous, sunlig state	No study on phototransformation of peracetic acid was conducted. Peracetic acid does not absorb light in the visible wavelength range.
Quantum yield of direct phototransformati in water at $\Sigma$ > 290 nm	Not applicable because of lack of absorption of light in the visible wavelength range
Flammability	15% product "PEROXYACETIC ACID 15%": Autoignition 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	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.

#### Classification and proposed labelling

with regard to physical/chemical data

The classification of the active substance peracetic acid is presented here as it was in the CARs of peracetic acid in aqueous solution (PT1-6, 11, 12). No classification separately for the active substance generated *in situ* is needed.

## 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

with regard to toxicological data

## 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 Specific Concentration Limits:

STOT SE 3; H335: C ≥ 1%

Pictograms: GHS05, GHS07 Signal Word Code:

Danger

with regard to fate and behaviour data with regard to ecotoxicological data

#### No classification

## Current classification of peracetic acid according to Regulation 1272/2008:

Aquatic Acute 1; H400 Very toxic to aquatic life M-factor 10

Pictogram:

GHS09

#### Chapter 2: Methods of Analysis

#### Analytical methods for the active substance

Technical active substance (principle of method)

No technical active substance exists for peracetic acid generated, but the following methods adapted from the CARs for aqueous solution (PTs 1-6 and 11,12) may be applicable.

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 were to be

submitted in product authorization.

Hydrogen peroxide: The sample is dissolved in 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 were to be submitted in product authorization.

The applicant has thereafter submitted further information on validation to eCA.

A validated method for determination of acetic acid had been requested at product authorisation for PTs 1-6 and 11,12.

Impurities in technical active substance (principle of method)

No technical active substance exists for peracetic acid generated.

#### Analytical methods for residues

Soil (principle of method and LOQ)

Air (principle of method and LOQ)

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

Reverse-phase HPLC with UV detection .

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 impregnated filters and then through the MTSO impregnated silica gel.

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 *via* the titanium peroxysulfate by molecular absorption spectrometry.

LOQ: 0.00072 mg/L (0.23 ppm) (peracetic acid), 0.32 ppm (hydrogen peroxide)

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.

Water (principle of method and LOQ)

MTSO is determined by reversed phase HPLC with UV detection.

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.

LOQ: 0.02 ppm (peracetic acid)

LOQ in the water method is not sufficiently low in comparison to the current lowest NOEC for aquatic environment. The eCA has received further information on method and a sound justification for non-submission on a revised method, based on measured short half-life of peracetic acid in water. This information has not yet been included in the CAR or fed in the evaluation process.

Body fluids and tissues (principle of method and LOQ)

This method is not required, due to the properties of peracetic acid.

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).

recovered as CO<sub>2</sub> after 72 hours with the majority

#### Chapter 3: Impact on Human Health

#### Absorption, distribution, metabolism and excretion in mammals

Not determined, 100% as a default. Rate and extent of oral absorption: Rate and extent of dermal absorption for the Not determined, 100% as a default. active substance: Rate and extent of dermal absorption for the Not determined, 100% as a default. representative product(s): Distribution: 20 % of radio-activity tissue-bound with highest levels found in liver, gastro-intestinal tract and exposed skin No evidence for bioaccumulation Potential for accumulation: Rate and extent of excretion: - approx. 30 - 60 % of the applied dose

Peracetic acid generated from TAED and sodium percarbonate	Product types 2, 3 and 4	Final CAR	December 2016
		formed after 24 hours; an initial lag phase of approx. 1 hour evident	
	the urine after	f given radioactivity e 72 hours; majority of red after 24 hours	
	the faeces and	of given radioactivity 17 % <i>via</i> urine after it al excretion occurred	72 hours;
Toxicologically significant metabolite(s)	None		
Acute toylelts			
Acute toxicity	1020 // //-	Neuto Tev. 4 # U2021	
Rat LD <sub>50</sub> oral	corresponding t Tox. 3; H301) 1700 mg/kg (A	Acute Tox. 4 *, H302) to 153 mg/kg (100%) cute Tox. 4 *, H302) to 85 mg/kg (100% P	PAA) (Acute
Rabbit LD <sub>50</sub> dermal	1147 mg/kg; (/ corresponding t	Acute Tox. 4 *, H312) to 00% PAA) (Acute Tox	
Rat LC <sub>50</sub> inhalation	1 mg/L ≤ LC50	≤ 5 mg/L; (Acute To	x.4 *, H332)
		ng/l (100% PAA) (A	
Skin corrosion/irritation	Corrosive; (Ski	n Corr. 1A, H314)	
Eye irritation	Corrosive (sevent) Corr. 1A H314)	ere damage to the	eyes); (Skin
Skin sensitization (test method used a result)	and Non-sensitising	(GPMT)	
Repeated dose toxicity			
•			
Species/ target / critical effect		cal irritation in sto no systemic effects	omach/gastro-
Lowest relevant oral NOAEL / LOAEL	00-days gayag	e study in rate NOA	El 15 ma/ka

Lowest relevant oral NOAEL / LOAEL

Lowest relevant dermal NOAEL / LOAEL Lowest relevant inhalation NOAEL / LOAEL

90-days gavage study in rats NOAEL 15 mg/kg bw/day corresponding to 0.055% PAA

Not established

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

In vitro: Positive results in in vitro cytogenetic assay (chromosome aberrations) in human lymphocytes. Negative results in Ames test, gene mutation assay in mammalian cells, negative/equivocal in vitro chromosome aberration assay with Chinese hamster lung fibroblasts

In vivo: Equivocal in three micronucleus tests and in vivo UDS. 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.

Weight of evidence indicates no concern of mutagenic / genotoxic potential

#### Carcinogenicity

Species/type of tumour

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)

No concern of mutagenic / genotoxic potential.

Site of contact carcinogenicity not tested.

lowest dose with tumours

n.a.

#### Reproductive toxicity

Species/ Reproduction target / critical effect

No indication of reproductive toxicity in 90-days oral and continuous breeding studies

In the absence of both teratogenic effect and findings on reproductive organs in repeated dose toxicity studies, no study is required for this 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

Species/Developmental target / critical effect

n.a.

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

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.

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

The toxicity of Peracetic acid has been investigated and it has been shown not to be mutagenic or teratogenic.

In the summary report of the Committee for Veterinary Medicinal Products (CVMP) on Peracetic acid (EMEA/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.

Studies related to the exposure of the a.s. to humans

Food and feeding stuffs

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.

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.

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.

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.

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.

No MRL setting is required as peracetic acid is not persistent, no systemic effects are observed and because of its high reactivity.

No information related to the residues on precursors is available.

Other tests related to exposure of the a.s. to human considered to be necessary

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.

Product types 2, 3 and 4

Final CAR

December 2016

Tests to assess toxic effects from metabolites of treated plants

Peracetic acid is not used in products for action against plants.

Therefore, no tests to assess toxic effects of metabolites from treated plants are required.

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.

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

Mechanistic studies

Further human health related studies

#### **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 form 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

No data available

Diagnosis of poisoning including specific signs of poisoning and clinical tests

Peracetic acid generated from TAED and sodium percarbonate	Product types 2, 3 and 4	Final CAR	December 2016
Sensitization/allergenicity observations	lergenicity observations  The cases of twheezing and exposed to PA vapours are in observed were continuous contightness apprexposure to Paremoval from		fter being (PAA-HP) symptoms ctivitis, nd chest urs of proved after cluded that enerated by an all prolonged tures caused ence of a
Specific treatment in case of an accident or poisoning: first aid measures and medical treatment	treatment is waknown. <u>Eyes:</u> In case of thoroughly with immediately. <u>Skin:</u> Remove of affected body and soap. <u>Ingestion:</u> Rins	ntamination and symptomic and symptomic and specific of contact with eyes represented the contaminated clothes are as carefully with presented the cout mouth and given the couth and give	antidote is rinse nysician s. Wash elenty of water

Prognosis following poisoning

#### Peracetic acid:

**Summary** 

ADI (acceptable daily intake, external longterm 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)

Value	Study	Safety factor
n.a.; PAA does not cause systemic effects	1	-
n.a.; PAA does not cause systemic effects	1	-
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/m³ (0.16 ppm)	Human data (NOAEC 0.5 ppm)	3.16
n.a.; PAA does not cause systemic effects	-	-
-	-	-

Inhalation: Ensure supply of fresh air. Contact a

physician as necessary.

Depending on severity of effects

	Product types 2, 3 and 4	Final CAR	December 2016
Reference value for dermal absorption concerning the active substance:	100% as a default	-	-
Reference value for dermal absorptio concerning the representative product(s) <sup>4</sup> :	n 100% as a default	-	-
Hydrogen peroxide:			
Skin irritating threshold	35%	classification limit for irritation	-
AEC inhalation	1.25 mg/m <sup>3</sup>	NOAEC in 90- day inhalation rat study	8
TAED:			
AEL short-term/ medium-term/ long-term	0.9 mg/kg bw/day	NOAEL in 90- day oral study in rats	100
DAED:		•	L
AEL short-term/ medium-term/ long-term	57 mg/kg bw/day	NOEL in 13- week rat feeding study	100
Sodium percarbonate:		•	L
dermal DNEL for local effects	6.4 mg/cm <sup>2</sup>		
		<del> </del>	

Other toxicological reference values of precursors could be completed at product authorisation when the guidance on precursors is available.

inhalation DNEL for local effects

2.5 mg/m<sup>3</sup>

Acceptable exposure scenarios (for method of calculation, please refer to Appendix III)		
Industrial and professional users:		
Production of active substance:	No risk characterisation is made.	
Formulation of biocidal product	No risk characterisation is made.	
Intended uses	PT2 Disinfection of surfaces in industrial, public and health care areas: PPE (goggles + skin protection)	
	PT2 Laundry disinfection in closed washing machines: PPE (goggles + skin protection)	
	PT3 Disinfection of animal houses by low-pressure manual spraying: PPE (goggles + skin protection + RPE)	
	PT3 Disinfection of equipment by dipping: PPE (goggles + skin protection)	
	PT4 Disinfection of equipment in the food and beverage industry by dipping and immersion: PPE (goggles + skin protection)	

protection + RPE)

PT4 Disinfection of surfaces and equipment by low pressure manual spraying: PPE (goggles + skin

Product types	Final CAR	December 2016
2, 3 and 4		2016
PT2: Inhalation e machine.	exposure during loadi	ing of washing
PT2: Dermal exp	osure via wearing of	clothes
PT2: Oral exposu	re via licking/sucking	g on clothes
PT2: Inhalation exposure during disinfection (wiping and mopping) and draining.		
		ected
PT2: Oral exposuobjects.	ire via disinfected su	rfaces/
PT2: Dermal and floors.	oral exposure via di	sinfected
		raying
		-
	PT2: Inhalation emachine. PT2: Dermal exp PT2: Oral exposu PT2: Inhalation eand mopping) and PT2, 3, 4: Dermal surfaces/objects. PT2: Oral exposu objects. PT2: Dermal and floors. PT3, 4: Inhalatio (animal houses a	PT2: Inhalation exposure during loadinachine.  PT2: Dermal exposure via wearing of PT2: Oral exposure via licking/sucking PT2: Inhalation exposure during disinand mopping) and draining.  PT2, 3, 4: Dermal exposure via disinfected surfaces/objects.  PT2: Oral exposure via disinfected surfaces.  PT2: Dermal and oral exposure via disinfected.

