CLH report

Proposal for Harmonised Classification and Labelling

Based on Regulation (EC) No 1272/2008 (CLP Regulation),
Annex VI, Part 2

International Chemical Identification: peracetic acid ...%

EC Number: 201-186-8

CAS Number: 79-21-0

Index Number: 607-094-00-8

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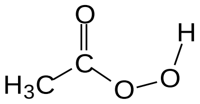
1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity and information related to molecular and structural formula of the substance

Name(s) in the IUPAC nomenclature or other international chemical name(s)	Peracetic acid ...%, peroxyethanoic acid
Other names (usual name, trade name, abbreviation)	Ethaneperoxoic acid, acetyl hydroperoxide, peroxyacetic acid
ISO common name (if available and appropriate)	Peracetic acid
EC number (if available and appropriate)	201-186-8
EC name (if available and appropriate)	-
CAS number (if available)	79-21-0
Other identity code (if available)	-
Molecular formula	$C_2H_4O_3$
Structural formula	
SMILES notation (if available)	CC(OO)=O
Molecular weight or molecular weight range	76.05 g/mol
Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)	Not applicable (the structure of the substance does not demonstrate stereo-isomerism)
Description of the manufacturing process and identity of the source (for UVCB substances only)	Not applicable (the substance is not an UVCB)
Degree of purity (%) (if relevant for the entry in Annex VI)	The specification is based on the minimum purity of the two starting materials hydrogen peroxide and acetic acid Minimum purity of hydrogen peroxide on a calculated dry weight basis: ca. 99.5 % (by wt) Minimum purity of acetic acid: > 99.8 % (by wt) Minimum purity on a calculated dry weight basis: ca. 99.5 % (by wt)

1.2 Composition of the substance

Table 2: Constituents (non-confidential information)

Constituent (Name and numerical identifier)	Concentration range (% w/w minimum and maximum in multi-constituent substances)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)
Peracetic acid ...% (CAS 79-21-0)		Flam. Liq. 3; H226 Org. Perox. D****; H242 Acute Tox. 4*; H302 Acute Tox. 4*; H312 Acute Tox. 4*; H332 Skin Corr. 1A; H314 Aquatic Acute 1; H400	

Table 3: Impurities (non-confidential information) if relevant for the classification of the substance

Impurity (Name and numerical identifier)	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)	The impurity contributes to the classification and labelling

Table 4: Additives (non-confidential information) if relevant for the classification of the substance

Additive (Name and numerical identifier)	Function	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)	The additive contributes to the classification and labelling

Table 5: Test substances (non-confidential information) (this table is optional)

Identification of test substance	Purity	Impurities and additives (identity, %, classification if available)	Other information	The study(ies) in which the test substance is used

2 PROPOSED HARMONISED CLASSIFICATION AND LABELLING

2.1 Proposed harmonised classification and labelling according to the CLP criteria

Table 6:

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	**Hazard statement Code(s)**	**Pictogram, Signal Word Code(s)**	**Hazard statement Code(s)**	**Suppl. Hazard statement Code(s)**		
Current Annex VI entry	607-094-00-8	Peracetic acid ...%	201-186-8	79-21-0	Flam. Liq. 3 Org. Perox. D**** Acute Tox. 4* Acute Tox. 4* Acute Tox. 4* Skin Corr. 1A Aquatic Acute 1	H226 H242 H332 H312 H302 H314 H400	GHS02 GHS05 GHS07 GHS09 Dgr	H226 H242 H332 H312 H302 H314 H400	-	STOT SE 3; H335: C ≥ 1 %	B, D
Dossier submitters proposal	607-094-00-8	Peracetic acid ...%	201-186-8	79-21-0	**Retain** Org. Perox. D**** Aquatic acute 1 **Add** Aquatic Chronic 2 **Modify** Acute Tox. 2 Acute Tox. 2 Acute Tox. 3 **Remove** Flam. Liq. 3	**Retain** H242 H400 **Add** H411 **Modify** H330 H310 H301 **Remove** H226	**Retain** GHS02 GHS09 **Add** GHS06 **Remove** GHS07	**Retain** H242 H400 **Add** H411 **Modify** H330 H310 H301 **Remove** H226	**Add** EUH071	**Add** inhalation: ATE = 0.204 mg/L (dusts and mists) dermal: ATE = 56.1 mg/kg bw oral: ATE = 70 mg/kg bw M=10	
Resulting Annex VI entry if agreed by RAC and COM	607-094-00-8	Peracetic acid ...%	201-186-8	79-21-0	Org. Perox. D**** Acute Tox. 2 Acute Tox. 2 Acute Tox. 3 Skin Corr. 1A Aquatic Acute 1 Aquatic Chronic 2	H242 H330 H310 H301 H314 H400 H411	GHS02 GHS05 GHS06 GHS09 Dgr	H242 H330 H310 H301 H314 H400 H411	EUH071	inhalation: ATE = 0.204 mg/L (dusts and mists) dermal: ATE = 56.1 mg/kg bw oral: ATE = 70 mg/kg bw STOT SE 3; H335: C ≥ 1 % M=10	B, D

Table 7: Reason for not proposing harmonised classification and status under consultation

Hazard class	**Reason for no classification**	**Within the scope of consultation**
Explosives	Hazard class not applicable	No
Flammable gases (including chemically unstable gases)	Hazard class not applicable	No
Oxidising gases	Hazard class not applicable	No
Gases under pressure	Hazard class not applicable	No
Flammable liquids	Conclusive but not sufficient for classification	Yes
Flammable solids	Hazard class not applicable	No
Self-reactive substances	Hazard class not applicable	No
Pyrophoric liquids	Hazard class not assessed in this dossier	No
Pyrophoric solids	Hazard class not applicable	No
Self-heating substances	Hazard class not applicable	No
Substances which in contact with water emit flammable gases	Hazard class not applicable	No
Oxidising liquids	Hazard class not assessed in this dossier	No
Oxidising solids	Hazard class not applicable	No
Organic peroxides	Harmonised classification proposed	Yes
Corrosive to metals	Hazard class not assessed in this dossier	No
Acute toxicity via oral route	Harmonised classification proposed	Yes
Acute toxicity via dermal route	Harmonised classification proposed	Yes
Acute toxicity via inhalation route	Harmonised classification proposed	Yes
Skin corrosion/irritation	Hazard class not assessed in this dossier	No
Serious eye damage/eye irritation	Hazard class not assessed in this dossier	No
Respiratory sensitisation	Hazard class not assessed in this dossier	No
Skin sensitisation	Hazard class not assessed in this dossier	No
Germ cell mutagenicity	Hazard class not assessed in this dossier	No
Carcinogenicity	Hazard class not assessed in this dossier	No
Reproductive toxicity	Hazard class not assessed in this dossier	No
Specific target organ toxicity-single exposure	Hazard class not assessed in this dossier	No
Specific target organ toxicity-repeated exposure	Hazard class not assessed in this dossier	No
Aspiration hazard	Hazard class not assessed in this dossier	No
Hazardous to the aquatic environment	Harmonised classification proposed	Yes
Hazardous to the ozone layer	Hazard class not assessed in this dossier	No

3 HISTORY OF THE PREVIOUS CLASSIFICATION AND LABELLING

Peracetic acid was first introduced to Annex 1 of the Council Directive 67/548/EEC in the twelft adaptation (1991) to technical progress (ATP) with classification O; R5 – Xn; R22 and C; R34 and Notas B and D. The classification was modified in the nineteenth ATP (1993) to R10 – O; R7 – Xn; R20/21/22 – C; R35 and Nota B and D. Environmental classification N; R50 was agreed in the meeting of the Commission Working Group on the Classification and Labelling of Dangerous Substances: Environmental Effects on 19-21 of March 1997, and added to Annex 1 in the twenty-fifth ATP (1998). The classification was subsequently translated into CLP classification in 2008.

4 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

[A.] There is no requirement for justification that action is needed at Community level.

5 IDENTIFIED USES

Peracetic acid is a biocidal active substance with strong bactericidal, fungicidal, and virucidal activity. Peracetic acid is mainly used as a bactericide, fungicide or virucide. Moreover, indications of potential efficacy against amoeboe and algae have been reported.

The uses belong to the Product Types PT 1 – 6, 11 and 12. They are wide-spread and have the following aims:

- PT1: Hand disinfection: the “organism to be protected” is man. The aim of the treatment is to prevent spreading of disease-causing micro-organisms. Hand disinfection products based on PAA are used in hospitals, healthcare areas, as well as in food production and catering environments.

- PT2: Disinfection of textiles during washing process: the “organism to be protected” is man. The aim of the treatment is to control infectious diseases or smell generating micro-organisms in laundry. Treatment of sewage / waste water including municipal waste water and disinfection of surfaces in industrial, public and health care areas, CIP (Clean-in-Place) in pharmaceutical and cosmetic industry: the “organism to be protected” is man. The aim of the treatments is to control infectious diseases or nuisance (smell generating) organisms.

- PT3: Disinfection of animal houses: the “organisms to be protected” are animals and man (as the consumer of animals). The aim of the treatments is to control infectious diseases.

- PT4: Disinfection in food and feed industry (CIP, dipping of equipment, automated spraying, and manual spraying, foaming): the organisms to be protected are man and animals. The aim of the treatments is to control infectious diseases and to avoid contamination of food or feed. Disinfection of equipment used in animal production (e.g. milking equipment): the “organisms to be protected” are animals and man (as the consumer of animal products such as milk). The aim of the treatments is to control infectious diseases.

- PT5: Disinfection of animal drinking water: the “organisms to be protected” are animals and man (consumption of products of animal origin). The aim of the treatments is to control infectious diseases.

- PT6: In-can preservation in the paper production. The purpose of the treatment is in-can preservation of coating products used in the production of paper.

- PT11: Preservatives for liquid-cooling and processing systems.

- PT12: Slimicides. Used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.

Equilibrium PAA products are exclusively applied by professional users except that PAA containing products for hand disinfection are also applied by non-professionals.

6 DATA SOURCES

The Competent Authority Report (2015) of peracetic acid under Regulation (EU) No 528/2012 was used as the main data source for the CLH report of peracetic acid. In addition, the data for peracetic acid were obtained from the REACH registration dossier, last modified on 07-Oct-2020, as well as from open literature sources.

7 PHYSICOCHEMICAL PROPERTIES

Table 8: Summary of physicochemical properties

Property	**Value**	**Reference**	**Comment (e.g. measured or estimated)**
Physical state at 20°C and 101,3 kPa	Liquid	REACH registration dossier	Pure peracetic acid is not available because it is explosive. For this reason it is technically not possible to perform experimental studies according to the guidelines.
Melting/freezing point	Melting point: -73°C (15% solution) Freezing point: -43.90°C (pure substance)	CAR: Mekelburger (2007), Doc. 112-003.A3.1.1/02, REACH registration dossier	Measured (melting point) Estimated (freezing point) The melting point of a peracetic acid solution depends on the acetic acid and hydrogen peroxide contents. Measured melting points of 5% equilibrium solutions are found in the range of -26°C to -30°C, while the measured melting points of 15% equilibrium solutions range from -30°C to -50°C. The freezing point was determined from a series of determinations equivalent to EU Method A.1.
Boiling point	105-110°C at 101.3 kPa (pure substance)	CAR: Mücke & Sprössig (1969), A3.1.2/01, CIS (2009), EPIWIN 3.20 experimental database	Estimated Pure peracetic acid explodes when heated to about 100 to 110°C. In addition, contact with metal ions or organic materials can cause explosions. However, peracetic acid solution containing less than 45% can be handled safely. Commercial solutions have a boiling point of about 100°C or slightly above which may be caused by the water content.
Relative density	1.135 at 20°C (5-35 % solution)	REACH registration dossier, OVA (2009)	Measured
Vapour pressure	17 hPa at 20°C (15 %)	REACH registration dossier, (Mekelburger, 2007)	Measured

Property	Value	Reference	Comment (e.g. measured or estimated)
Surface tension	54.0 mN/m at 20°C (5% solution) 47.7 mN/m at 20°C (15% solution)	CAR: Mekelburger (2007), Doc. No. 216-003; 216-002	Measured (ring method) Not surface active
Water solubility	>10 000 mg/L	CAR: Swern (1970)	Measured Completely miscible in water

Partition coefficient n-octanol/water	$\log P_{ow}$ = -0.26 at pH 7	REACH registration dossier: Brachthold (2007)	Estimated The log P_{ow} value of pure peracetic acid cannot be determined in an aqueous solution, as the substance would dissociate into acetic acid and hydrogen peroxide.
Flash point	74 to 83°C (5% solution) 68 to 81°C (15% solution)	REACH registration dossier	Measured
Flammability	Flammable	REACH registration dossier	Most of the peracetic acid equilibrium grades ranging from 5% to 15% exhibit closed-cup flash points but no measurable open-cup flash points (ECETOC; 2001). Thus, these grades are not flammable under conditions where the liquid is open to the atmosphere. However, a sustained flame is possible in a closed system. Decomposition of peracetic acid produces oxygen. A closed system prevents the release of the oxygen, which in the presence of the organic (acetic acid) can sustain a flame. Thus, all the gases produced remain in the system and they can burn. Equilibrium grades of concentrations 30% peracetic acid or higher exhibit both open and closed-cup flash points and are flammable.
Explosive properties	The liquid itself can be made to explode.	Anonymous (1977), CAR A3.15/01	Vapour/air explosive limit: Pure or highly concentrated stabilized PAA may form explosive vapour/air mixtures above 40.5 °C. Detailed explosive limits are unknown in the literature.

Self-ignition temperature	435°C (5% solution), 280°C (15% solution)	REACH registration dossier: Mekelburger (2007)	Measured EU Method A.15 Solutions with concentrations not exceeding 15% peracetic acid are regarded as not flammable under conditions where the liquid is open to the atmosphere. Solutions with more than 15% peracetic acid exhibit both open and closed-cup flash points and vapours can be flammable.
Oxidising properties	Oxidizing	REACH registration dossier	Peracetic acid is an organic peroxide with oxidising properties; no test is required.
Granulometry	Not applicable	-	-
Stability in organic solvents and identity of relevant degradation products	Not determined	-	-
Dissociation constant	pK_a = 8.24 at 20°C (15% solution)	REACH registration dossier: Mekelburger (2007)	Measured OECD TG 122
Viscosity	1.22 mm^2/s (5% solution) 1.50 mm^2/s (15% solution) 2.89 mm^2/s at 20°C (pure substance)	REACH registration dossier: Mekelburger (2007), Turunen (1996)	Measured OECD TG 114 (5% and 15% solutions) Estimated (pure substance)

8 EVALUATION OF PHYSICAL HAZARDS

8.1 Explosives

Hazard class not applicable.

The explosive properties do not have to be determined according to the CLP Annex I, Chapter 2.1, because explosive properties are incorporated in the decision logic for organic peroxides.

8.2 Flammable gases (including chemically unstable gases)

Hazard class not applicable.

8.3 Oxidising gases

Hazard class not applicable.

8.4 Gases under pressure

Hazard class not applicable.

8.5 Flammable liquids

Table 9: Summary table of studies on flammable liquids

Method	Results	Remarks	Reference
Determination of flash point - Pensky Martin closed-cup method	62.3°C (61°C; 63°C; 63°C)	dPAA solution: PAA 39.6 % (Peracetic acid) AA 2.0 % (Acetic acid) H_2O_2 0.34 % (Hydrogen peroxide)	Anonymous (2017)

8.5.1 Short summary and overall relevance of the provided information on flammable liquids

The flash point measurements were carried out with the Pensky Martin closed-cup tester (non-equilibrium method). The flash point was measured from the dPAA solution: PAA 39.6% (peracetic acid), AA 2.0% (acetic acid) and H_2O_2 0.34% (hydrogen peroxide). The flash point was measured 3 times. Results of 3 different measurements were 61°C, 63°C and 63°C.

8.5.2 Comparison with the CLP criteria

The Pensky-Martens closed cup method is one of the suitable test methods listed in CLP Annex I, Table 2.6.3 for determining the flash point of flammable liquids.

For classification purposes it is recommended to use the mean of at least two test runs. If the experimentally determined flash point is found to be within ± 2 °C of the threshold limit when using a non-equilibrium method, it is recommended to repeat the determination with an equilibrium method. The arithmetic mean of the three measurement is 62.5 °C that is outside ± 2 °C of the threshold limit. Equilibrium methods are also advised if the boiling points of the components of the mixture cover a wide range of temperatures or their concentrations are very different. The composition of the PAA solution tested is PAA 39.6%, AA 2.0% and H_2O_2 0.34%. Therefore, the equilibrium method should have been used.

The flash point for liquid organic peroxides is only relevant in the temperature range where the organic peroxide is thermally stable (Guidance on the Application of the CLP Criteria 2.15.4.3.2). Above the SADT of the organic peroxide determination of the flash point is not relevant because decomposition products are evolved. The SADT is 55 °C for PAA 38% and 40 °C for PAA 41.5% (Table 10).

Peracetic acid currently has a harmonised classification as Flam. Liq. 3, H226; Flammable liquid and vapour. Flammable liquid means a liquid having a flash point of not more than 60 °C (criteria for flammable liquids category 3: Flash point $\geq 23\,^{\circ}$C and $\leq 60\,^{\circ}$C).

8.5.3 Conclusion on classification and labelling for flammable liquids

The current harmonised classification Flam. Liq. 3 is removed as the hazard class is not applicable because the SADT is below 60 °C and below the flash point.

8.6 Flammable solids

Hazard class not applicable.

8.7 Self-reactive substances

Hazard class not applicable (CLP, Annex I, 2.8.1.1.).

8.8 Pyrophoric liquids

Not assessed in this dossier.

8.9 Pyrophoric solids

Hazard class not applicable.

8.10 Self-heating substances

Hazard class not applicable (CLP Guidance, 2.11.4.2.).

8.11 Substances which in contact with water emit flammable gases

Hazard class not applicable (CLP, Annex I, 2.12.4.1.).

8.12 Oxidising liquids

Not assessed in this dossier.

8.13 Oxidising solids

Hazard class not applicable.

8.14 Organic peroxides

Table 10: Summary table of studies on organic peroxides

Method	Results	Remarks	Reference
UN RTDG Detonation / Test A	Neither peroxy acetic acid will propagate a detonation.	Classification of the following compositions was determined: PAA 38% HP 1.4% AA 2 % PAA 13.4% HP 15.2% AA 22% Previously determined test results were used, too: Detonation (Test series A) PAA$_{40.9}$HP$_{1}$AA$_{1}$ – no PAA$_{38.3}$HP$_{22.8}$AA$_{12.8}$ – no PAA$_{20.5}$HP$_{15.0}$AA$_{27.5}$ – no Deflagration (Test series C) PAA$_{40.9}$HP$_{1}$AA$_{1}$ – no PAA$_{38.3}$HP$_{22.8}$AA$_{12.8}$ – yes, slowly PAA$_{20.5}$HP$_{15.0}$AA$_{27.5}$ – no Sensitivity to heating under confinement (Test series E)	Anonymous (1997b)
UN RTDG Deflagration / Test C	Neither peroxy acetic acid will propagate a deflagration.		
UN RTDG Heating under confinement / Test E	The sensitivity to heating under confinement of composition PAA$_{38}$HP$_{1.4}$AA$_{2}$ is ‘Low’. The sensitivity to heating under confinement of composition PAA$_{13.4}$HP$_{15.2}$AA$_{22}$ is ‘No’.		
UN RTDG Explosive power / Test F	The explosive power of either composition will be ‘No’.		
UN RTDG SADT / Test H	According to the test in the AST applied to scale of a 24 m^3 tank transport, the SADT is 55°C for both compositions.		

Method	Results	Remarks	Reference
		$PAA_{40.9}HP_{1}AA_{1}$ medium $PAA_{38.3}HP_{22.8}AA_{12.8}$ medium $PAA_{20.5}HP_{15.0}AA_{27.5}$ no Explosive power (Test series F) $PAA_{40.9}HP_{1}AA_{1}$ low $PAA_{20.5}HP_{15.0}AA_{27.5}$ not low Final classification $PAA_{40.9}HP_{1}AA_{1}$ D $PAA_{38.3}HP_{22.8}AA_{12.8}$ D $PAA_{20.5}HP_{15.0}AA_{27.5}$ F	
UN RTDG Detonation / Test A	Not relevant. In none of the previous investigations, did any of the similar samples of distilled PAA show detonative properties at all.	Composition PAA 41.5% HP 1% AA 3%	Anonymous (1999)
UN RTDG Deflagration / Test C	The distilled PAA 41.5% will not deflagrate under confinement (Test C.1) The distilled PAA 41.5% will not deflagrate under atmospheric conditions (Test C.2)		
UN RTDG Heating under confinement / Test E	Koenen test was considered not relevant. In none of the previous investigations, did any of the similar samples of distilled PAA show sensitivity to heating under high confinement at all. For distilled PAA 41.5%, the sensitivity to heating under low confinement is 'Low' (Test E.2).		
UN RTDG Explosive power / Test F	The explosive power of distilled PAA 41.5% is 'Low' (Test F.4)		
UN RTDG SADT / Test H	The SADT is 40°C for distilled PAA 41.5% (Test H.2)		

8.14.1 Short summary and overall relevance of the provided information on organic peroxides

The tests for different compositions of peracetic acid, hydrogen peroxide, acetic acid and water were performed in accordance with the test series A to H as described in Part II of the UN RTDG, Manual of Tests and Criteria.