Indirect exposure as a result of use

Inhalation exposure during m&l, hand-washing and draining.

Dermal exposure via wearing of clothes

Oral exposure via licking/sucking on clothes

#### 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 pН and temperature)

Determined for an initial TS concentration (Co) of 0.001 mol PAA/L (95 ppm):

\_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 metabolites

No study on phototransformation of peracetic acid was conducted. Peracetic acid does not absorb light in the visible wavelength range.

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.

Readily biodegradable (yes/no)

Biodegradation in seawater

Non-extractable residues

Distribution in water / sediment systems (active substance)

yes

50% degradation within 2 minutes

Not formed

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, Distribution in water / sediment systems (metabolites)

2.99 % to the air and only 0.00001 % into sediment (fugacity level III calculation according to Mackay using EPIWIN v.3.20).

Peracetic acid remains mainly in the water phase due to its high solubility in water and low  $K_{\text{oc}}$ . Any amount coming in contact with the sediment is rapidly decomposed.

According to a fugacity level III calculation, peracetic acid only partitions into the sediment at very low rates (see above).

#### Route and rate of degradation in soil

Mineralization (aerobic)

Laboratory studies (range or median, with number of measurements, with regression coefficient) 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.

DT<sub>50lab</sub> (20°C, aerobic): No reliable data available

At the WG II 2016 it was agreed to use  $DT_{50}$  of hydrogen peroxide of 12 hrs in the absence of reliable  $DT_{50}$  for peracetic acid.

DT<sub>90lab</sub> (20°C, aerobic): No reliable data available

DT<sub>50lab</sub> (10°C, aerobic): No reliable data available

DT<sub>50lab</sub> (20°C, anaerobic): not data

Degradation in the saturated zone: no data.

Field studies (state location, range or median with number of measurements)

DT<sub>50f</sub>: no data from field studies available

DT<sub>90f</sub>: no data from field studies available

Anaerobic degradation

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.

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

% Perace

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<sub>2</sub>, water and oxygen.

Soil accumulation and plateau concentration

No accumulation due to rapid and complete degradation to CO<sub>2</sub>, water and oygen.

#### Adsorption/desorption

Ka , Kd

The adsorption coefficient was calculated applying QSAR (according to page 26 of TGD) for soil and

Peracetic acid generated from TAED and sodium percarbonate	Product types 2, 3 and 4	Final CAR	December 2016
$Ka_{oc}$ , $Kd_{oc}$ pH dependence (yes / no) (if yes type of dependence)	sediment.  The calculated has consequently, as mobile in soi	peracetic acid is to	be considered

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

Peracetic acid generated from TAED and sodium percarbonate	Product types 2, 3 and 4	Final CAR	December 2016

Activated sludge	3 hours	Respiration rate	EC <sub>50</sub> = 5.1 mg/L
			-+30

#### Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms  $| 14\text{-day LC}_{50} | > 1000 \text{ mg/kg dry soil equals} > 885 \text{ mg/kg wet soil.}$ 

Reproductive toxicity to ........................

Effects on soll micro-organisms

Nitrogen mineralization 28-day EC<sub>50</sub>: > 933.6 mg/kg dry soil equals 826.2 mg/kg wet soil

Carbon mineralization 28-day EC<sub>50</sub>: > 933.6 mg/kg dry soil equals 826.2

mg/kg wet soil

**Effects on terrestrial plants** 

21-day EC<sub>50</sub>: 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

**Bioconcentration** 

Bioconcentration factor (BCF)

The low  $logP_{ow}$  (<< 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.

Peracetic acid generand sodium percarb		Product types 2, 3 and 4	Final CAR	December 2016
		Not experiment	ally determined	
Depuration time	(DT <sub>50</sub> )	Not applicable:	no test performed	
(DT <sub>90</sub> )		can be excluded	cetic acid into the org I due the instantane peracetic acid in con II.	ous
Level of metabolites (%) in organisms accounting for > 10 % of residues		Not applicable:	no test performed	

Chapter 6: Other End Points

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

# **Appendix II: List of Intended Uses**

Object and/or situation	Product Name*	Organisms controlled	Formulation	Application	Applied amount per treatment	Remarks:
			Туре	method, number and interval between applications (min)		Data accepted to support intended use*):
MG1/PT2  Laundry disinfection in closed washing machines – household use	In situ PAA product 1	Bacteria, yeasts and viruses	Powder	The product is manually dosed into the washing machine using a dosing cup.  Daily/weekly use	350 - 700 ppm in situ PAA, depending on the dosage of the product.  Dosing of product depends on water hardness and the degree of pollution of the textiles and ranges from 14 g/kg dry textiles (= 20 mL/kg) to 28 g/kg dry textiles (= 40 mL/kg).	Efficacy at 525 ppm in situ formed PAA against bacteria (30-40 °C, contact time ≥5min) and against viruses (40 °C, contact time ≥ 30 min) was shown
MG1/PT2 Soaking or hand-washing of laundry in households	In situ PAA product 1	Bacteria, yeasts and viruses	Powder	The product is manually dosed with a dosing cup into a washbowl or wash basin filled with water.  Daily/weekly use	350 - 700 ppm in situ PAA, depending on the dosage of the product.  Dosing of product depends on water hardness and the degree of pollution of the textiles and ranges from 14 g/kg dry textiles (= 20 mL/kg) to 28 g/kg dry textiles (= 40 mL/kg).	Efficacy at 525 ppm in situ formed PAA against bacteria (30-40 °C, contact time ≥5min) and viruses (40 °C, contact time ≥ 30 min) was shown
MG1/PT2 Laundry disinfection in closed washing machines – Industrial & Institutional use (professional use)	In situ PAA product 2	Bacteria, yeasts and viruses	Powder	The product is manually dosed into the washing machine using a dosing cup.  Daily use	48 - 143 ppm <i>in situ</i> PAA, depending on the dosage of the product.  Dosing of product depends on water hardness and the degree of pollution of the textiles and ranges from 14 g/kg dry textiles (= 24 mL/kg) to 42 g/kg dry textiles (= 72 mL/kg).	Efficacy at 133 ppm in situ formed PAA against bacteria (60 °C, contact time 15 min) and at 47 ppm in situ formed PAA against yeasts (45°C, contact time 15 min) was shown.

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

MG1/PT2 Disinfection of hard surfaces, floors and walls in industrial, public and health care areas by wiping	In situ PAA product 3	Bacteria, spores, yeasts and viruses	Powder	The product is mixed with water and then the solution is applied by wiping of hard surfaces with flat mops or cleaning cloths.  Daily use	1250 - 2500 ppm (corresponding to a 1 - 2 % (w/v) application solution of Theoretical in situ product 3) ca. 0.02 L/m² of a 2 % application solution are needed	Efficacy at 2500 ppm in situ formed PAA against bacteria (20°C, contact time 5 min), yeasts (20°C, contact time 15 min), bacterial spores (20°C, contact time ≥5 min), and viruses (20°C, contact time ≥10 min) was shown.
MG1/PT3  Disinfection of surfaces in animal houses by low pressure manual spraying	In situ PAA product 3	Bacteria, spores, yeasts and viruses	Powder	Floors and walls of animal houses are disinfected by low pressure spraying with a hand held spray wand. The spraying is performed at low pressure avoiding the formation of aerosols.  Frequency: two times a year - weekly applications	1250 - 2500 ppm (corresponding to a 1 - 2 % (w/v) application solution of Theoretical in situ product 3) ca. 0.4 L/m² of a 2 % application solution are needed	Efficacy at 2500 ppm in situ formed PAA against bacteria (20°C, contact time 5 min), yeasts (20°C, contact time 15 min), bacterial spores (20°C, contact time ≥5 min), and viruses (20°C, contact time ≥5 min) was shown. Test parameters relevant to PT2,4.  Efficacy of PAA at 250-500 ppm against bacteria and viruses relevant to PT3 has been shown. See CAR of PAA PT1-6.
MG1/PT3  Disinfection of equipment in animal houses by dipping	In situ PAA product 3	Bacteria, spores, yeasts and viruses	Powder	Equipment in animal houses is dipped into baths containing the freshly prepared in-use solution and removed after 30 minutes.	1250 - 2500 ppm (corresponding to a 1 - 2 % (w/v) application solution of Theoretical <i>in</i> <i>situ</i> product 3)	Efficacy at 2500 ppm in situ formed PAA against bacteria (20°C, contact time 5 min), yeast (20°C, contact time 15 min), bacterial spores (20°C, contact time ≥5 min), and viruses (20°C, contact time

		and sodium	percarbonate	2, 3 and 4	2016	
						≥10 min) was shown. Test parameters relevant to PT2,4.  Efficacy of PAA at 250- 500 ppm against bacteria and viruses relevant to PT3 has been shown. See CAR
MG1/PT4  Disinfection of hard surfaces, floors and walls in food and beverage industry by wiping with flat mops and cleaning cloths or by low pressure manual spraying	In situ PAA product 3	Bacteria, spores, yeasts and viruses	Powder	The product is first mixed with water and then the solution is applied by wiping of hard surfaces with flat mops or cleaning cloths or by low pressure manual spraying.  Daily use	1250 - 2500 ppm (corresponding to a 1 - 2 % (w/v) application solution of Theoretical in situ product 3) ca. 0.02 L/m² of a 2 % application solution are needed	of PAA PT1-6.  Efficacy at 2500 ppm in situ formed PAA against bacteria (20°C, contact time 5 min), yeasts (20°C, contact time 15 min), bacterial spores (20°C, contact time ≥5 min), and viruses (20°C, contact time ≥10 min) was shown.
MG1/PT4  Disinfection of equipment by dipping in food & beverage industries	In situ PAA product 3	Bacteria, spores, yeasts, and viruses	Powder	Equipment in food & beverage industries is dipped into baths containing the freshly prepared in-use solution and removed after 30 minutes.	1250 - 2500 ppm (corresponding to a 1 - 2 % (w/v) application solution of Theoretical <i>in</i> <i>situ</i> product 3)	Efficacy at 2500 ppm in situ formed PAA against bacteria (20°C, contact time 5 min), yeasts (20°C, contact time 15 min), bacterial spores (20°C, contact time ≥5 min), and viruses (20°C, contact time ≥10 min) was shown.

**Product types** 

Final CAR

December

Peracetic acid generated from TAED

<sup>\*)</sup> Products referred to in the CAR are theoretical products and hence efficacy data on real products appropriately simulating in-use conditions (e.g. for PT 3: high level soiling and organisms representative for the application area) have to be submitted at product authorisation phase.