8.14.2 Comparison with the CLP criteria

Peracetic acid currently has a harmonised classification as Org. Perox. D ****.

The classification of organic peroxides shall be performed in accordance with test series A to H as described in Part II of the UN RTDG, Manual of Tests and Criteria.

According to the criteria specified in the UN RTDG, the investigated three compositions (PAA 38%, PAA 13.4%, PAA 41.5%) should be classified as a type F organic peroxides (Table 10). However, based on previous determinations PAA 40.9% is classified as Org. Perox. D, PAA 38.3% is classified as Org. Perox. D and PAA 20.5% is classified as Org. Perox. D. Therefore, it is clear that not only the concentration of PAA influences the classification but the concentrations of HP and AA do have an marked influence on the test result.

A list of currently classified organic peroxides is included in the UN RTDG Model regulations, Section 2.5.3.2.4. Peroxyacetic acid with concentration ≤ 43% is classified as organic peroxide type D, E or F.

8.14.3 Conclusion on classification and labelling for organic peroxides

The current harmonised classification is not changed due to the variability of the classification values based on composition, especially in high PAA concentrations.

8.15 Corrosive to metals

Not assessed in this dossier.

9 TOXICOKINETICS (ABSORPTION, METABOLISM, DISTRIBUTION AND ELIMINATION)

Table 11: Summary table of toxicokinetic studies

<table>
<tr><th>Method</th><th>Remarks</th><th>Results</th><th>Reference</th></tr>
<tr>
<td>Absorption, distribution and excretion following a single dermal administration

OECD TG 417 (with incorporation of TG 427)
GLP
Key study

Test material: ^{14}C-radiolabelled Proxitane 0510 (5.02% peracetic acid)

Acceptable</td>
<td>Sprague-Dawley rat
4 males in treatment group, 4 controls
Volume: 100 µL
Control substance: ^{14}C-labelled acetic acid/hydrogen peroxide solution (70%/30%)

The test material was topically applied to an enclosed area of approx. 4.5 cm^2, and the fate of the radioactivity was studied in treated skin, major organs, carcass, respired air, urine and faeces up to 72 hours post treatment.</td>
<td>Radioactivity recovered after 72 hours (% of the administered dose):
<table>
<tr><th></th><th>Treated rats</th><th>Control rats</th></tr>
<tr><td>CO_2</td><td>33-46 (mean 36)</td><td>22-33 (mean 27)</td></tr>
<tr><td>Urine</td><td>7.6-14.5 (mean 10.5)</td><td>12-20 (mean 16.7)</td></tr>
<tr><td>Faeces</td><td>1.6-4.4 (mean 2.6)</td><td>1.7-4.7 (mean 3.4)</td></tr>
<tr><td>Tissues, carcass</td><td>9.1-13.5 (mean 12.1)</td><td>5.5-9.5 (mean 6.9)</td></tr>
</table>
The absence of systemic bioavailability is confirmed by the rapid degradation upon dermal contact resulting in severe damage as well as by the observation that the kinetic behaviour was comparable in both groups. The main differences were the lower amount evaporating from the skin, the apparent lag phase in exhalation of radioactive CO_2, the lower excretion in urine and a higher retention of radioactivity in tissues and carcass.</td>
<td>Anonymous (1994)
Doc. No.: 511-001 A6.2/01, ECETOC JACC Report No.40</td>
</tr>
</table>

Method	Remarks	Results	Reference
In vitro metabolism in blood Non-guideline GLP Test material: Peraclean 15 solutions (15.22% (w/w) peracetic acid) Acceptable	Wistar rat, 1 male Concentrations: 5.4, 10.8 and 21.6 mg/L Vehicle: physiological saline Control: test solution without blood After incubation, samples were taken before and after addition of blood and at 5, 15, 30, 60, 120 and 240 minutes and after 24 hours.	Rapid degradation of peracetic acid and hydrogen peroxide occurred in samples containing ≤10 mg/L of the test substances. The half-lives were well below 5 minutes. In the absence of blood, peracetic acid was quite stable at the highest concentration and none was present in neat blood. Degradation by approx. 50% before addition of blood can be explained by the known high reactivity of peracetic acid with organic material.	Anonymous (2003c) Doc. No.: 514-001 A6.2/03
In vitro metabolism in blood Non-guideline GLP Test material: Proxitane 15 solutions (15.1% peracetic acid) Acceptable	Wistar rat, 1 male Concentrations: 1.0 and 5.0 mg/L Vehicle: physiological saline Control: test solution without blood After incubation, samples were taken after addition of blood and at 5, 15, 30, 60, 120 and 240 minutes.	After 5 minutes of incubation less than 0.1 mg/L peracetic acid was present in both solutions. Hence, the half-life of peracetic acid in diluted rat blood was <5 minutes. The concurrent control solution showed a much slower degradation: after 5 minutes, only a small amount of peracetic acid had degraded and the half-life was about 4 hours.	Anonymous (2005c) Doc. No.: 593-001 A6.2/02

9.1 Short summary and overall relevance of the provided toxicokinetic information on the proposed classification(s)

A few toxicokinetic studies are available for peracetic acid (Table 11). The only in vivo study is with dermal exposure; no toxicokinetic data are available for other routes. Based on the physicochemical properties, peracetic acid has a low molecular weight (76.05 g/mol), high water solubility (>10 000 mg/L) and an octanol/water partition coefficient of -0.3. The high water solubility and the low octanol/water partition coefficient may limit absorption via biological membranes. No bioaccumulation is expected for the substance.

Anonymous (1994) studied absorption, distribution and excretion following a single dermal administration of peracetic acid in Sprague-Dawley rats. The study followed the OECD TG 417 (incorporating the TG 427) and the principles of GLP. The test material was containing 5.02% peracetic acid, 22.3% hydrogen peroxide and acetic acid concentration was not specified. Four male rats were given a single application of the test substance to an enclosed area (approx. 4.5 cm^2) of clipped dorsal skin. The treated animals were then placed in metabolism cages and respired air, urine and faeces were analysed for radioactivity up to 72 hours post-treatment. Approximately 36% of the administered dose was recovered as CO_2 in treated animals. There was a lag phase of 1 hour in the formation of CO_2, which may be due to a lower blood flow in skin capillaries and a slower distribution due to formation of micro-emboli resulting from oxygen formation after contact and severe damage to the skin. There was no volatilisation from treated skin since only a small portion of the administered dose (<1%) was recovered as unchanged peracetic acid. As the skin of the animals was severely damaged due to the corrosive effects of the test solution, the results cannot be used to assess absorption of peracetic acid through intact skin.

In the non-guideline study Anonymous (2003c), the fate of peracetic acid was investigated in blood with samples drawn from one male Wistar rat. The samples were diluted 1000 times with test solutions (containing 15.22% (w/w) peracetic acid and 14.27% (w/w) hydrogen peroxide) in different concentrations (0, 5.4, 10.8 and 21.6 mg/L peracetic acid and 0, 5.1, 10.1 and 20.3 mg/L hydrogen peroxide, respectively) in physiological saline. The solutions were incubated at 37°C and measured for their peracetic acid (or hydrogen peroxide) concentration with the Merck Reflectoquant test systems. Samples were taken immediately before and after addition of blood, at 5, 15, 30, 60, 120 and 240 minutes and after 24 hours. Peracetic acid was rapidly degraded in diluted rat blood, with half-lives below five minutes.

The non-guideline study Anonymous (2005) followed a similar principle: samples were drawn from one male Wistar rat and diluted 1000 times with test solutions (containing 15.1% peracetic acid, 23.0% hydrogen peroxide and 16.6% acetic acid) of different concentrations (1.0 and 5.0 mg/L peracetic acid) in physiological saline. The solutions were incubated at 37°C and samples were taken immediately after addition of blood and at 5, 15, 30, 60, 120 and 240 minutes. Peracetic acid oxidises methyl-p-tolylsulfide (MTS), which was added to each of the samples. The resulting methyl-p-tolylsulfoxide (MTSO) was monitored by HPLC, and the concentration of peracetic acid was calculated. According to the results, peracetic acid was rapidly degraded in blood, with a half-life below five minutes.

Overall, peracetic acid is degraded by catalases found in blood, stomach fluid, saliva and in various organs (CAR 2015). Most importantly, degradation by catalases in human erythrocytes has been demonstrated. Non-enzymatic degradation to acetic acid and oxygen has been reported at pH values of around 7, which is close to physiological pH values both in blood and in cells.

10 EVALUATION OF HEALTH HAZARDS

Acute toxicity

10.1 Acute toxicity - oral route

Table 12: Summary table of animal studies on acute oral toxicity

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance, vehicle	Dose levels, duration of exposure	Signs of toxicity	Value LD_{50}	Reference
Acute oral toxicity study EPA-FIFRA guideline 81-1 (compatible with OECD TG 401 (1987)) GLP Reliability: 1 **Key study**	CD rat, males and females 5 animals per sex per dose No control animals	Peracetic acid 5%, hydrogen peroxide 22%, acetic acid 10% Administration: by gavage Vehicle: tap water (concentration in vehicle: 1.25% peracetic acid) Total volume applied: not specified	1000, 2000 and 4000 mg/kg bw Observations for toxicity were conducted at approximately 0.5, 1, 2, 3, 4 and 6 hours following dosing and daily thereafter for 14 days. Body weights were recorded on days 0, 7 and 14 or upon discovery of death.	9/10 animals (4 males, 5 females) died at 4000 mg/kg bw and 6/10 animals (3 males, 3 females) died at 2000 mg/kg bw. No deaths occurred at 1000 mg/kg bw. Clinical signs (most significant): abdominal gripping, abdominal distention, loss of muscle control, squinting eyes, staggered gait, tremors, walking on toes, hypersensitivity to touch, splayed hindlimbs and hypothermia. All signs of toxicity subsided by day 13, however, recovery was essentially complete on day 7. Pathology: blanched stomach and intestines, mottled blanched livers, distended stomach with thin linings, darkened red adrenals, white trachea, blood in stomach and intestines.	1922 mg/kg bw (combined), 1993 mg/kg bw (males), 1859 mg/kg bw (females) Correspond to 96.1, 99.7 and 93.0 mg/kg bw of 100% peracetic acid*, respectively.	Anonymous (1998b) A 6.1.1/01
Acute oral toxicity study Similar to OECD TG 401 (1987) GLP Reliability: 1	Sprague-Dawley rat, males and females 5 animals per sex per dose	Oxy-15 (peracetic acid 15.2%, hydrogen peroxide 11.2%, acetic acid 36.3%) Administration: by gavage Vehicle:	1250, 1880, 2500 mg/kg bw Signs of toxicity were recorded frequently on the day of administration and at least twice daily thereafter for a total of 14	9/10 animals (4 males, 5 females) died at 2500 mg/kg bw and 10/10 animals died at 1880 mg/kg bw. No deaths occurred at the lowest dose. Clinical signs (at all dose levels): slight to severe depression,	1780 mg/kg bw (only the results from the 10% formulation experiments were used for the deduction of the value)	Anonymous (1995) A6.1.1/04