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

# Appendix III: Tables of Risk Characterisation for Human Health

# Tables Appendix III-1: Product 1 in PT2

# Primary exposure non-professional user

_	Concentrated product [%]	Exposure				
Exposure scenario	In-use concentration [%]	Inhalation [mg/m³] or [mg/kg bw/day]	Dermal [mg/kg bw/day] or [mg/cm <sup>2</sup> ]	Total [mg/m³] or [mg/kg bw/day]	% AEL/AEC/DNEL**	Model used
PT2: Private area and public healt	h area disinfecta:			, , , , , , , , , , , , , , , , , , , ,		•
	Filling: 15 (TAED)/ 40 (SP)*	0.005 mg/m <sup>3</sup> (SP)	Not relevant (HP*) 3.1×10 <sup>-4</sup> mg/cm <sup>2</sup> (SP)	0.005 mg/m³ (SP) 3.1×10 <sup>-4</sup> mg/cm² (SP)	0.2% (SP, inhalation) 0.005% (SP, dermal)	Filling: Data from the Disinfection Products Factsheet of ConsExpo (Mixing and loading:
	Application:	3.1×10 <sup>-6</sup> (TAED)	1.08×10 <sup>-4</sup> (TAED)	1.1×10 <sup>-4</sup> (TAED)	0.01% (TAED)	dissolving powder and granules, p. 26)
Laundry disinfection in closed washing machines  • Filling and unloading of washing machine	0.0012 (TAED) 0.0787 (DAED) 0.084 (PAA) 0.0718% (HP)***  Post- application	Not relevant (DAED)	3.3×10 <sup>-4</sup> (DAED)	3.3×10 <sup>-4</sup> (DAED)	0.0006% (DAED)	Unloading: generic model and HERA TGD 2005.
	(removal): 0.000032 (TAED) 0.00197 (DAED)					
Laundry disinfection by soaking/hand-washing  Filling of	Filling: 15 (TAED)/ 40 (SP)	0.00014 mg/m <sup>3</sup> (PAA, appl.) 0.0007 mg/m <sup>3</sup> (PAA, p-a)	Not relevant (PAA)	0.00014 mg/m <sup>3</sup> (PAA, appl.) 0.0007 mg/m <sup>3</sup> (PAA, p-a)	0.03% (PAA, appl.) 0.14% (PAA, p-a)	Filling: Data from the Disinfection Products Factsheet of ConsExpo (Mixing and loading:

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

washbowl/wash basin, manual disinfection, draining of disinfection solution, removal of laundry from washbowl/wash basin		0.005 mg/m³ (SP) 0.00012 mg/m³ (HP, appl.) 0.0006 mg/m³ (HP, p-a)	Not relevant (HP) 3.2×10 <sup>-4</sup> mg/cm <sup>2</sup> (SP)	0.005 mg/m³ (SP) 3.2×10 <sup>-4</sup> mg/cm² (SP) 0.00012 mg/m³ (HP, appl.) 0.0006 mg/m³ (HP, p-a)	0.2% (SP, inhalation) 0.005% (SP, dermal) 0.01% (HP, inhalation, appl.) 0.05% (HP, inhalation, p-a)	dissolving powder and granules, p. 26) Manual disinfection: Data from the Cleaning Products Fact Sheet of ConsExpo (Hand wash, p. 35) for dermal exposure; TNsG, part II: "dipping model no. 4" for
	Application/post-application (draining): 0.00105 (TAED) 0.0655 (DAED) 0.07 (PAA)*** 0.06 (HP)***  Post-application (removal): 0.000105% (TAED) 0.00655% (DAED)	3.1×10 <sup>-6</sup> (TAED)  2x10 <sup>-6</sup> (DAED)	0.00268 (TAED)  0.16088 (DAED)	0.0027 (TAED)  0.161 (DAED)	0.3% (TAED)  0.3% (DAED)	inhalation Unloading: generic model and HERA TGD 2005. Draining: Mixing and loading model no 7 (revised), "pouring liquids"

<sup>\*:</sup> SP = Sodium percarbonate; HP = Hydrogen peroxide

<sup>\*\*:</sup> Inhalation AEC for peracetic acid = 0.5 mg/m³ and for hydrogen peroxide = 1.25 mg/m³; AEL<sub>TAED</sub> = 0.9 mg/kg bw/day; AEL<sub>DAED</sub> = 57 mg/kg bw/day; dermal DNEL for local effects of sodium percarbonate = 6.4 mg/cm², (proposed) inhalation DNEL for local effects = 2.5 mg/m³ (according to or based on REACH registration dossier)

<sup>\*\*\*:</sup> In-use concentration of peracetic acid is below the dermal NOAEC (0.2% in short/medium-term exposure and 0.1% in long-term exposure). In-use concentration of hydrogen peroxide is below the concentration limit for classification as skin irritating (35%).

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

### Secondary exposure – short term (acute)

		Exposure route		In-use	Expos		
	Intended use (MG/PT)		Person	concentration [%]	Inhalation [mg/m³] or [mg/kg bw/day]	Systemic [mg/kg bw/day]	% AEL/AEC*
Secondary inhalation exposure during mixing/loading, manual disinfection of laundry and draining of disinfection solutions			0.07 (PAA) **	0.00014 mg/m <sup>3</sup> (PAA, appl.) 0.0007 mg/m <sup>3</sup> (PAA, p-a)	n.a. (PAA)	0.03% (PAA, appl.) 0.14% (PAA, p-a)	
	PT2	PT2 inhalation adul	adult	0.06 (HP)**	0.005 mg/m³ (SP) 0.00012 mg/m³ (HP, appl.) 0.0006 mg/m³ (HP, p- a)	n.a. (HP)	0.2% (SP) 0.01% (HP, appl.) 0.05% (HP, p-a)
				0.00105 (TAED)	3.1×10 <sup>-6</sup> (TAED)	3.1×10 <sup>-6</sup> (TAED)	0.0003% (TAED)
				0.0655 (DAED)	2x10 <sup>-6</sup> (DAED)	2x10 <sup>-6</sup> (DAED)	0.000004% (DAED)

<sup>\*:</sup> Inhalation AEC for peracetic acid = 0.5 mg/m³ and for hydrogen peroxide = 1.25 mg/m³; AEL<sub>TAED</sub> = 0.9 mg/kg bw/day; AEL<sub>DAED</sub> = 57 mg/kg bw/day

<sup>\*\*:</sup> In-use concentration of peracetic acid is below the dermal NOAEC (0.2% in short/medium-term exposure). In-use concentration of hydrogen peroxide is below the concentration limit for classification as skin irritating (35%).

n.a.: not applicable

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

### Secondary exposure - long term (chronic)

F		lad		In-use	Ехро		
Exposure scenario	Intended use (MG/PT)	Exposure route	Person	concentration [%]*	Dermal**/Oral [mg/kg bw/day]	Systemic** [mg/kg bw/day]	% AEL***
Exposure <i>via</i> disinfected laundry	PT2	dermal	adult	0.000105 (TAED) 0.00655 (DAED)	1.93×10 <sup>-3</sup> (TAED) 0.12(DAED)	1.93×10 <sup>-3</sup> (TAED) 0.12 (DAED)	0.2% (TAED) 0.2% (DAED)
Exposure via disinfected laundry	PT2	oral	infant	0.000105 (TAED) 0.00655 (DAED)	0.0006 (TAED) 0.038 (DAED)	0.0006 (TAED) 0.038 (DAED)	0.07% (TAED) 0.07% (DAED)

#### **Combined exposure – long term (chronic)**

Exposure scenario	Intended use (MG/PT)	Exposure route	Person	Exposure Systemic** [mg/kg bw/day]	% AEL***
Combined exposure: Laundry disinfection with washing machines and exposure via disinfected laundry	PT2	dermal and inhalation	adult	0.00204 (TAED) 0.1203 (DAED)	0.2% (TAED) 0.2% (DAED)
Combined exposure: Laundry disinfection by soaking/hand-washing and exposure <i>via</i> disinfected laundry	PT2	dermal and inhalation	adult	0.0058 (TAED) 0.352 (DAED)	0.6% (TAED) 0.6% (DAED)

<sup>\*\*:</sup> Dermal penetration of 25% for TAED concentrations >5%, 75% for TAED concentrations ≤5% and for DAED (concentration ≤5%).

<sup>\*:</sup> In use concentrations after rinsing (10 % of initial in-use concentrations)
\*\*: Dermal penetration of 25% for TAED concentrations >5%, 75% for TAED concentrations ≤5% and for DAED (concentration ≤5%).

<sup>\*\*\*:</sup> AELTAED = 0.9 mg/kg bw/day; AELDAED = 57 mg/kg bw/day

<sup>\*\*\*:</sup> AELTAED = 0.9 mg/kg bw/day; AELDAED = 57 mg/kg bw/day

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

### Tables Appendix III-2: Product 2 in PT2

## Primary exposure professional use

		Concentrated product [%]		Exposure			
Exposure scenario	Working conditions	In-use concentration	Inhalation	Dermal	Total	% AEL/AEC/ DNEL**	Model used
		[%]	[mg/kg bw/day] or [mg/m³]	[mg/kg bw/day] or [mg/cm <sup>2</sup> ]	[mg/kg bw/day] or [mg/m <sup>3</sup> ]		
PT2: Private area and public l	nealth area di:	sinfectants and other bio	ocidal products				
Laundry Disinfection in Closed Washing Machines –	Goggles and gloves	Filling: 4 (TAED)	0.99 mg/m <sup>3</sup> (SP)	Not relevant (HP) 0.78 mg/cm <sup>2</sup> (SP,	I U.33 M2/M-13PJ - I	40% (SP, inhalation) 12% (SP, dermal)	Loading: Mixing/loading
Professional Use	(for local	15 (SP)*		no gloves)	0.78 mg/cm <sup>2</sup> (SP,	1270 (SI , derillar)	model no. 5
<ul> <li>Loading of washing machines</li> </ul>	effects)				no gloves)		(Lundehn et al) Unloading:
<ul> <li>Unloading of washing machine</li> </ul>	No PPE	Application (initial contents in washing	0.046 (TAED)	0.5356 (TAED)	0.582 (TAED)	65% (TAED)	generic model and HERA TGD
		liquor): 0.000336 (TAED) 0.021 (DAED) 0.0143 (PAA) 0.031 (HP)*	Not relevant (DAED)	3.2×10 <sup>-3</sup> (DAED)	3.2×10 <sup>-3</sup> (DAED)	0.006% (DAED)	2005.
		Post-application (removal) 0.0000084 (TAED) 0.000525 (DAED)					

<sup>\*:</sup> SP/HP = Sodium percarbonate/Hydrogen peroxide

<sup>\*\*:</sup> AEL<sub>TAED</sub> = 0.9 mg/kg bw/day; AEL<sub>DAED</sub> = 57 mg/kg bw/day; dermal DNEL for local effects of sodium percarbonate = 6.4 mg/cm<sup>2</sup>, (proposed) inhalation DNEL for local effects = 2.5 mg/m<sup>3</sup> (according to or based on REACH registration dossier)