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, vehicle**	**Dose levels, duration of exposure**	**Signs of toxicity**	**Value LD$_{50}$**	**Reference**
Key study The test material was initially administered as 25% (w/v) formulation but was then changed to a 10% (w/v) formulation in order to avoid explicit mortality and corrosivity.	No control animals	distilled water (concentration in vehicle: 1.52% peracetic acid) Total volume applied: not specified	days. Body weights were measured on the day of dosing, on day 7 and at the time of necropsy or an unscheduled death.	saliva stains, piloerection, respiratory distress, bloating of the abdominal region and emaciation. Pathology: congested kidney in one animal and enlarged stomach with semi-liquid food-like content in one animal. In animals that died during the study, general observations of irritation or corrosion were observed.	Corresponds to 271 mg/kg bw of 100% peracetic acid*.	
Acute oral toxicity study EPA guideline no. 81-1 Study was performed prior to implementation of GLP, but study is compatible with FDA GLP guidelines. Reliability: 1 **Key study**	Sprague-Dawley rat, males and females 5 animals per sex per dose No control animals	Peracetic acid 5%, hydrogen peroxide 26.7%, acetic acid 6.7% Administration: by gavage Vehicle: distilled water (concentrations in vehicle: 12.6, 20.0, 32.0, 50.0 % w/v) Total volume applied: 10.0 ml/kg	1260, 2000, 3200, 5000 mg/kg bw Observations for toxicity were performed soon after dosing and at frequent intervals on day 1. On subsequent 13 days the animals were observed at least twice per day. Body weights were recorded on day 1, 8 and 15 and at death.	10/10 animals died at 5000 mg/kg bw and at 3200 mg/kg bw, 7/10 animals (2 males, 5 females) died at 2000 mg/kg bw and 2/10 animals (1 male, 1 female) died at 1260 mg/kg bw. Clinical signs: piloerection, hunched posture, abnormal gait, lethargy and pallor of extremities in all rats. Predominantly at higher dose levels: decreased respiratory rate, ptosis, increased salivation, rales, abdominal distension, comatose-like condition, gasping and increased lacrimation. Pathology: distension and congestion of the stomach wall with thickening of the pyloric sphincter, congestion of duodenum, possibly ulcerated area in stomach.	1700 mg/kg bw (combined), 1900 mg/kg bw (males), 1400 mg/kg bw (females) Correspond to 85.0, 95.0 and 70.0 mg/kg bw of 100% peracetic acid*, respectively.	Anonymous (1985) A6.1.1/02

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, vehicle**	**Dose levels, duration of exposure**	**Signs of toxicity**	**Value LD$_{50}$**	**Reference**
Acute oral toxicity study OECD TG 401 (1987) GLP Reliability: 1 Dose levels were selected based on a preliminary study with dose levels of 188, 375, 750, 1500 and 3000 mg/kg (2 rats per sex per dose, observation period 7 days).	Sprague-Dawley rat, males and females 5 animals per sex per dose No control animals	Oxystrong 5 (peracetic acid 5.6%, hydrogen peroxide 26.9%, acetic acid 7.6%) Administration: by gavage Vehicle: Alembicol D (fractionated coconut oil) (concentration in vehicle not specified) Total volume applied: 10 ml/kg	1200, 1680, 2352, 3293 mg/kg bw Animals were checked for signs of toxicity immediately upon dosing, approximately 1, 2 and 4 hours after dosing and daily thereafter for a total of 14 days. Body weights were checked on days -3, 1, 8 and 15, or at time of discovery after death.	3/10 animals (2 males, 1 female) died at 3293 mg/kg and 4/10 animals (2 males, 2 females) died at 2352 mg/kg bw. No deaths occurred at the two lowest dose levels. Clinical signs: Common: soft/mucoid faeces, reduced activity, piloerection Sporadic: moribund appearance, hunched posture, swollen abdomen, prolapsed penis, part-closed eyes and pallor. Surviving animals had generally recovered within 3 days of dosing. Changes in body weight of the surviving animals were generally not remarkable. Pathology: Surviving animals showed no abnormalities. Animals that died during the study showed significant abnormalities in liver (either dark or pale spots), stomach (thickened and white) and the GIT (dark red and containing dark red material).	3622 mg/kg bw (combined) 3271 mg/kg bw (males) 4217 mg/kg bw (females) Correspond to: 202.8, 183.2 and 236.2 mg/kg bw of 100% peracetic acid*, respectively.	Anonymous (1998c) A6.1.1/05
Acute oral toxicity study Non-guideline, similar to OECD TG 401 (1987) GLP Reliability: 2 (body weight was not recorded for	Sprague-Dawley rat, males and females 5 animals per sex per dose No control animals	Peracetic acid 6.11%, hydrogen peroxide 26.92%, available oxygen 13.92% Administration: by gavage Vehicle: distilled water (concentration of PAA in	790, 1250, 1980, 5000 mg/kg bw Signs of toxicity and body weights were recorded for 14 days at the two highest dose levels; at 790 and 1250 mg/kg bw, the animals were observed for a total of 35 days. Animals of the lowest dose	10/10 animals died at 5000 mg/kg, 6/10 animals (2 males, 4 females) died at 1980 mg/kg, 5 animals (2 males, 3 females) died at 1250 mg/kg and 1/10 animals (1 female) died at 790 mg/kg bw. Animals at the highest dose died within 24 hours, other deaths occurred within 13 days. Clinical signs:	1270 mg/kg bw Corresponds to 77.6 mg/kg bw of 100% peracetic acid*.	Anonymous (1993) A6.1.1/05

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance, vehicle	Dose levels, duration of exposure	Signs of toxicity	Value LD_{50}	Reference
one animal at necropsy, animals of the 790 mg/kg group were not weighed on day 14 but on day 18 instead, observation period was 35 days for the two lowest dose levels)		vehicle: 1.53%) The test material was administered as 25% (w/v) formulation. Dilution was utilised to decrease the corrosive effect of the undiluted test material. Total volume applied: not specified	group were not weighed on day 14.	gasping, depression, laboured breathing, ataxia, stained fur, emaciation, bloated abdomen, eye squinting, piloerection, red material on muzzle, alopecia and hunched posture. Pathology: foamy material throughout abdominal cavity, white liver, spleen, stomach, upper intestines, lower intestines haemorrhagic, mottled lungs, stomach bloated with gas, pale and/or congested kidney and the stomach adhered to adjacent tissues.		
Acute oral toxicity study Non-guideline, similar to OECD TG 401 (1987) Non-GLP Reliability: 2 (exact composition of the test substance not specified, body weights or body weight gain/loss not recorded, no individual data on clinical signs, necropsy and histology)	Wistar rat, males and females 5 animals per sex per dose No control animals	Peracetic acid 15% (concentrations of other components not specified) Administration: by gavage Vehicle: demineralised water (concentration in vehicle: 15%) Total volume applied: 2.15 ml/kg bw	532, 781, 1146, 1682 mg/kg bw Observations for toxicity were made 0.5, 1, 2, 4, 8 and 24 h after dosing and then once daily until sacrifice on day 14.	5/10 animals (5 females) died at 1682 mg/kg bw, 7/10 animals (4 males, 3 females) died at 1146 mg/kg bw and 2/10 (1 male, 1 female) died at 781 mg/kg bw. No deaths occurred at 532 mg/kg bw. Most of the deaths occurred within the first 6 days. Clinical signs: piloerection, writhing syndrome, stilted gait, tremor, drawn-in flanks and laboured breathing. The signs appeared 10 minutes after administration and resolved by day 5. Pathology: peritoneal adhesions, discoloured mucosa of the GIT and of the contact area between liver and stomach. In sporadic cases there were liquid deposits in the abdominal cavity.	1026 mg/kg bw (males) 1015 mg/kg bw (females) Correspond to 153.9 and 152.3 mg/kg bw of 100% peracetic acid*, respectively.	Anonymous (1982) A6.1.1/03

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, vehicle**	**Dose levels, duration of exposure**	**Signs of toxicity**	**Value LD_{50}**	**Reference**
Acute oral toxicity study EPA Guideline no. 81-1 GLP Reliability: 2 (only females in the lowest dose group)	Albino HSD:SD rat, males and females 5 animals per sex (only females in the lowest dose group) No control animals	Proxitane AHC (peracetic acid 4.89%, hydrogen peroxide 19.72%, concentration of acetic acid not specified) Administration: by gavage Vehicle: none Total volume applied: 0.044, 0.089, 0.223, 0.445, 0.891 and 4.5 ml/kg (for 50, 100, 250, 500, 1000 and 5050 mg/kg bw, respectively)	50, 100, 250, 500, 1000, 5050 mg/kg bw Observations for toxicity were made three times on the day of dosing and then once daily until sacrifice on day 14. Body weights were recorded on days 0, 7 and 14 or at time of discovery after death.	10/10 animals died at 5050 mg/kg, 6/10 animals (3 males, 3 females) died at 1000 mg/kg, 6 animals (3 males, 3 females) died at 500 mg/kg, 8/10 animals (3 males, 5 females) died at 250 mg/kg and 5/10 animals (1 male, 4 females) died at 100 mg/kg. None of the 5 females died at 50 mg/kg bw. Clinical signs: piloerection, salivation, activity decrease, nasal and ocular discharge, diarrhoea, polyuria, gasping, staining of the muzzle, respiratory gurgle and chirp, ptosis and crust around the nose. In animals that died during the study: sensitivity to touch, dark urine, laboured breathing, crust around the eyes and red discharge in the genital area. Pathology: No abnormalities in surviving animals. In animals that died: discolouration of the tongue, liver, stomach, small intestine, lungs and contents of the GIT, ocular discharge, gas in GIT, stained muzzle, anal and urogenital hair, matted hair around eyes and muzzle.	185 mg/kg bw (combined), 316 mg/kg bw (males), 118 mg/kg bw (females) Correspond to 9.0, 15.5 and 5.8 mg/kg bw of 100% peracetic acid*, respectively.	Anonymous (1996a) A6.1.1/05
Acute oral toxicity study EPA Guideline no. 81-1	Albino HSD:SD rat, males and females	Proxitane WW12 (peracetic acid 11.69%, hydrogen peroxide 18.05%,	50, 250, 500, 1000, 5050 mg/kg bw Observations for toxicity were made three times	10/10 animals died at 5050 mg/kg, 8/10 animals (4 males, 4 females) died at 1000 mg/kg, 3 females died at 500 mg/kg and 3 females died at 250	652 mg/kg bw (combined) 846 mg/kg bw (males) 314 mg/kg bw (females)	Anonymous (1996b) A6.1.1/05