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

#### Secondary exposure – short term (acute)

			In-use	Ехро			
Exposure scenario	e Intended use Exposure route Person concent		concentration	Inhalation [mg/kg bw/day] or [mg/m³]	Systemic [mg/kg bw] or [mg/m³]	% AEL/DNEL**	
Disinfection of laundry – loading of	PT2	inhalation	adult	4 (TAED)	0.046 (TAED)	0.046 (TAED)	5.1% (TAED)
washing machines				15 (SP)*	0.99 mg/m <sup>3</sup> (SP)	Not relevant (SP)	40% (SP)

<sup>\*:</sup> SP = Sodium percarbonate

### Secondary exposure - long term (chronic)

F	Intended			In use concentration	Ехро		
Exposure scenario	use (MG/PT)	Exposure route	Person	In-use concentration [%]	Dermal/Oral [mg/kg bw/day]	Systemic* [mg/kg bw/day]	% AEL**
Exposure <i>via</i> disinfected laundry	PT2	dermal	adult	0.0000084 (TAED) 0.00525 (DAED)	1.54×10 <sup>-4</sup> (TAED) 0.0096(DAED)	1.54×10 <sup>-4</sup> (TAED) 0.0096(DAED)	0.02% (TAED) 0.02% (DAED)
Exposure <i>via</i> disinfected laundry	PT2	oral	infant	0.0000084 (TAED) 0.00525 (DAED)	0.00006 (TAED) 0.0039 (DAED)	0.00006 (TAED) 0.0039 (DAED)	0.007% (TAED) 0.007% (DAED)

<sup>\*:</sup> Dermal penetration of 75% for TAED and DAED (concentrations ≤5% ).
\*\*: AEL<sub>TAED</sub> = 0.9 mg/kg bw/day; AEL<sub>DAED</sub> = 57 mg/kg bw/day

<sup>\*\*:</sup> AEL<sub>TAED</sub> = 0.9 mg/kg bw/day; AEL<sub>DAED</sub> = 57 mg/kg bw/day; (proposed) inhalation DNEL for local effects of sodium percarbonate = 2.5 mg/m³ (according to or based on **REACH registration dossier)** 

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

# Combined exposure – long term (chronic)

Exposure scenario	Intended use (MG/PT)	Exposure route	Exposure Systemic** [mg/kg bw/day]	% AEL***
Combined exposure: Laundry disinfection with washing machines and exposure via disinfected laundry	PT2	dermal and inhalation	0.5822 (TAED) 0.0128 (DAED)	65% (TAED) 0.02% (DAED)

<sup>\*\*:</sup> Dermal penetration of 25% for TAED concentrations >5%, 75% for TAED concentrations ≤5% and for DAED (concentration ≤5%).

<sup>\*\*\*:</sup> AELTAED = 0.9 mg/kg bw/day; AELDAED = 57 mg/kg bw/day

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

### Tables Appendix III-3: Product 3 in PT2, 3 and 4

#### Primary exposure industrial/professional use

		Concentrated product [%]		Exposure			
Exposure scenario	Working conditions	In-use	Inhalation	Dermal	Total	% AEL/ AEC/DNEL**	Model used
		concentration [%]	[mg/m³] or [mg/kg bw/day]	[mg/kg bw/day] or [mg/cm²]	[mg/m³] or [mg/kg bw/day]		
PT2: Private area and public	health area di	sinfectant					
Disinfection of floors, walls and hard surfaces in industrial, public and health care areas by wiping with			0.072 mg/m <sup>3</sup> (PAA, appl.) 0.0024 mg/m <sup>3</sup> (PAA, p-a)	Not relevant (PAA)	0.072 mg/m <sup>3</sup> (PAA, appl.) 0.0024 mg/m <sup>3</sup> (PAA, p-a)	14% (PAA, appl.) 0.5 (PAA, p-a)	Mixing/loading model no. 5 (Lundehn et al) + TNsG, part II:
flat mops and cleaning cloths  • preparation of disinfection solution		Mixing and loading: 25 (TAED) 50 (SP)*	0.31 mg/m <sup>3</sup> (SP)	Not relevant (HP) 0.0025 mg/cm <sup>2</sup> (SP)	0.31 mg/m³ (SP) 0.0025 mg/cm² (SP)	12% (SP, inhalation) 0.04% (SP, dermal)	mixing/loading model no. 7 (revised) "pouring liquids"
<ul> <li>disinfection by wiping</li> <li>draining of disinfection solution</li> </ul>	Goggles, gloves	30 (31 )	0.051 mg/m <sup>3</sup> (HP, appl.) 0.002 mg/m <sup>3</sup> (HP, p- a)		0.051 mg/m <sup>3</sup> (HP, appl.) 0.002 mg/m <sup>3</sup> (HP, p- a)	4% (HP, appl.) 0.2% (HP, p-a)	+ Surface disinfection (manual) model. no. 1 + 2
		Application/ post-	0.0029 (TAED)	0.0034 (TAED)	0.0063 (TAED)	0.7% (TAED)	
		application 0.005 (TAED) 0.312 (DAED) 0.25 (PAA)*** 0.176 (HP)*	0.01 (DAED)	0.144 (DAED)	0.154 (DAED)	0.3% (DAED)	

<sup>\*:</sup> SP/HP = Sodium percarbonate/Hydrogen peroxide

<sup>\*\*:</sup> Inhalation AEC values for peracetic acid = 0.5 mg/m³ and for hydrogen peroxide = 1.25 mg/m³; AEL<sub>TAED</sub> = 0.9 mg/kg bw/day; AEL<sub>DAED</sub> = 57 mg/kg bw/day; dermal DNEL for local effects of sodium percarbonate = 6.4 mg/cm², (proposed) inhalation DNEL for local effects of sodium percarbonate = 2.5 mg/m³ (according to or based on REACH registration dossier)
\*\*\*: In-use concentration is **over** the dermal NOAEC for PAA (0.1% in long-term exposure, 0.2% in short/medium-term exposure).

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

Primary exposure industrial/professional use (cont'd)

		Concentrated product [%]		Exposure				
Exposure scenario	Working conditions	In-use concentration [%]	Inhalation [mg/m³] or [mg/kg bw/day]	Dermal [mg/kg bw/day] or [mg/cm²]	Total [mg/m³] or [mg/kg bw/day]	% AEL/ AEC/DNEL**	Model used	
PT3: Veterinary hygiene pro	oducts							
Manual spraying of animal houses  • preparation of disinfection solution • loading of sprayer • disinfection by			aerosols: 0.19 mg/m³ (PAA), 0.0048 mg/m³ (PAA, RPE40) vapour: 17.3 mg/m³ (PAA), 0.43 mg/m³ (PAA, RPE40)	Not relevant (PAA)	17.49 mg/m³ (PAA) 0.437 mg/m³ (PAA, RPE40)	3500% (PAA) 87% (PAA, RPE40)	Mixing/loading model no. 5 (Lundehn et al) + spraying model no. 2 (includes loading) for	
manual spraying     (aerosols and     vapour)	Goggles, gloves, coverall, boots and RPE in spraying	Mixing and loading: 25 (TAED) 50 (SP)*	0.94 mg/m³ (SP)  aerosols: 0.13 mg/m³ (HP), 0.0033 mg/m³ (HP, RPE40)  vapour: 1.97 mg/m³ (HP), 0.049 mg/m³ (HP, RPE40)	Not relevant (HP) 0.0075 mg/cm <sup>2</sup> (SP)	0.94 mg/m <sup>3</sup> (SP)  0.0075 mg/cm <sup>2</sup> (SP)  2.1 mg/m <sup>3</sup> (HP)  0.053 mg/m <sup>3</sup> (HP, inhalation, RPE40)	38% (SP, inhalation) 0.1% (SP, dermal) 168% (HP, inhalation) 4.2% (HP, inhalation, RPE40)	aerosols and ConsExpo 4.1 (evaporation - the area of release increases over time) for vapou	
		Application: 0.005 (TAED)	0.0085 (TAED)	0.046 (TAED)	0.0131 (TAED)	1.5% (TAED)		
		0.312 (DAED) 0.25 (PAA)*** 0.176 (HP*)	0.00996 (DAED)	0.0886(DAED)	0.098 (DAED)	0.2% (DAED)		

<sup>\*:</sup> SP/HP = Sodium percarbonate/Hydrogen peroxide

<sup>\*\*:</sup> Inhalation AEC values for peracetic acid = 0.5 mg/m³ and for hydrogen peroxide = 1.25 mg/m³; AEL<sub>TAED</sub> = 0.9 mg/kg bw/day; AEL<sub>DAED</sub> = 57 mg/kg bw/day; dermal DNEL for local effects of sodium percarbonate = 6.4 mg/cm²; (proposed) inhalation DNEL for local effects of sodium percarbonate = 2.5 mg/m³ (according to or based on REACH registration dossier)
\*\*\*: In-use concentration is **over** the dermal NOAEC for PAA (0.1% in long-term exposure, 0.2% in short/medium-term exposure).

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

#### Primary exposure industrial/professional use (cont'd)

		Concentrated product [%]		Exposure			
Exposure scenario	Working conditions	In-use	Inhalation	Dermal	Total	% AEL/ AEC/DNEL**	Model used
	conditions	concentration [%]	[mg/m³] or [mg/kg bw/day]	[mg/kg bw/day] or [mg/cm²]	[mg/m³] or [mg/kg bw/day]		
PT3: Veterinary hygiene pr	oducts						
Disinfection of equipment by dipping  • preparation of disinfection			0.0005 mg/m <sup>3</sup> (PAA, appl.) 0.0024 mg/m <sup>3</sup> (PAA, p-a)	Not relevant (PAA)	0.0005 mg/m <sup>3</sup> (PAA, appl.) 0.0024 mg/m <sup>3</sup> (PAA, p-a)	0.1% (PAA, appl.) 0.5% (PAA, p-a)	Mixing/loading model no. 5 (Lundehn et al) + TNsG, part II:
solution  disinfection by dipping/immersion		Mixing and loading:	0.31 mg/m <sup>3</sup> (SP)	Not relevant (HP) 0.0025 mg/cm <sup>2</sup> (SP)	0.31 mg/m <sup>3</sup> (SP)	12% (SP, inhalation) 0.044% (SP, dermal)	mixing/loading model no. 7 (revised)
<ul> <li>draining of disinfection solution</li> </ul>	Goggles, gloves	25 (TAED) 50 (SP)*	0.0004 mg/m³ (HP, appl.) 0.002 mg/m³ (HP, p- a)		0.0025 mg/cm <sup>2</sup> (SP) 0.0004 mg/m <sup>3</sup> (HP, appl.) 0.002 mg/m <sup>3</sup> (HP, p- a)	0.03% (HP, appl.) 0.2% (HP, p-a)	"pouring liquids" + "dipping model no. 4"
		Application/ post-	0.0028 (TAED)	0.0022 (TAED)	0.005 (TAED)	0.6% (TAED)	
		application: 0.005 (TAED) 0.312 (DAED) 0.25 (PAA)*** 0.176 (HP)*	0.000012 (DAED)	0.071 (DAED)	0.071 (DAED)	0.1% (DAED)	

<sup>\*:</sup> SP/HP = Sodium percarbonate/Hydrogen peroxide

<sup>\*\*:</sup> Inhalation AEC values for peracetic acid = 0.5 mg/m³ and for hydrogen peroxide = 1.25 mg/m³; AEL<sub>TAED</sub> = 0.9 mg/kg bw/day; AEL<sub>DAED</sub> = 57 mg/kg bw/day; dermal DNEL for local effects of sodium percarbonate = 6.4 mg/cm², (proposed) inhalation DNEL for local effects of sodium percarbonate = 2.5 mg/m³ (according to or based on REACH registration dossier)
\*\*\*: In-use concentration is **over** the dermal NOAEC for PAA (0.1% in long-term exposure, 0.2% in short/medium-term exposure).

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

#### Primary exposure industrial/professional use (cont´d)

		Concentrated product [%]		Exposure			
Exposure scenario	Working	In-use	Inhalation	Dermal	Total	% AEL/ AEC/DNEL**	Model used
	conditions	concentration [%]	[mg/m³] or [mg/kg bw/day]	[mg/kg bw/day] [mg/m³] or or [mg/cm²] [mg/kg bw/day]			
PT4: Food and feed area dis	sinfectants						
Disinfection of floors, walls and hard surfaces in industrial, public and health care areas by			0.072 mg/m <sup>3</sup> (PAA, appl.) 0.0024 mg/m <sup>3</sup> (PAA, p-a)	Not relevant (PAA)	0.072 mg/m <sup>3</sup> (PAA, appl.) 0.0024 mg/m <sup>3</sup> (PAA, p-a)	14% (PAA, appl.) 0.5% (PAA, p-a)	Mixing/loading model no. 5 (Lundehn et al) + TNsG, part II:
wiping with flat mops and cleaning cloths  • preparation of disinfection solution		Mixing and loading: 25 (TAED) 50 (SP)*	0.31 mg/m <sup>3</sup> (SP)	Not relevant (HP) 0.0025 mg/cm <sup>2</sup> (SP)	0.31 mg/m <sup>3</sup> (SP, inhalation) 0.0025 mg/cm <sup>2</sup> (SP, dermal)	12% (SP, inhalation) 0.044% (SP, dermal)	mixing/loading model no. 7 (revised) and "pouring liquids"
<ul> <li>disinfection by wiping</li> <li>draining of disinfection solution</li> </ul>	Goggles, gloves		0.051 mg/m <sup>3</sup> (HP, appl.) 0.002 mg/m <sup>3</sup> (HP, p- a)		0.051 mg/m <sup>3</sup> (HP, appl.) 0.002 mg/m <sup>3</sup> (HP, p- a)	4% (HP, appl.) 0.2% (HP, p-a)	+ Surface disinfection (manual) model. no. 1 + 2
00.0		Application/ post-	0.0029 (TAED)	0.0034 (TAED)	0.0063 (TAED)	0.7% (TAED)	1
		application: 0.005 (TAED) 0.312 (DAED) 0.25 (PAA)*** 0.176 (HP)*	0.01 (DAED)	0.144 (DAED)	0.15413 (DAED)	0.3% (DAED)	

<sup>\*:</sup> SP/HP = Sodium percarbonate/Hydrogen peroxide

<sup>\*\*:</sup> Inhalation AEC values for peracetic acid = 0.5 mg/m³ and for hydrogen peroxide = 1.25 mg/m³; AEL<sub>TAED</sub> = 0.9 mg/kg bw/day; AEL<sub>DAED</sub> = 57 mg/kg bw/day; dermal DNEL for local effects of sodium percarbonate = 6.4 mg/cm², (proposed) inhalation DNEL for local effects of sodium percarbonate = 2.5 mg/m³ (according to or based on REACH registration dossier)
\*\*\*: In-use concentration is **over** the dermal NOAEC for PAA (0.1% in long-term exposure, 0.2% in short/medium-term exposure).

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

## Primary exposure industrial/professional use (cont'd)

		Concentrated product [%]		Exposure			
Exposure scenario	Working conditions	In-use	Inhalation	Dermal	Total	% AEL/ AEC/DNEL**	Model used
Collucions	conditions	concentration [%]	[mg/m³] or [mg/kg bw/day]	[mg/kg bw/day] or [mg/cm²]	[mg/m³] or [mg/kg bw/day]		
PT4: Food and feed area dis	sinfectants						
Disinfection of equipment by dipping  • preparation of disinfection			0.0005 mg/m <sup>3</sup> (PAA, appl.) 0.0024 mg/m <sup>3</sup> (PAA, p-a)	Not relevant (PAA)	0.0005 mg/m <sup>3</sup> (PAA, appl.) 0.0024 mg/m <sup>3</sup> (PAA, p-a)	0.1% (PAA, appl.) 0.5% (PAA, p-a)	Mixing/loading model no. 5 (Lundehn et al) + TNsG, part II:
solution     disinfection by dipping/immersion     draining of disinfection solution	Goggles, gloves	Mixing and loading: 25 (TAED) 50 (SP)*	0.31 mg/m³ (SP)  0.0004 mg/m³ (HP, appl.) 0.002 mg/m³ (HP, p-a)	Not relevant (HP) 0.0025 mg/cm <sup>2</sup> (SP)	0.31 mg/m³ (SP)  0.0025 mg/cm² (SP)  0.0004 mg/m³ (HP, appl.)  0.002 mg/m³ (HP, p-a)	12% (SP, inhalation) 0.04% (SP, dermal) 0.03% (HP, appl.) 0.2% (HP, p-a.)	mixing/loading model no. 7 (revised) "pouring liquids" + "dipping model no. 4"
		Application/ post-	0.0028 (TAED)	0.0022 (TAED)	0.005 (TAED)	0.6% (TAED)	
		application: 0.005 (TAED) 0.312 (DAED) 0.25 (PAA)*** 0.176 (HP)*	0.000012 (DAED)	0.071 (DAED)	0.071 (DAED)	0.1% (DAED)	

<sup>\*:</sup> SP/HP = Sodium percarbonate/Hydrogen peroxide

<sup>\*\*:</sup> Inhalation AEC values for peracetic acid = 0.5 mg/m³ and for hydrogen peroxide = 1.25 mg/m³; AEL<sub>TAED</sub> = 0.9 mg/kg bw/day; AEL<sub>DAED</sub> = 57 mg/kg bw/day; dermal DNEL for local effects of sodium percarbonate = 6.4 mg/cm²; (proposed) inhalation DNEL for local effects of sodium percarbonate = 2.5 mg/m³ (according to or based on REACH registration dossier)
\*\*\*: In-use concentration is **over** the dermal NOAEC for PAA (0.1% in long-term exposure, 0.2% in short/medium-term exposure).

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## Primary exposure industrial/professional use (cont'd)

		Concentrated product [%]					
Exposure scenario	Working	In-use	Inhalation	Dermal	Total	% AEL/	Model used
· co	conditions	concentration [%]	[mg/m³] or [mg/kg bw/day]	[mg/kg bw/day] or [mg/cm²]	[mg/m³] or [mg/kg bw/day]	AEC/DNEL**	
PT4: Food and feed area di	sinfectants			-			
Manual spraying in the food and beverage industry			0.19 mg/m³ (PAA) 0.048 mg/m³ (PAA, RPE)	Not relevant (PAA)	0.19 mg/m³ (PAA) 0.048 mg/m³ (PAA,	38% (PAA) 10% (PAA, RPE)	Mixing/loading model no. 5 (Lundehn et al)
<ul> <li>preparation of</li> </ul>			****		RPE)		]+
disinfection solution loading of sprayer disinfection by manual spraying (only aerosol	Goggles, gloves,	Mixing and loading: 25 (TAED) 50 (SP)*	0.94 mg/m³ (SP)	Not relevant (HP) 0.0075 mg/cm <sup>2</sup> (SP)	0.94 mg/m³ (SP) 0.0075 mg/cm² (SP)	38% (SP, inhalation) 0.1% (SP, dermal) 11% (HP,	spraying model no. 2 (includes loading)
exposure calculated here)	coverall, boots and RPE in spraying		0.134 mg/m³ (HP) 0.033 mg/m³ (HP, RPE)		0.134 mg/m <sup>3</sup> (HP) 0.033 mg/m <sup>3</sup> (HP, RPE)	inhalation) 2.6% (HP, inhalation, RPE)	
		Application/ post-	0.0085 (TAED)	0.0334 (TAED)	0.042 (TAED)	5% (TAED)	1
		application: 0.005 (TAED) 0.312 (DAED) 0.25 (PAA)*** 0.176 (HP*)	0.00996 (DAED)	0.0886(DAED)	0.098 (DAED)	0.2% (DAED)	

<sup>\*:</sup> SP/HP = Sodium percarbonate/Hydrogen peroxide

<sup>\*\*:</sup> Inhalation AEC values for peracetic acid = 0.5 mg/m³ and for hydrogen peroxide = 1.25 mg/m³; AEL<sub>TAED</sub> = 0.9 mg/kg bw/day; AEL<sub>DAED</sub> = 57 mg/kg bw/day; dermal DNEL for local effects of sodium percarbonate = 6.4 mg/cm², (proposed) inhalation DNEL for local effects of sodium percarbonate = 2.5 mg/m³ (according to or based on REACH registration dossier)
\*\*\*: In-use concentration is **over** the dermal NOAEC for PAA (0.1% in long-term exposure, 0.2% in short/medium-term exposure).