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, vehicle**	**Dose levels, duration of exposure**	**Signs of toxicity**	**Value LD_{50}**	**Reference**
GLP Reliability: 2 (only females at the two lowest dose levels)	5 animals per sex per dose (only females at the two lowest dose levels) No control animals	concentration of acetic acid not specified) Administration: by gavage Vehicle: none Total volume applied: 0.0433, 0.216, 0.433, 0.866 and 4.37 ml/kg (for 50, 250, 500, 1000 and 5050 mg/kg bw, respectively)	on the day of dosing and then once daily until sacrifice on day 14. Body weights were recorded on days 0, 7 and 14 or at time of discovery after death.	mg/kg bw. No deaths occurred at 50 mg/kg bw. Clinical signs: activity decrease, crust around nose and eyes, diarrhoea, gasping, nasal and ocular discharge, piloerection, polyuria, ptosis, staining of muzzle and back, salivation, respiratory chirp, emaciation and laboured breathing. Pathology: No abnormalities in surviving animals. Animals that died during the observation period showed stained and matted muzzle and anal areas, discoloured tongue, gas in the GIT, discoloured stomach, lungs, liver, spleen and contents of the GIT.	Correspond to: 76.2, 98.9 and 36.7 mg/kg bw of 100% peracetic acid*, respectively.	
Acute oral toxicity study Council Directive 79/831/EEC, Annex V, Part B and in line with OECD guidelines Non-GLP Reliability: 2	Sprague-Dawley rat, males and females 5 animals per sex per dose 5 controls per sex	Peracetic acid 2.6%, hydrogen peroxide 27%, acetic acid 4%, strong mineral acid < 1%) Administration: by gavage Vehicle: water (concentration in vehicle: 0, 25.2, 31.8, 35.6, 40.0, 50.4 g/100 ml for the 0, 1260, 1590, 1780, 2000, 2520 mg/kg bw doses, respectively) Total volume applied: 5 ml/kg bw	1260, 1590, 1780, 2000, 2520 mg/kg bw After administration the animals were observed 1, 2 and 4 hours after administration on the first day and daily thereafter for 14 days. Body weights were recorded on days –1, 0, 7 and 14.	10/10 animals died at 2520 mg/kg, 8/10 animals (4 males, 4 females) died at 2000 mg/kg, 6 animals (3 males, 3 females) died at 1780 mg/kg, 3/10 animals (1 male, 2 females) died at 1590 mg/kg, and 1 female died at 1260 mg/kg bw. Clinical signs: weariness, ataxia, piloerection and swollen abdomen. Pathology: increased thymus, dilated and congested stomach, peritoneal adhesions and ascites.	1656 mg/kg bw (combined) Corresponds to 43 mg/kg bw of 100% peracetic acid*.	Anonymous (1984) A6.1.1/05

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, vehicle**	**Dose levels, duration of exposure**	**Signs of toxicity**	**Value LD$_{50}$**	**Reference**
Acute oral toxicity study EPA Guideline F 81-1 (compatible with OECD TG 401 (1987)) GLP Reliability: 2 (only one dose level tested, not all concentrations are given)	Sprague-Dawley rat, males and females 5 per sex No control animals	Peracetic acid 0.15%, stabilisers, hydrogen peroxide, acetic acid (concentrations not specified) Administration: by gavage Vehicle: deionised water (concentration in vehicle 0.15%) Total volume applied: 1.2-1.3 ml (males); 1.0-1.2 ml (females)	5000 mg/kg bw Observations for toxicity were made after 0.5, 1, 2, 3, 4 and 6 hours and twice daily until sacrifice on day 14. Body weights were recorded on days 0, 7 and 14.	No mortality Clinical signs: none. All rats remained healthy and gained weight during the study. Pathology: no gross lesions observed	>5000 mg/kg bw (no lethal effect at maximal dose) Corresponds to >7.5 mg/kg bw of 100% peracetic acid*	Anonymous (1991e) A6.1.1/05
Acute oral toxicity study EPA-FIFRA Guideline 81-1 (compatible with OECD TG 401 (1987)) GLP Reliability: 2 (on 4 days, the relative humidity was slightly elevated (70-90%); due to a balancing error, an excess of the test material of appr. 12% was used)	Wistar rat, males and females 5 animals per sex per dose 5 control animals per sex	Proxitane 0103 (peracetic acid 0.89%, hydrogen peroxide 7.27%, acetic acid 10.85%) Administration: by gavage Vehicle: none Total volume applied: 0.5, 1.0 and 2.0 ml/kg (low, mid and high dose, respectively)	514, 1027, 2054 mg/kg bw Observations for toxicity were made after 0, 0.5, 2 and 5 hours and once daily until sacrifice on day 14. Body weights were recorded on days –1, 0, 2, 7 and 14.	1 male of the low dose group, 1 female of the mid-dose group and 3 females of the high dose group were killed in extremis within 5 days post dosing. Clinical signs: abnormal posture and gait, decreased locomotor activity, sniffing breathing, respiratory difficulties, decreased respiratory rate, vocalization upon handling, ptosis, extended abdomen, stained mouth/nose and nasal discharge. Signs in survivors were generally slight in severity, recovery was usually complete within 2 days after dosing. Females of the highest dose did not fully recover within the 14-day period. Mean body weight and weight gain were slightly reduced at	>2000 mg/kg bw (combined), >2000 mg/kg bw (males), 1663 mg/kg bw (females) Correspond to >17.8, >17.8 and 14.8 mg/kg bw of 100% peracetic acid*, respectively.	Anonymous (1994) A6.1.1/05

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, vehicle**	**Dose levels, duration of exposure**	**Signs of toxicity**	**Value LD_{50}**	**Reference**
				2054 mg/kg bw. Pathology: red spots on lung lobes, maculate thymus, moist skin around mouth, slightly dilated uterus, severe inflammatory changes in GIT (sometimes accompanied by adhesive fibrino-purulent peritonitis).		
Acute oral toxicity study Non-guideline, similar to EPA Guideline no. 81-1 GLP Reliability: 2 (only 2 dose levels were tested, stability not determined)	Sprague-Dawley rat, males and females 5 animals per sex per dose No control animals	Peracetic acid 36.4%, hydrogen peroxide 7.3% (concentration of acetic acid not specified) Administration: by gavage Vehicle: none Total volume applied: not specified, calculated to 0.0442 and 0.442 ml/kg bw based on the specific gravity of the test material (1.13 g/ml)	50 and 500 mg/kg bw (dose levels were set following a preliminary study) Observations for toxicity were conducted at approximately 3 hours after dosing and daily thereafter for 14 days. Body weights were recorded on days 0, 7 and 14 of the study.	10/10 animals died within 3 days at 500 mg/kg bw. 1 male died at 50 mg/kg bw on day 13. Clinical signs: dyspnea, oral discharge, chromorhinorrhea and decreased locomotion. All survivors gained weight during the study. Pathology: Surviving animals had no gross lesions. In animals that died blood-filled stomach and intestines, white livers, spleens, kidneys and stomachs were observed. A consolidated lung was observed in 1 rat.	50-500 mg/kg bw Corresponds to 17.5-175 mg/kg bw of 100% peracetic acid*.	Anonymous (1987) A6.1.1/05
Acute oral toxicity study (limit test) OECD TG 401 (1987) GLP Reliability: 1	Wistar rat, males and females 5 per sex No control animals	Peracetic acid 15%, hydrogen peroxide 22%, acetic acid 16.7%, phosphonic acid 0.3%, sulphuric acid 0.73% Administration: by gavage Vehicle: demineralised water (concentration in vehicle: 20	200 mg/kg bw Signs of toxicity were observed 1 and 4 hours after dosing and subsequently at least once daily for 14 days. Body weights were recorded immediately before dosing and on days 3, 7 and 14.	1/5 females died on day 13; all other animals survived until termination of the study. Clinical signs: sluggishness, soiled fur, swollen abdomen and diarrhoea in 1 male. 1 male showed encrustation of the nose 4 and 24 h after treatment and a swollen abdomen on day 2 and 3. Sluggishness and	>200 mg/kg bw Corresponds to >30 mg/kg bw of 100% peracetic acid*.	Anonymous (1993a) A6.1.1/05

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, vehicle**	**Dose levels, duration of exposure**	**Signs of toxicity**	**Value LD_{50}**	**Reference**
		mg/ml) Total volume applied: 10.0 ml/kg		weakness were observed in 3 females after 48 and 72 h. All other animals did not show any signs of toxicity. Pathology: no treatment-related gross alterations		
Acute oral toxicity study OECD TG 401 (1987) GLP Reliability: 2	Sprague-Dawley rat, males and females 5 per sex per dose No control animals	Bactipal D (peracetic acid 10.85%, hydrogen peroxide 17.19%) Administration: by gavage Vehicle: for 200 mg/kg distilled water, for other dose levels none (concentration in vehicle for 200 mg/kg not specified) Total volume applied: 2.5, 0.9, 1.4, 1.9 and 2.7 ml/kg bw (for 200, 1000, 1500, 2100 and 3000 mg/kg bw, respectively)	200, 1000, 1500, 2100, 3000 mg/kg bw The animals were observed for mortalities (twice daily) and clinical signs (1, 2, 3, 4, 5, 6 h after dosing and daily thereafter) for 14 days. Body weights were recorded shortly before treatment and on days 3, 7 and 14.	10/10 animals died at 3000 mg/kg, 6/10 animals (3 males, 3 females) died at 2100 mg/kg, 6/10 animals (3 males, 3 females) died at 1500 mg/kg and 10/10 animals died at 1000 mg/kg bw. No deaths occurred at 200 mg/kg bw. Clinical signs: piloerection, decreased activity, laboured breathing, decreased tonicity, abnormal contractions and hypersalivation. Pathology: signs of congestion in abdominal cavity, enlarged and pale stomach mucosa, adherence of stomach, liver and GIT.	200-1000 mg/kg bw Corresponds to 21.7-109 mg/kg bw of 100% peracetic acid*.	Anonymous (1998c) A6.1.1/05
Acute oral toxicity study EPA PB 82-232984 GLP Reliability: 2 (stability of the test material was not warranted for two test	Sprague-Dawley rat, males and females 10 per sex per dose No control animals	Peracetic acid 17%, hydrogen peroxide 22.9%, acetic acid and water (concentrations not specified) Administration: by gavage Vehicle: none Total volume applied: not specified	250, 397, 500, 630, 794, 1000, 1260 mg/kg bw (the three lowest doses only in females) Results from two levels (250 and 630 mg/kg bw) were considered not relevant due to the lack of mortality and clinical signs attributed to	18/20 animals (8 males, 10 females) died at 1260 mg/kg, 14/20 animals (4 males, 10 females) died at 1000 mg/kg, 13 animals (3 males, 10 females) died at 794 mg/kg, 3/20 animals (3 males) died at 630 mg/kg, 6/20 animals (6 females) died at 500 mg/kg and 8/20 animals (8 females) died at 397	Approximately 1000 – 1260 mg/kg bw (males) and < 397 mg/kg bw (females). Corresponds to approximately 170 – 214.2 mg/kg and < 67.5 mg/kg bw of 100% peracetic acid*, respectively.	Anonymous (1983a) A6.1.1/05

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, vehicle**	**Dose levels, duration of exposure**	**Signs of toxicity**	**Value LD_{50}**	**Reference**
concentrations)			instability of the test material (these dose levels were tested later than the other dose levels). Observations for toxicity were conducted at 0.5, 1, 2, 3, 4 and 6 hours on the day of dosing and twice daily thereafter for 13 days; on day 14 they were observed once. Body weights were recorded on days 0, 7 and 14 of the study.	mg/kg bw. No deaths occurred at 250 mg/kg bw. Clinical signs: decreased locomotion, rales, haematuria, abdominal distension, abdominogenital staining, unthriftiness, recumbancy and oral, ocular and nasal discharge. The signs continued throughout the study. Pathology (in both decedents and survivors): severe destruction of the GIT, adhesions between stomach and intestines, irritated gastric linings, fibrous tissues and ulcerations in and around gastric mucosa.		
Acute oral toxicity study Non-guideline, similar to OECD TG 401 Non-GLP Reliability: 3 (composition of the PAA solution not specified, only females were used, animals were observed for only 72 hours, vehicle not specified) Supportive study	Albino rat, female 5 animals per dose Control animals (amount not specified)	Wofasteril and peracetic acid solutions; Wofasteril: peracetic acid 36-40%, hydrogen peroxide 5%, acetic acid 30%, mixture of stabilisers 0.25% PAA solution: composition not specified Administration: by gavage Vehicle: not specified (very likely water) Concentrations in vehicle: Wofasteril: 0.48, 0.75, 0.96, 1.20 and 1.45% for the 120, 180, 240,	Wofasteril: 120, 180, 240, 300, 360 mg/kg bw Peracetic acid solution: 210, 240, 270, 300, 330 mg/kg bw Post exposure period 72 hours	Mortalities at all dose levels except at the lowest Wofasteril dose. Most of the animals receiving lethal doses died within 5 hours, some within 3 days. No further details are provided. Clinical signs (for both Wofasteril and PAA solution): agitation, increased respiration, wallowing and mucosal cyanosis. Pathology: severe acute enteritis, oedema of the GIT, disintegration of epithelial cells of mucosa of stomach and intestines, and necrosis in kidney tubules.	Wofasteril: 263.0 mg/kg bw Corresponds to: 95-105 mg/kg bw of 100% peracetic acid* Peracetic acid solution: 314.8 mg/kg bw Due to lack of information on the exact composition a corresponding value for pure peracetic acid cannot be determined.	Anonymous (1974) A6.1.1/05

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance, vehicle	Dose levels, duration of exposure	Signs of toxicity	Value LD_{50}	Reference
		300 and 360 mg/kg bw groups, respectively. Peracetic acid solution: 0.85, 0.96, 1.08, 1.20 and 1.35% for the 210, 240, 270, 300 and 330 mg/kg bw groups, respectively. Total volume applied: not specified				
Acute oral toxicity study Non-guideline, similar to OECD TG 401 Non-GLP Reliability: 3 (exact composition of the used solution, dose levels and vehicle not specified) Supportive study	Sprague-Dawley rat, males and females 10 per sex per dose No control animals	Peracetic acid 10% (other components not specified) Administration: by gavage Vehicle: not specified Total volume applied: 1.26, 1.59, 2.00, 2.52, 3.18 ml/kg bw	1.26, 1.59, 2.00, 2.52, 3.18 ml/kg bw Correspond to 1450, 1830, 2300, 2900, 3650 mg/kg bw, respectively. The animals were observed for 4 weeks for clinical signs, change in behaviour, food consumption and body weight.	20/20 animals died at 3.18 ml/kg, 14/20 animals (6 males, 8 females) died at 2.52 ml/kg, 4/20 animals (1 male, 3 females) died at 2.00 ml/kg, 2/20 animals (1 male, 1 female) died at 1.59 ml/kg. No deaths occurred at 1.26 ml/kg bw. At the highest dose all animals died within 72 hours. Clinical signs: sedation, decreased food consumption, decreased body weight gain, ataxia, dyspnea, piloerection, bloody nasal discharge and coma. Pathology: scarred adhesion of stomach and adjacent tissues, bloody material in GIT, perforation and haemorrhagic erosion of stomach and oesophagus, and intra-peritoneal blood deposits.	2.21 ml/kg bw (males), 2.08 ml/kg bw (females) (based on the rate of mortality after 14 days) Correspond to 254 mg/kg and 239 mg/kg bw of 100% peracetic acid*, respectively.	Anonymous (1977) A6.1.1/05
Acute oral toxicity study OECD TG 423 (Acute	Wistar rat, males and females 3 animals	Blend of peracetic acid, hydrogen peroxide and acetic acid;	200 mg/kg bw (2000 mg/kg bw was considered to produce severe signs of	No mortality No clinical signs. Body weights were unaffected by the	200-2000 mg/kg bw Corresponds to 10-100 mg/kg bw of 100%	Anonymous (1998c) A6.1.1/05

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance, vehicle	Dose levels, duration of exposure	Signs of toxicity	Value LD_{50}	Reference
toxic class method, limit test) GLP Reliability: 3 (composition of the test substance not specified, relative humidity was higher than the recommended top limit) Supportive study	per sex No control animals	concentrations not specified Administration: by gavage Vehicle: water (concentration in vehicle 20 mg/ml) Total volume applied: 10 ml/kg bw	corrosion) The animals were observed 1 and 4 hours after dosing for toxicity and daily thereafter for an observation period of 14 days. Body weights were recorded prior to dosing and on days 3, 7 and 14 of the study.	treatment. No gross pathological lesions	peracetic acid (assuming 5% concentration)*.	

***Note: this is a theoretical calculated value which does not take into account that both hydrogen peroxide and acetic acid contribute to the acute toxicity observed for the test substance via acute toxicity and/or corrosivity/irritative property.**

Table 13: Summary table of human data on acute oral toxicity

No human studies are available.

Table 14: Summary table of other studies relevant for acute oral toxicity

No other studies are available.

10.1.1 Short summary and overall relevance of the provided information on acute oral toxicity

A total of 18 oral acute toxicity studies were carried out in rats using different test substances containing concentrations of PAA ranging from 0.15 to 35%. The key studies were carried out in accordance with standard OECD/US-EPA and GLP guidelines.

According to the results of all acute oral toxicity studies for peracetic acid concentrations <1% the oral LD_{50} is >2000 mg/kg bw and for peracetic acid concentrations of 5.0 - 15.2 % the oral LD_{50} is from 95.0 to 250 mg/kg bw in males, from 70 to 240 mg/kg bw in females, and from 76.2 to 271 mg/kg bw as combined (male/female). Anonymous (1996b) study is exluded from the female results as the value 36.7 mg/kg bw does not correlate with the other findings. According to the results of the studies, females are more sensitive to PAA, and the classification should therefore be based on the LD_{50} for females.

The key studies were performed with test substances containing peracetic acid ranging from 5 – 15.2 %, which showed LD_{50} values ranging from 95 to 99.7 mg/kg bw in males, from 70 to 93 mg/kg bw in females, and from 85 to 271 mg/kg bw as combined (male/female) for 100 % peracetic acid. The most significant clinical signs observed were piloerection, respiratory difficulties, abdominal gripping, abdominal distention, loss of muscle control, squinting eyes, staggered gait, tremors, hypersensitivity to touch, splayed hindlimbs and hypothermia. In the concentration of 15 % the main clinical signs observed were oral and ocular discharges, respiratory distress and abdominal distention.

During necropsy blanched stomach and intestines, mottled blanched livers, distended stomach with thin linings, darkened red adrenals, white trachea and blood in stomach and intestines were noted. The animals that died during the observation period had severely irritative and corrosive findings in the gross necropsy.

The lowest LD_{50} was 5.8 mg/kg bw (Anonymous 1996a), but also LD_{50} values higher than 200 mg/kg bw were reported (Anonymous 1977). The high variability of the LD_{50} is probably due to methodological differences in the peracetic acid concentration and volume of the test material solutions applied by gavage. If the stock solution was diluted and a constant volume was administered, the toxicity was lower as compared to studies where undiluted test material was administered or volumes increasing with higher dose levels. For example LD_{50} was 9.0 mg/kg bw for a product containing 4.89% peracetic acid applied undiluted with volumes ranging from 0.04 to 4.5 ml/kg bw (Anonymous, 1996a), whereas the LD_{50} values ranged from 77.6 to 96.1 mg/kg bw in the other studies conducted with similar products (4.5 - 6.11% peracetic acid), but administered in higher volumes containing lower concentrations of peracetic acid. In the study showing the highest LD_{50} (202.8 mg/kg bw), coconut oil was used as vehicle, whereas water was used in all other studies. Similar differences were seen in the other study conducted by Anonymous (1996b) with a test substance containing 11.7% peracetic acid. It can be concluded that the toxicity is higher when tissue is damaged due to the corrosive properties of peracetic acid at higher concentrations.

10.1.2 Comparison with the CLP criteria

Peracetic acid currently has a harmonised classification as Acute Tox. 4*; H302 for the oral route.