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## Secondary exposure – short term (acute)

			In-use	Ехро	sure			
Exposure scenario	Intended use (MG/PT)	Exposure route	"" ====		Inhalation [mg/m³] or [mg/kg bw/day]	Systemic [mg/kg bw/day]	% AEL/ AEC*	
Disinfection of				0.25 (PAA)	0.072 mg/m <sup>3</sup> (PAA, appl.) 0.0024 mg/m <sup>3</sup> (PAA, p-a)	n.a. (PAA)	14% (PAA, appl.) 0.5% (PAA, p-a)	
surfaces in industrial, PT2 public and health care	inhalation adu	adult	adult	0.176 (HP)	0.051 mg/m <sup>3</sup> (HP, appl.) 0.002 mg/m <sup>3</sup> (HP, p-a)	n.a. (HP)	4% (HP, appl.) 0.2% (HP, p-a)	
areas by wiping						0.005 (TAED)	0.00017 (appl.+p-a, TAED)	0.00017 (appl.+p-a, TAED)
			0.312 (DAED)	0.01 (appl.+p-a, DAED)	0.01 (appl.+p-a, DAED)	0.02% (DAED)		
Disinfection of surfaces and equipment in animal houses and in the food and beverage industry by spraying				0.25 (PAA)	0.19 mg/m³ (PAA, aerosols) 17.5 mg/m³ (PAA, aerosols+vapour in animal houses)	n.a. (PAA)	38% (PAA, aerosols) 3500% (PAA, aerosols+vapou in animal houses)	
	PT3/PT4 inhalation adult	adult	0.176 (HP)	0.13 mg/m³ (HP, aerosols) 2.1 mg/m³ (HP, aerosols+vapour in animal houses)	n.a. (HP)	11% (HP, aerosols) 168% (HP, aerosols+vapou in animal houses)		
				0.005 (TAED)	0.00016 (TAED)	0.00016 (TAED)	0.02% (TAED)	
				0.312 (DAED)	0.00996 (DAED)	0.00996 (DAED)	0.02% (DAED)	

<sup>\*:</sup> Inhalation AEC values for peracetic acid = 0.5 mg/m³ and for hydrogen peroxide = 1.25 mg/m³; AEL<sub>TAED</sub> = 0.9 mg/kg bw/day; AEL<sub>DAED</sub> = 57 mg/kg bw/day

# Secondary exposure – long term (chronic)

Evnesure	Intended use			In-use		Expos	ure	
Exposure scenario	(MG/PT)	Exposure route	Species	concentration [%]	Dermal [mg/kg bw/c		iystemic* mg/kg bw/day]	% AEL**
Exposure via disinfected surfaces/objects after spraying of animal houses	PT3	dermal	humans	0.005 (TAED) 0.312 (DAED)	0.021 (TAED) 1.28 (DAED)		0.021 (TAED) 28 (DAED)	2.3% (TAED) 2.3% (DAED)
Exposure scenario	Intended use (MG/PT)	Exposure route	Species	In-use concentration [%]*	Exposure  Oral Systemic [mg/kg bw/day] [mg/kg bw/da			% AEL**
Exposure via disinfected surfaces/objects after wiping of public and health care areas	PT2	oral	humans	0.005 (TAED) 0.312 (DAED)	0.0013 (TAED 0.078 (DAED)	-	0.0013 (TAED) 0.078 (DAED)	0.11% (TAED) 0.11% (DAED)
Exposure scenario	Intended use (MG/PT)	Exposure route	Species	In-use concentration [%]*	Dermal [mg/kg bw/ day]	Expos Oral [mg/kg w/day]	Systemic	% AEL**
Exposure via disinfected floors after wiping of public and health care areas	PT2	dermal and oral	humans (infants crawling over treated area)	0.005 (TAED) 0.312 (DAED)	0.034 (TAED) 2.11 (DAED)	0.00045 (TAED) 0.28 (DAED)	0.035 (TAED) 2.39 (DAED)	3.9% (TAED) 4.2% (DAED)

<sup>\*\*</sup> Dermal penetration of 75 % for both TAED and DAED.

\*\*\*: AEL<sub>TAED</sub> = 0.9 mg/kg bw/day; AEL<sub>DAED</sub> = 57 mg/kg bw/day

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# Appendix IV: 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		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	COLLARDS FARM	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
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

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and sodium percarbonate	2, 3 and 4		2016

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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, HB.	2007	AND BOILING POINT OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
	Mücke, H. Sprössig, M.	1969	DIE EIGENSCHAFTEN DER PERESSIGSÄURE Source: Wissenschaftliche Zeitschrift der Humboldt-Universität zu Berlin, MathNat. R XVIII, 1969, Vol. 6, pp. 1167-1170 Report No.: Not applicable Not GLP; (published) Doc. No.: 192-002	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, HB.	2007	Report No.: AN-ASB 0363.3	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
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, HB.	2007	DETERMINATION OF THE UV/VIS SPECTRUM OF PEROXYACETIC ACID 15% Source: Aqura GmbH, Marl, Germany	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 3.4/02	Mekelburger, HB.	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

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Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A3.4/03	Mekelburger, HB.	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, HB.	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, HB.	2007	DETERMINATION OF THE SOLUBILITY IN ORGANIC SOLVENTS OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Mari, 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
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 P3-TSUNAMI 100 UND P3-oxonia active 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

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Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A3.15/01  Post- submission	Kratz, W.	1977	Report No.: 261	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	PEROXIDE IN A DISINFECTANTS	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	OXONIA ACTIVE 150 DURCH POTENTIOMETRISCHE TITRATION MIT NATRONLAUGE	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 4.1/03	Richarz, J.	2007	Source: Henkel KGaA	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	DIPHOSPHONSÄURE IN OXONIA ACTIVE 150	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.

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Section No.i Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 4.2c/01	van Egdom, 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	van Egdom, T.R.	2005	DEGRADATION OF PERACETIC ACID IN DILUTED RAT BLOOD (HPLC METHOD) Source: SOLVAY PHARMACEUTICALS, NL Report No.: E.SOL.S.013 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.
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	d'Hygiene, Dinard Cedex, France	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	d'Hygiene, Dinard Cedex, France	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.

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Section No. Reference No.	/Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/06	Sagripanti, J L. Bonifacino, A.		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.
A 5.3/08	Kliene, L.B. Hull, R.N.	1960	THE VIRUCIDAL PROPERTIES OF PERACETIC ACID Source: American Journal of Clinical Pathology, 1960, 30-33 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-051	No .	N.R.
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 5.3/10	Meyer, E.	1976	ABWASSERDESINFEKTION IN TIERKÖRPERBESEITIGUNGSANSTALTEN MIT HILFE DER PERESSIGSÄURE Source: Journal of Hygiene, Epidemiology, Microbiology and Immunology 20, 1976, No. 3, pp. 266-273 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-004	No	N.R.
A 5.3/11	Juhr, NC. 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 5.3/12	Poffé, R. De Burggrave, A. Houtmeyers, J. Verachtert, H.		DISINFECTION OF EFFLUENTS FROM MUNICIPAL SEWAGE TREATMENT PLANTS WITH PEROXY ACID Source: Zbl. Bakt. Hyg., I.AbtOrig. B 167, pp. 337-346, 1978 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-007	No	N.R.

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/13	Jäger, P. Püspök, J.	1980	PERESSIGSÄURE ALS DESINFEKTIONSMITTEL IN BRAUEREIEN UND BETRIEBEN DER ALKOHOLFREIEN GETRÄNKEINDUSTRIE Source: Sonderdruck aus der Zeitschrift "Mitteilungen der Versuchsstation für das Gärungsgewerbe in Wien" - Nr. 3/4/1980 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-008	No	N.R.
A 5.3/14	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 5.3/15	Fraser, J.A.L.	1986		No	N.R.
	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 5.3/17	Anonymous	1988	REVIEW OF OPERATIONAL & EXPERIMENTAL TECHNIQUES FOR THE REMOVAL OF BACTERIA, VIRUSES & PATHOGENS FROM SEWAGE EFFLUENTS Source: Department of the EnvironmentConsultants in environmental sciences Ltd Report No.: PECD 7/7/260 Not GLP; (published) Doc. No.: 392-012	No	N.R.
	Hopkinson, L.M.	1989	COMPARISON OF DISINFECTION TECHNIQUES FOR SEWAGE AND SEWAGE EFFLUENTS Source: J. IWEM. 1989, Vol. 3 December, pp. 612 -618 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-013	No	N.R.
	Lefevre, F. Audic, J.M. Ferrand, F.	1992	PERACETIC ACID DISINFECTION OF SECONDARY EFFLUENTS DISCHARGED OFF COASTAL SEAWATER Source: Wst. Sci. Tech., Vol. 25, No. 11, pp. 155-164, 1992 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-014	No	N.R.

Peracetic acid generated from TAED	Product types	Final CAR	December
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Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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 5.3/21	Liberti, L. Lopez, A. Notamicola, M.	1998	DISINFECTION WITH PERACETIC ACID FOR MUNICIPAL WASTEWATER REUSE IN AGRICULTURE Source: Proc. Of Innovations 2000 - WEF/EWPCA Specialty Conference, 7-10 July 1998, Cambridge UK Report No.: Not applicable Not GLP; (published) Doc. No.: 392-023	No	N.R.
A 5.3/22	Veschetti, E. Cutilli, D. Bonadonna, L. Della Libera, S. Ottaviani, M.	1998	PRELIMINARY RESULTS ON THE POSSIBILITY OF USING PERACETIC ACID AS DISINFECTANT OF WASTEWATER Source: AWT98 - Advanced Wastewater Treatment, Recycling and Reuse, Milano 14+16 September 1998 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-024	No	N.R.
A 5.3/23	Liberti, L. Notarnicola, M.	1999	ADVANCED TREATMENT AND DISINFECTION FOR MUNICIPAL WASTEWATER REUSE IN AGRICULTURE Source: Wat. Sci. Tech. Vol 40, No. 4-5, pp. 235-245, 1999 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-025	No	N.R.
A 5.3/24	Baldry, M.G. French, M.S. Slater, D.	1991	THE ACTIVITY OF PERACETIC ACID ON SEWAGE INDICATOR BACTERIA AND VIRUSES Source: Wat. Sci. Tech., Vol. 24, No. 22, pp. 353-357, 1991 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-030	No	N.R.
A 5.3/25	Schließer, T Wiest, J.M.	1979	ZUR TEMPERATURABHÄNGIGKEIT DER BAKTERIZIDEN WIRKUNG EINIGER CHEMISCHER DESINFEKTIONSMITTEL - ABOUT THE TEMPERATURE DEPENDENCE OF THE BACTERICIDAL EFFECT OF SOME CHEMICALS DISINFECTANTS Source: Zbi. Bakt. Hyg., I. Abt. Orig. B 169, pp. 560-566, 1979 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-031	No	N.R.
A 5.3/26	Baldry, M.G. et al.	N.I.	DÉSINFECTION PAR L'ACIDE PERACÉTIQUE DES EFFLUENTS URBAINS - L'EXPÉRIENCE ANGLAISE Source: L'EAU, L'Industrie, Les Nuisances, N° 137, pp. 42-44, Mai 1990 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-032	No	N.R.

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Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 5.3/27	Gönholm, L. et al.	1999	SCREENING OF ANTIMICROBIAL ACTIVITIES OF DISINFECTIONS AND CLEANING AGENTS FOODBORNE SPOILAGE MICROBES Source: Z Lebensm. Unters Forsch A 208 (1999), 289-298 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-035	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		N.R.
A 5.3/30	Colgan, S. Gehr, R.	2001	DISINFECTION - PERACETIC ACID GAINS FAVOR AS AN EFFECTIVE, ENVIRONMENTALLY BENIGN DISINFECTION ALTERNATIVE FOR MUNICIPAL WASTEWATER TREATMENT APPLICATIONS Source: WE&T, pp. 29-33, November 2001 Report No.: Not applicable Not GLP; (published) Doc. No.: 792-015	No	N.R.
A 5.3/31	Clapp, P.A. et al.	1994		No	N.R.
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.

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Section No. <i>i</i> Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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.		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.
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: Zbi. 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.

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Section No.i Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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.	1944	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		N.R.
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'Interrégion Sud-Est, 2005 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-063	No	N.R.

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Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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.
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 DICHLOROISOCYNURATE (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	Nattermann, 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 0157;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.

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Section No. Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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.
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, JY. 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, JH. 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.