Classification for acute oral toxicity under the CLP Regulation is required for substances with an acute oral LD_{50} value of ≤ 2000 mg/kg bw. Category 4 is assigned for substances with an LD50 value of > 300 and ≤ 2000 mg/kg bw and Category 3 for substances with an LD50 value of > 50 and ≤ 300 mg/kg according to the table 3.1.1 of Annex I to the CLP Regulation.

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 314-1859 mg/kg bw (70-93 mg/kg bw for 100% PAA). In order to derive a correct classification/ATE value for a mixture containing peracetic acid, a 100 % substance should be classified even if the substance cannot exist in such a high concentration. Therefore, peracetic acid (100 %) should be classified as Acute Tox. 3; H301 based on the calculated LD_{50} values for peracetic acid in the equilibrium test substance (LD_{50} oral 70 mg/kg).

Hydrogen peroxide is classified for acute oral toxicity (Acute Tox. 4*; H302, Xn; R22, C ≥ 8 %). If ATEmix is calculated for the test substance containing different concentrations of PAA and H202 using LD_{50} of 70 mg for PAA and converted acute toxicity point estimate of 500 (cat 4, oral) for H2O2, then all of the formulations in the table 12 would be classified as Acute Tox. 4; H302. Acetic acid is not taken into account since it is not classified for acute oral toxicity in the C&L inventory.

10.1.3 Conclusion on classification and labelling for acute oral toxicity

Based on the available data, there is sufficient evidence to remove the asterisk from the classification, since the relevant LD_{50} value is in the range of > 50 and ≤ 300 mg/kg bw based on the CLP classification criteria. **Acute Tox. Category 3** is therefore proposed for 100 % peracetic acid, with the corresponding hazard statement **H301: Toxic if swallowed** with an oral ATE value of 70 mg/kg bw for the classification of mixtures containing peracetic acid.

10.2 Acute toxicity - dermal route

Table 15: Summary table of animal studies on acute dermal toxicity

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, vehicle**	**Dose levels, duration of exposure**	**Signs of toxicity**	**Value LD_{50}**	**Reference**
Acute dermal toxicity study EPA guideline no. 81-2 GLP Reliability: 1 **Key study**	New Zealand white rabbit, males and females 5 animals per sex per dose No control animals	Proxitane AHC (4.89% peracetic acid, 19.72% hydrogen peroxide, 10% acetic acid) Vehicle: none Application area: appr. 20 x 10 cm, occlusive coverage Total volume applied: 0.445, 0.891, 1.80 mL/kg bw (500, 1000, 2020 mg/kg bw)	500, 1000, 2020 mg/kg bw (24, 49 and 99 mg/kg bw of peracetic acid, respectively) Duration of exposure: 24 hours Post-exposure period 14 days Signs of toxicity were observed 3 times on day 0 and at least once daily thereafter. Signs of dermal irritation were observed 1 hour after removal of wrappings and on days 4, 7, 10 and 14. Body weights were recorded prior to dosing and on days 7 and 14, or at discovery of death.	9/10 animals (4 males, 5 females) died at 2020 mg/kg, 2/10 animals (1 male, 1 female) died at 1000 mg/kg and 2/10 animals (1 male, 1 female) died at 500 mg/kg bw. Clinical signs: activity decrease, diarrhoea, lateral recumbency, nasal discharge, ptosis, salivation and star-gazing; the signs had resolved in all surviving animals by day 6. Signs of dermal irritation: well-defined to severe erythema, slight to severe oedema, atonia, blanching, bleeding, coriaceousness, desquamation, eschar, fissuring, sloughing and necrosis. Body weight gain was unaffected in surviving animals except for 1 low-dose female, which failed to gain weight and 1 male in the 1000 mg/kg and 1 male in the 2020 mg/kg group who both lost weight between days 0 and 7. Pathology: No effects in surviving animals. Animals that died during the observation period showed wet, matted and/or stained muzzle, urogenital and anal areas, discoloured ears, air in blood vessels, heart and pericardium, fluid in pericardium, discolouration of lungs, mesentery, spleen and thymus.	1147 mg/kg bw (combined), 1280 mg/kg bw (males), 1040 mg/kg bw (females) Correspond to 56.1, 62.6 and 50.9 mg/kg bw of 100% peracetic acid*, respectively.	Anonymous (1996c) A6.1.2/01

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, vehicle**	**Dose levels, duration of exposure**	**Signs of toxicity**	**Value LD$_{50}$**	**Reference**
Acute dermal toxicity study EPA guideline no. 81-2 GLP Reliability: 1 **Key study**	New Zealand white rabbit, males and females 5 animals per sex per dose No control animals	Proxitane WW12 (11.69% peracetic acid, 18.05% hydrogen peroxide, 20% acetic acid) Vehicle: none Application area: appr. 20 x 10 cm, occlusive coverage Total volume applied: 0.433, 1.75, 1.99 mL/kg bw (500, 2020, 2293 mg/kg bw, respectively)	500, 2020 and 2293 mg/kg bw (58, 236 and 268 mg/kg bw of peracetic acid, respectively) Duration of exposure: 24 hours Post-exposure period 14 days Signs of toxicity were observed 3 times on day 0 and at least once daily thereafter. Signs of dermal irritation were observed 1 hour after removal of wrappings and on days 4, 7, 10 and 14. Body weights were recorded on days -1, 7 and 14, or at discovery of death.	9/10 animals (4 males, 5 females) died at 2293 mg/kg and 6/10 animals (3 males, 3 females) died at 2020 mg/kg bw. No deaths occurred at 500 mg/kg bw. Clinical signs: decreased activity in all dose groups, which had subsided by day 4 in surviving animals. Slight to severe oedema, atonia, blanching, bleeding (only at high dose), coriaceousness, desquamation, eschar, sloughing and necrosis were seen in all dose groups. There was a slight impact on body weight gain in surviving animals. One 500 mg/kg male failed to gain weight, one male and one female at 500 mg/kg and one male at 2293 mg/kg lost weight during the first week. Pathology: no effects in surviving animals. Animals that died prematurely showed discoloured ears matted chin hair, nasal and anal/genital discharge, atelectasis of lungs, and air bubbles in major blood vessels and heart.	1957 mg/kg bw (combined), 1912 mg/kg bw (males), 1990 mg/kg bw (females) Correspond to 228.8, 223.5 and 232.6 mg/kg bw of 100% peracetic acid*, respectively.	Anonymous (1996d) A6.1.2/07
Acute dermal toxicity study EPA guideline no. 81-2 Reliability: 1 (the relative humidity was outside the target range,	Wistar rat, males and females 5 animals per sex No control animals	Proxitane 0103 (0.89% peracetic acid, 7.27% hydrogen peroxide, 10.85% acetic acid) Application area: appr. 40 cm^2, occlusive	2000 mg/kg bw (17.8 mg/kg bw of peracetic acid) Duration of exposure: 24 hours Post-exposure period: 14 days Observations for toxicity were conduted at 0-0.5,	No mortality Clinical signs: white and/or red spots on the treated skin after removal of the bandage. These spots got brown and encrusted during the observation period. The skins were healed after 12 days.	>2000 mg/kg bw Corresponds to >17.8 mg/kg bw of 100% peracetic acid*.	Anonymous (1994) A6.1.2/05

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, vehicle**	**Dose levels, duration of exposure**	**Signs of toxicity**	**Value LD$_{50}$**	**Reference**
with actual values of 70-90%; not considered to have adversely affected the study) **Key study**		coverage Total volume applied: 2 mL/kg bw	1.5, 4, 24 and 48 hours after application and thereafter once on each day until the end of the study. Body weights were recorded on days -1, 0, 2, 7 and 14.	No other clinical signs were observed. Transient weight loss was observed in both sexes in the first 2 days of the study; body weight gain appeared to be normal thereafter. Pathology: no treatment-related abnormalities; one female showed a maculate thymus (not considered treatment-related).		
Acute dermal toxicity study EPA guideline no. 81-2 GLP Reliability: 2	Sprague-Dawley rat, males and females 5 animals per sex No control animals	Peracetic acid 0.15%, stabilisers, acetic acid, hydrogen peroxide, water (concentrations not specified) Vehicle: deionized water Application area: appr. 5 x 5 cm, occlusive coverage	2000 mg/kg bw (3 mg/kg bw of peracetic acid) Duration of exposure: 24 hours Observations for toxicity were conducted at 0.5, 1, 2, 3, 4 and 6 hours on the day of dosing and twice daily thereafter for 13 days; on day 14 they were conducted once. Body weights were recorded on days 0, 7 and 14.	No mortality All rats remained healthy and gained weight during the study. No irritation was noted on any of the test sites. Pathology: no treatment-related abnormalities.	>2000 mg/kg bw Corresponds to >3 mg/kg bw of 100% peracetic acid*.	Anonymous (1991f) A6.1.2/02
Acute dermal toxicity study (limit test) OECD TG 402 (1981) GLP Reliability: 2 (treated skin was not cleaned with water after 24 hours, the humidity sometimes exceeded the recommended top limit of	Wistar rat, males and females 5 animals per sex No control animals	Sopuroxid 15 (peracetic acid 15%, hydrogen peroxide 22%, phosphonic acid 0.3%, sulphuric acid 0.73%, water, acetic acid 16.7%) Vehicle: demineralized water Application area: at least 20 cm^2, occlusive coverage	400 mg/kg bw (60 mg/kg bw of peracetic acid) Duration of exposure: 24 hours Post-exposure period 14 days Observations for toxicity were made within 1 hour and within 4 hours after dosing, and subsequently at least once daily.	No mortality Clinical signs: 1 female showed some tape-related effects after bandage removal. On day 3, very slight erythema was observed in 1 female, very slight encrustations in 1 male and 1 female, slight encrustations in 1 male and very slight scaliness in 3 males and 3 females. On day 7 and 14, no signs of skin irritation were observed in males or females.	>400 mg/kg bw Corresponds to >60 mg/kg bw of 100% peracetic acid*.	Anonymous (1993b) A6.1.2/03