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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 5.3/63	Hatunen, T.	2004	PRESERVATION TEST - STORA ENSO OY, PANKAKOSKI, FINLAND Source: Kemira Oyi, Vaasa / Finland Report No.: Not indicated	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Kemira
A 5.3/64	Hatunen, T.	2005	Source: Kemira Oyi, Vaasa / Finland Report No.: Not indicated	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Kemira
A 5.3/65	Krapu, S.	2006	Report No.: Not indicated	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Kemira
A 5.3/66	Hatunen, T.	2004		Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Kemira
A 5.3/67	Krapu, S.	2006	PRESERVATION TEST - STORA ENSO OY, PANKAKOSKI Source: Kemira Oyi, Vaasa / Finland Report No.: Not indicated	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Kemira
A 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.

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Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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.
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.
A 6.1.1/01		1998	Report No.:	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.1/02		1985	ACUTE ORAL TOXICITY TO RATS OF 5% PEROXYACETIC ACID Source: Report No.:	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.1/03		1982	BERICHT - ÜBER DIE TOXIKOLOGISCHE PRÜFUNG VON PERESSIGSÄURE 15% NACH EINMALIGER ORALER GABE AN DER RATTE	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.1/04		1995	ACUTE ORAL TOXICITY IN RATS - MEDIAN LETHAL DOSAGE DETERMINATION OF:	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.2/01		1996	ACUTE DERMAL TOXICITY STUDY IN RABBITS Source:	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

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A 6.1.2/02		1996	- ACUTE DERMAL TOXICITY STUDY IN RABBITS Source:  Report No. 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
A 6.1.3/01		1994	ACUTE INHALATION TOXICITY STUDY WITH IN MALE AND FEMALE RATS Source: Report No.: 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		1985	INHALATION APPROXIMATE LETHAL CONCENTRATION (ALC) OF PEROXYACETIC ACID Source: Report No.: 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		1987	PRIMARY IRRITATION STUDY OF PROXITANE 0512, TO THE SKIN OF THE MALE RABBIT	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.4/02		1988	PEROXYACETIC ACID 5% - ACUTE TOXICITY - TESTING THE PRIMARY	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.1.4/03		1982	BERICHT ÜBER DIE PRÜFUNG DER LOKALEN REIZWIRKUNG VON	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

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A 6.1.4/04		1991	PERACETIC ACID 0.15% USE DILUTION - PRIMARY EYE IRRITATION STUDY IN RABBITS Source: Report No.: 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		1983	PRIMARY EYE IRRITATION STUDY OF DILUTE PERACETIC ACID IN RABBITS Source: Report No.: 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		2000	UNTERSUCHUNGEN ZUR SENSIBILISIERUNG DER HAUT DURCH IM MEERSCHWEINCHEN- MAXIMIERUNGSTEST Source: Report No.: 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		1994	PHARMACOKINETIC STUDIES ON PEROXYACETIC ACID AS A COMPONENT OF IN THE RAT Source:  Report No.:  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		2005	DEGRADATION OF PERACETIC ACID IN DILUTED RAT BLOOD (HPLC METHOD) Source: Report No.: 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 6.2/03		2003	DEGRADATION OF PERACETIC ACID AND HYDROGEN PEROXIDE IN RAT BLOOD Source:  Report No.: 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.

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Section No. Reference No.	/Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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, NC. 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		2004		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.
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. VetMed. 36, 1981, pp. 343-349 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-016	No	N.R.

Peracetic acid generated from TAED	<b>Product types</b>	Final CAR	December
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Section No.i Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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, MathNat. 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. VetMed., 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) Dog. No.: 533-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
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.
	Heinze, W. Nattermann, H.	1984	PERESSIGSÄURE-AEROSOL-WIRKUNG BELANGZEITANWENDUNG NIEDRIGER KEIMWIRKSAMER KONZENTRATION AUFVERSUCHSTIERE Source: Wissenschaftliche Zeitschrift der Humboldt-Universität zu Berlin, MathNat. 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.

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

Section No. <i>l</i> Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.6.1/01	Wallat	1984		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		Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.2/02		2002		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		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		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	Source:	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

Section No. Reference No.	/Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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
A 6.6.4/04		2003	Bone Marrow Micronucleus Test by Oral Route in Mice Source:  Report 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		2002		Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 6.6.5/02		1994	AN IN VIVO UNSCHEDULED DNA SYNTHESIS ASSAY WITH Source: Report No.: 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	The state of the s	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.

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
	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.
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 GENOTOSSICITÁ 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 GENOTOSSICITÁ 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.

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

Section No.i 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 6.6.7/01I	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 MICROUNUCLEUS 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		No	N.R.
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.

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and sodium percarbonate	2, 3 and 4		2016

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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 Internation, 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.
A 6.8.1/01		2005	PRENATAL DEVELOPMENT TOXICITY STUDY WITH IN THE RAT USING ORAL (DRINKING WATER) ADMINISTRATION Source: Report No.: 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		2007	PRENATAL DEVELOPMENT TOXICITY STUDY WITH IN THE RAT USING ORAL (DRINKING WATER) ADMINISTRATION  Peer Review and Re- Evaluation of Discoloration in Fetal Liver Preprations; Source  Report No. 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		2010		Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

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Section No. Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 6.11/01		1983		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.
A 6.12.2/02	Mücke, H. Sprössig, M.	1969	DIE EIGENSCHAFTEN DER PERESSIGSÄURE Source: Wissenschaftliche Zeitschrift der Humboldt-Universität zu Berlin, MathNat. 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	Source: SOLVAY PHARMACEUTICALS, NL Report No.: Not indicated	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.

Peracetic acid generated from TAED	Product types	Final CAR	December
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Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A 7.1.1.1.1/01a		2000	Source: Bioxal	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.1.1.1.1/01b		2007	RESULTS GAMET, J. C. ET AL. (2000),	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.1.1.1.1/02a	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 7.1.1.1/0b	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 7.1.1.2.1/01a	Richterich Gode		PRÜFMUSTERZUGABE	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	N.R.
A 7.1.1.2.1/01b	Steber, J. Berger, H.	2002		Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A 7.1.1.2.1/02	L´Haridon, J.	2003	Source: Centre International de Toxicologie,	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

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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 Egdom, 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 PERASAN TM AND PERASAN TM "A" (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
	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		2003	ACUTE TOXICITY IN THE RAINBOW TROUT UNDER SEMI-STATIC CONDITIONS Source:  Report No.: 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		1996	STATIC RENEWAL ACUTE TOXICITY OF 5% PERACETIC ACID ( ) TO BLUEGILL (LEPOMIS MACROCHIRUS) Source: Report No.: 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
A7.4.1.1/03		1987	PLAICE PLEURONECTES PLATESSA UNDER SEMI-STATIC CONDITIONS	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

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Section No. Reference No.	/Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A7.4.1.1/04/0	5	2005	PACIFIC HERRING TOXICITY TESTING USING 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 A7.4.1.2/05/0	6	2005	TOXICOLOGICAL EVALUATIONS OF PERACETIC ACID (15%)  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
A 7.4.1.2/01	Gardner, C. Bucksath, J.D.	1996	137/377 N 5/4	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			PAR Task Force
A7.4.1.2/03	Butler, R.	1987			PAR Task Force
A7.4.1.2/04	Tinsley, D. Sims, I.	1987			PAR Task Force
A 7.4.1.3/01	Hicks, S.L.	1996	- Indiana - Indi	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

Section No.i Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A7.4.1.3/02/0 3	Anonymous	2005	ALGAL TOXICITY TESTING USING PERACLEAN® OCEAN 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
A 7.4.1.4/01	Hanstveit, A.O. Schoonmade, J.A. van Asten, J.G.	1999	SCREENING OF THE EFFECT OF SOPUROXID 15 ON THE RESPIRATION RATE OF ACTIVATED SLUDGE Source: TNO, Department of Environmental Toxicology, Delft, Netherlands Report No.: IMWV-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
A 7.4.1.4/02	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		2007	PERACETIC ACID 15 % - EARLY-LIFE STAGE TOXICITY TEST WITH ZEBRAFISH (DANIO RERIO) UNDER FLOW-THROUGH CONDITIONS (INCLUDING EXPERT STATEMENT)  Report No.:  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
A 7.4.3.4/01	Wetton, P. M. Mullee, D.M.	2000	FENNOSAN 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
A7.5.1.1/01	Scheerbaum, 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

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

Section No. <i>l</i> Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A7.5.1.1/02	Scheerbaum, D.	2008	ORGANISMS - NITROGEN TRANSFORMATION TEST Dr. Noack Laboratorium für angewandte	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.5.1.2/01	Winkelmann, G.	2007	IN ARTIFICAL SOIL - LIMIT-TEST Noack-Laboratorium für angewandte Biologie,	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
A7.5.1.3/01	Fiebig, S.	2007	Noack-Laboratorium für angewandte Biologie,	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

# Reference list Doc IIIB by Section Points:

Section No./ Reference No.		Year	Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
B3.2/01	Mekelburger, HB.	2007	Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.6	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
В 3.2/02	Mekelburger, HB.	2007	Report No.: AN-ASB 0363.14	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B3.4/01	Mekelburger, HB.	2007	TEMPERATURE OF PEROXYACETIC ACID 5% Source: Aqura GmbH, Marl, Germany	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
В 3.4/02	Mekelburger, HB.	2007	15% Source: Aqura GmbH, Marl, Germany	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B3.6/01	Mekelburger, HB.	2007	DENSITY OF PEROXYACETIC ACID 5 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.1	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.6/02	Mekelburger, HB.	2007	DENSITY OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0363.2	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B3.10/01	Mekelburger, HB.	2007	DETERMINATION OF THE SURFACE TENSION OF AQUEOUS SOLUTIONS OF PEROXYACETIC ACID 5 % Source: Aqura GmbH, Marl, Germany	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B 3.10/02	Mekelburger, HB.	2007	DETERMINATION OF THE SURFACE TENSION OF AQUEOUS SOLUTIONS OF PEROXYACETIC ACID 15 % Source: Aqura GmbH, Marl, Germany	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
B3.11/01	Mekelburger, HB.	2007	DETERMINATION OF THE KINEMATIC VISCOSITY OF PEROXYACETIC ACID 5 % Source: Aqura GmbH, Marl, Germany Report No.: AN-ASB 0362.5	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

Section No. <i>l</i> Reference No.		Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
B 3.11/02	Mekelburger, HB.	2007		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	Source: ECOLAB GmbH & Co. OHG, Düsseldorf, Germany	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	Source: Scientific Consulting Company, Wendelsheim, Germany	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

# Reference list (sorted by authors) for theoretical in-situ product 1 (PT 2 for household use)

Author(s)	Section No./ Reference No.	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
Bäumer, U. Weide, M.	B 5.10/01	2007	DETERMINATION OF BACTERICIDAL EFFICACY OF A BLEACH-ACTIVE HDD FRAME FORMULA Source: Henkel KGaA Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0210	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
Kintrup, L. Liebs, H.	B 3/02	2007	HENKEL INTERNER BRIEF - UNTERSUCHUNGSBERICHT - PROBEN - FRAME FORMULA 20.03.07 & SIL OXI, REZEPTUR NR. 14 Source: Henkel KGaA Report No.: 07-06759 Not GLP; (unpublished) Doc. No.: 243-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Henkel
Kyas, A. Heinzel, M.	B 5.10/02	2007	EXPERT'S JUDGEMENT ON THE VIRUCIDAL EFFICIENCY OF A BLEACH-ACTIVE HDD FRAME FORMULA TESTED AGAINST ADENOVIRUS AND POLIOVIRUS Source: Henkel KGaA Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0211	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
Schambil, F. Speckmann, H D.	B 3/01	2007	PHYSICO-CHEMICAL PARAMETERS OF FRAME FORMULA WASHING DETERGENT PT1 CONTAINING 15% TAED AND 40% SODIUM PERCARBONATE Source: Henkel KGaA Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 219-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Henkel

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

## Reference list (sorted by authors) for theoretical in-situ product 2 (PT 2 for I & I use)

Author(s)	Section No./ Reference No.	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
Anonymous	B 3/01	2007	SAFETY DATA SHEET - THEORETICAL PRODUCT - WASHING POWDER Source: ECOLAB GmbH & Co. OHG, Düsseldorf, Germany Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 954-004	No	N.R.
Anonymous	B 5.3/01	2007	IN-SITU BESTIMMUNG VON PES IN ELTRA (7 G/L) Source: ECOLAB GmbH & Co. OHG, Düsseldorf, Germany Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 231-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ECOLAB
Anonymous	B 5.5/01	2003	VORWORT ZUR LISTE DER VOM ROBERT KOCH INSTITUT GEPRÜFTEN UND ANERKANNTEN DESINFEKTIONSMITTEL UND - VERFAHREN Source: Bundesgesundheitsbl Gesundheitsforsch- Gesundheitsschutz,2003, 46, 72-95 Report No.: Not applicable Not GLP; (published) Doc. No.: 392-039	No	N.R.
Hermann, M. Kaiser, C.	B 9.1/01	2007	ELTRA HAZARD ASSESSMENT Source: Henkel KGaA Report No.: ASS 0401948-0 Not GLP; (unpublished) Doc. No.: 951-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ECOLAB
Merz, T. Forth, P.	В 3/02	2007	PHYSICO-CHEMICAL PARAMETERS OF PRODUCT	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ECOLAB
Uyttendaele, M	B 5.10/06	2008	BEPALING VAN DE DESINFECTERENDE	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	Christeyns
Werner. H.P. Kaß, D.	B 5.10/01	2002	PRÜFBERICHT - ELTRA CHEMOTHERMISCHE WÄSCHDESINFEKTION BEI 60° C/15 MIN Source: HygCen GmbH, Schwerin, Germany Report No.: SN-2434 Not GLP; (unpublished) Doc. No.: 336-0204	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ECOLAB

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

# Reference list (sorted by authors) for theoretical in-situ product 3 (PT 2, 3 & 4)

Author(s)	Section No./ Reference No.	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
Anonymous	В 3/01	2007	SAFETY DATA SHEET - THEORETICAL PRODUCT FOR PT 2,3,4 Source: ECOLAB GmbH & Co. OHG, Düsseldorf, Germany Report No.: Not indicated Not GLP; (unpublished) Doc, No.: 954-005	No	N.R.
Biering, H. Meyer, B.	B 5.3/01	2004	STORAGE STABILITY AND SHELF LIFE OF SEKUSEPT AKTIV Source: ECOLAB GmbH & Co. OHG, Düsseldorf, Germany Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 245-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ECOLAB
Doc III B B3/03 Post- Submission 11.12.2009	Clemens, J.	2008	TEST OF EXPLOSIVE PROPERTIES OF SEKUSEPT AKTIV (ANALYSENERGEBNIS 080422.JCS.0-5) Solvay Chemicals GmbH, Bad Hönningen, Germany Report No.: Bericht 080422.JCS.0-5 Not GLP, unpublished Doc. No.: 241-008	No	Ecolab Deutschland GmbH
Doc III B B3/04 Post- Submission 11.12.2009	Clemens, J.	2008	TEST OF OXIDISING PROPERTIES OF SEKUSEPT AKTIV (ANALYSENERGEBNIS 080422.JCS.0-1) Solvay Chemicals GmbH, Bad Hönningen, Germany Report No.: Bericht 080422.JCS.0-1 Not GLP, unpublished Doc. No.: 243-002	No	Ecolab Deutschland GmbH
Hölzgen, U. Bragulla, S.	В 3/02	2007	SPECIFICATION OF PHYSICO-CHEMICAL PARAMETERS OF FRAME FORMULA FOR PT 2,3,4 CONTAINING 25% TAED AND 50% SODIUM PERCARBONATE Source: ECOLAB GmbH & Co. OHG, Düsseldorf, Germany Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 219-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	
Мауег, В.	B 5.3/02	2004	RATIONALE FOR THE USE DILUTION SHELF LIFE OF SEKUSEPT AKTIV Source: ECOLAB GmbH & Co. OHG, Düsseldorf, Germany Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0203	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ECOLAB
Pears, E.	B 5.10/01	2003	BACTERICIDAL ACTIVITY IN GENERAL USE CONDITIONS (FOR DIRTY CONDITIONS) Source: Andarik QC, England Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0206	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	
Pears, E.	B 5.10/02	2003	FUNGICIDAL ACTIVITY IN GENERAL USE CONDITIONS Source: Andarik QC, England Report No.: 1650-28/31/36 B Not GLP; (unpublished) Doc. No.: 336-0207		ECOLAB
Pears, E.	B 5.10/03	2005	BACTERICIDAL AND FUNGICIDAL ACTIVITY ON SURFACES IN GENERAL		ECOLAB

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

Author(s)	Section No. <i>l</i> Reference No.	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
			USE CONDITIONS (FOR DIRTY CONDITIONS) Source: Andarik QC, England Report No.: 13697/5-8A Not GLP; (unpublished) Doc. No.: 336-0209	existing a.s. submitted for the first time for entry into Annex I.)	
Pears, E.	B 5.10/04	2005	SPORICIDAL ACTIVITY IN GENERAL USE CONDITIONS Source: Andarik QC, England Report No.: 13704 - 20 Ai Not GLP; (unpublished) Doc. No.: 336-0208	Yes (Data on existing a.s. submitted for the first time for entry into Annex [.)	
Trzcinska, A.	B 5.10/05	2005	LABORATORY EVALUATION OF VIRUCIDAL ACTIVITY OF INCIDIN AKTIV Source: National institute for hygiene, PL, Warschau Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 336-0205	Yes (Data on existing a.s. submitted for the first time for entry into Annex	

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

## Reference list (sorted by authors) for the precursor substances sodium percarbonate and TAED

Author(s)	Section No./ Reference No.	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
Anonymous	B 3-SP/01	2007	SAFETY DATA SHEET - SODIUM PERCARBONATE Q 30 Source: Degussa AG, Hanau, Germany Report No.: 7.5 / REG_EU Not GLP; (unpublished) Doc. No.: 955-033	No	N.R.
Anonymous	B 3-TAED/01	2002	HERA - TETRAACETYLETHYLENEDIAMINE (TAED) - CAS 10543-57-4 - DRAFT Source: Hera Report No.: Not indicated Not GLP; (published) Doc. No.: 032-006	No	N.R.
Anonymous	B 3-TAED/02	2007	SAFETY DATA SHEET - PERACTIVE AN Source: Clariant GmbH, D-Frankfurt Report No.: SXR037046 Version : 4 - 11 / EU Not GLP; (unpublished) Doc. No.: 955-030	No	N.R.
Anonymous	B 3-TAED/03	2007	LITERATURE SEARCH - N,N,N',N'- TETRAACETYLLETHYLENEDIAMINE Source: NIST - National Institute of Standards and Technology Report No.: Not applicable Not GLP; (published) Doc. No.: 191-002	No	N.R.
Anonymous	B 3-TAED/04	N.I.	THE CLEAN AND CLEVER WAY OF BLEACHING Source: Clariant GmbH, D-Frankfurt Report No.: Not applicable Not GLP; (published) Doc. No.: 031-008	No	N.R.
Anonymous	B 3-TAED/05	2000	IUCLID DATA SET - N,N' -ETHYLENEBIS[N-ACETYLACETAMIDE] Source: EC Report No.: Not indicated Not GLP; (published) Doc. No.: 987-003	No	N.R.
Anonymous	B 4.1/01-SP	1997	DETERMINATION OF PEROXIDE OXYGEN FROM BLEACHING AGENTS BY PERMANGANATOMETRIC TITRATION Source: Henkel KGaA Report No.: Not Indicated Not GLP; (unpublished) Doc. No.: 421-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
Anonymous	B 6.5-SP/01	2002	HERA - SODIUM PERCARBONATE - CAS NO. 15630-89-4 Source: Hera Report No.: Not indicated Not GLP; (published) Doc. No.: 032-007	No	N.R.
Anonymous	B 6.5-TAED/01	2002	HERA - TETRAACETYLETHYLENEDIAMINE (TAED) - CAS 10543-57-4 - DRAFT Source: Hera Report No.: Not indicated Not GLP; (published) Doc. No.: 032-006	No	N.R.
Anonymous	B 7.3-SP/01	2002	HERA - SODIUM PERCARBONATE - CAS NO. 15630-89-4 Source: Hera Report No.: Not indicated Not GLP; (published)	No	N.R.

Peracetic acid generated from TAED	Product types	Final CAR	December
and sodium percarbonate	2, 3 and 4		2016

Author(s)	Section No./ Reference No.	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
Anonymous	B 7.3-TAED/01	2002	Doc. No.: 032-007 HERA - TETRAACETYLETHYLENEDIAMINE (TAED) - CAS 10543-57-4 - DRAFT Source: Hera Report No.: Not indicated Not GLP; (published) Doc. No.: 032-006	No	N.R.
Arens, M. Hirschen, M. Klotz, H.	B 4.1/01-TAED	1997	POTENTIOMETRISCHE TITRATION DES TAED- GEHALTS VON TAED-GRANULATEN - DEUTSCHE EINHEITSMETHODEN ZUR UNTERSUCHUNG VON FETTEN, FETTPRODUKTEN, TENSIDEN UND VERWANDTEN STOFFEN: ANALYSE VON GRENZFÄCHENAKTIVEN STOFFEN Source: Fett/Lipid, 1997, 99, 8, 291-293 Report No.: Not applicable Not GLP; (published) Doc. No.: 492-022	No	N.R.
Glöckner, T. Görg, J.	B 3-TAED/06	2007	STATEMENT RELATED TO THE EXPLOSIVE PROPERTIES OF TETRAACETYLETHYLENEDIAMINE (TAED) Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 834-005 Not GLP; (unpublished) Doc. No.: 141-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force
Glöckner, T. Görg, J.	B 3-TAED/07	2007	STATEMENT RELATED TO THE OXIDISING PROPERTIES OF TETRAACETYLETHYLENEDIAMINE (TAED) Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 834-005 Not GLP; (unpublished) Doc. No.: 143-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	PAR Task Force