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, vehicle**	**Dose levels, duration of exposure**	**Signs of toxicity**	**Value LD_{50}**	**Reference**
70%, only one dose level was used)		Total volume applied: 10 mL/kg bw (of a 40 mg/mL dilution of the test substance)	Dermal reactions were recorded on days 1, 3, 7 and 14. Body weights were recorded immediately before dosing and on days 3, 7 and 14 of the study.	All animals showed a slight decrease in body weight on day 3 and gained weight again thereafter. Pathology: no treatment-related abnormalities.		
Acute dermal toxicity study OECD TG 402 (1981) GLP Reliability: 3 (composition of the test substance not specified, dose used for limit test was only 400 mg/kg bw instead of 2000 mg/kg bw; higher doses not tested due to anticipated corrosivity of test material) Supportive study	Wistar rat, males and females 5 animals per sex No control animals	Sopuroxid 5 (blend of peracetic acid, hydrogen peroxide and acetic acid; concentrations not specified) Vehicle: water Application area: at least 20 cm^2, occlusive coverage Total volume applied: 5 mL/kg bw (of a 80 mg/mL aqueous dilution of the test substance)	400 mg/kg bw Duration of exposure: 24 hours Post-exposure period 14 days Observations for toxicity were conducted 1 and 4 hours after dosing, then at least daily. Dermal reactions were observed on days 1, 3, 7 and 14. Body weights were recorded prior to dosing and on days 3, 7 and 14.	No mortality No clinical signs were observed during the observation period. Apart from very slight erythema in 3 males and in all females on day 1, and scaliness in all females on day 3 of the study, no signs of dermal irritation were observed. All animals gained weight during the observation period. Pathology: no treatment-related abnormalities.	>400 mg/kg bw Corresponds to >20 mg/kg bw of 100% peracetic acid* (assuming 5% concentration).	Anonymous (1998d) A6.1.2/05
Acute dermal toxicity study EPA guideline no. 81-2 GLP Reliability: 3 (composition of the test substance not specified, only one dose level was used) Supportive	New Zealand white rabbit, males and females 5 animals per sex No control animals	Dilute peracetic acid; assumed to contain 17% peracetic acid, 22.9% hydrogen peroxide, acetic acid and water Vehicle: none Application area: 10 x 10 cm, occlusive coverage Total volume	200 mg/kg bw (34 mg/kg bw of peracetic acid) Duration of exposure: 24 hours Post-exposure period 14 days Observations for toxicity were conducted at 0.5, 1, 2, 3, 4, 6 hours and then twice daily; on day 14 the animals were observed once. Signs of dermal	No mortality Clinical signs: all animals remained healthy throughout the study. 24 hours after application, all rabbits had erythema and blanching of the test site, which resulted in eschar formation by day 7 of the study. At termination, eschar was still present in all animals, three of which also had exfoliation. 4 rabbits gained weight, 5 lost weight	>200 mg/kg bw Corresponds to >34 mg/kg bw of 100% peracetic acid* (assuming 17% concentration).	Anonymous (1983b) A6.1.2/07

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, vehicle**	**Dose levels, duration of exposure**	**Signs of toxicity**	**Value LD_{50}**	**Reference**
study		applied: 4.2-5.1 mg/cm^2	irritation were recorded on days 1, 3, 7 and 14. Body weights were recorded on days 0, 7 and 14.	and one animal showed no weight change by day 14 of the study. Pathology: the only abnormality observed was pitted kidneys in 1 male.		

*Note: this is a theoretical calculated value which does not take into account that both hydrogen peroxide and acetic acid contribute to the acute toxicity observed for the test substance via acute toxicity and/or corrosivity/irritative property.

Table 16: Summary table of human data on acute dermal toxicity

No human studies are available.

Table 17: Summary table of other studies relevant for acute dermal toxicity

No other studies are available.

10.2.1 Short summary and overall relevance of the provided information on acute dermal toxicity

There are 7 studies on the acute dermal toxicity in the rat available for PAA. Three studies therefrom have selected as key studies. All key studies were carried out in accordance with standard OECD/US-EPA and GLP guidelines. The remaining acute dermal studies in the rat and in the rabbit serve as supportive information on this endpoint.

In the key study Anonymous 1996c (4.89 % peracetic acid, 19.72 % hydrogen peroxide) conducted in accordance with EPA guideline no. 81-2, undiluted test subtance at levels of 500, 1000 and 2020 mg/kg bw were applied to the intact skin of male and female albino rabbits and occlusively covered. After 24 hours, the cover and test substance were removed and the animals observed for mortality, clinical signs, dermal irritation and body weight development for an observation period of 14 days. A gross necropsy was performed in all animals at study termination. Mortalities occurred at all dose levels during the study. Clinical signs included activity decrease, diarrhoea, lateral recumbency, nasal discharge, ptosis, salivation and star-gazing. These had completely resolved in all surviving animals on day 6. Signs of skin irritation included severe erythema, slight to severe oedema, atonia, blanching, bleeding, coriaceousness, desquamation, eschar, fissuring, sloughing and necrosis. There were no significant effects on the body weights. There were no pathological effects in surviving animals revealed by necropsy. Animals that died during the observation period showed wet, matted and/or stained muzzle, urogenital and anal areas, discoloured ears, air in blood vessels, heart and pericardium, fluid in pericardium, discolouration of lungs, mesentery, spleen and thymus. The acute dermal LD_{50} in rabbits was 1280 mg/kg bw in males, 1040 mg/kg bw in females and 1147 mg/kg bw as combined (male/female) correspond to 62.6 mg/kg bw in males, 50.9 mg/kg bw in females and 56.1 mg/kg as combined (male/female) of 100 % peracetic acid.

In the key study Anonymmous 1996d (11.69 % peracetic acid, 18.05 % hydrogen peroxide) conducted in accordance with EPA guideline no. 81-2, undiluted doses at levels of 500, 2020 and 2293 mg/kg bw were applied to the intact skin of male and female albino rabbits and occlusively covered. After 24 hours, the cover and test substance were removed and the animals observed for mortality, clinical signs, dermal irritation and body weight development for an observation period of 14 days. A gross necropsy was performed in all animals at study termination. No mortality occurred at the 500 mg/kg bw level.

The only clinical sign was activity decrease in all dose groups, which was no longer evident in surviving animals by day 4. Signs of skin irritation included atonia, blanching, coriaceousness, oedema, erythema, eschar, necrosis and sloughing, which were seen in all dose groups. Additionally bleeding was observed in the highest dose group. There was an apparent effect on body weight gain in four surviving animals, three males (two in the lowest ,one in the highest dose group) and one female of the lowest dose group. Abnormal necropsy findings occurred only in the animals dying during the study and pertained to the ears, muzzle, anal/genital areas, lungs, heart and major blood vessels. The acute dermal LD_{50} in rabbits was 1912 mg/kg bw in males, 1990 mg/kg bw in females and 1957 mg/kg bw as combined (male/female) correspond to 223.5 mg/kg bw in males, 232.6 mg/kg bw in females and 228.8 mg/kg bw as combined (male/female) of 100 % peracetic acid.

In the key study Anonymous (1994) (0.89% peracetic acid, 7.27% hydrogen peroxide) conducted in accordance with EPA guideline no. 81-2, a single dermal dose of 2000 mg/kg bw was applied under an occlusive dressing to the intact skin of five male and five female Wistar rats. Any sign of intoxication occurring during the 14-day observation period was recorded. Gross post-mortem examination was done in all rats at the end of the 14-day observation period. None of the rats died within the 14-day observation period. White and/or red spots were noted on the treated skin after removal of the bandage. These spots got brown and encrusted during the observation period. The skin symptoms subsided after 12 days. No other clinical signs were observed. Transient weight loss was observed in both sexes in the first few days of the study. Thereafter body weight gain appeared to be normal. At autopsy, no treatment related abnormalities were recorded for any of the animals.

The skin of the all animals were severely damaged due to the corrosive effects of the applied test substances and therefore the results can not be used to evaluate absorbtion of PAA throught intact skin. 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. Oxygen bubbles liberated in the blood stream/capillaries may cause reduced blood flow and gas embolies as well as reversible blanching of the exposed tissue area. In acute dermal toxicity studies with 90% hydrogen peroxide in rabbits, cats, pigs and rats, Hrubetz et al. (1951) found that the rabbit appeared to be the most sensitive animal species. The high susceptibility of the rabbit to embolism, and interspecies differences in the levels of tissue and blood catalases were noted. The authors also proposed that there may be more hydrogen peroxide available subcutaneously in the rabbit to enter the blood stream and release the oxygen which gives rise to lethal embolic effects. According to the Guidance on the Application of the CLP Criteria (ECHA 2017b) classification should based on the lowest ATE value available i.e. the lowest ATE in the most sensitive appropriate species tested. If there is information available to inform on species relevance, then the studies conducted in the species most relevant for humans should normally be given precedence over the studies in other species. As the mechanism that causes mortality is not completely known and we can not exlude the relevance for humans, we should use rabbit as the most sensitive species.

10.2.2 Comparison with the CLP criteria

The acute dermal LD_{50} of test substance containing 5 – 15 % peracetic acid was between 56.1 and 228.8 mg/kg bw in the rabbit. In rats, the acute dermal LD_{50} values were greater than 60 mg/kg bw which was the highest dose level tested and which neither caused mortalities nor signs of toxicity.

Classification for acute dermal toxicity under the CLP Regulation is required for substances with an acute dermal LD_{50} value of ≤ 2000 mg/kg bw. Category 3 is assigned for substances with an LD_{50} value of > 200 and ≤ 1000 mg/kg kg bw and Category 2 for substances with an LD_{50} value of > 50 and ≤ 200 mg/kg according to the table 3.1.1 of Annex I to the CLP Regulation.

In order to derive a correct classification/ATE value for a mixture containing peracetic acid, a 100 % substance should be classified even if the substance cannot exist in such a high concentration. Therefore, peracetic acid (100 %) should be classified as Acute Tox. 2; H310 based on the calculated LD_{50} values for peracetic acid in the equilibrium test substance (LD_{50} dermal 56.1 mg/kg).

Based on the results obtained in rabbits, classification of the aforementioned formulations (PAA conc. 5-15 %) as Acute Tox. 4 with the hazard statement H312: "Harmful in contact with skin" in accordance with the criteria of the CLP Regulation (reference value 1000 < ATE 2000 ≤ mg/kg bw) is warranted. Neither hydrogen peroxide nor acetic acid is classified for acute dermal toxicity in Annex VI of the CLP Regulation or in the C&L inventory and therefore they do not have to be taken into account.

10.2.3 Conclusion on classification and labelling for acute dermal toxicity

Based on the available data, there is sufficient evidence to remove the asterisk from the classification, since the relevant LD_{50} value is in the range of > 50 and ≤ 200 mg/kg bw based on the CLP classification criteria. **Acute Tox. Category 2** is therefore proposed for 100 % peracetic acid, with the corresponding hazard statement **H310: Fatal in contact with skin** with a dermal ATE value of 56 mg/kg bw for the classification of mixtures containing peracetic acid.

10.3 Acute toxicity - inhalation route

Table 18: Summary table of animal studies on acute inhalation toxicity

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, , form and particle size (MMAD)**	**Dose levels, duration of exposure**	**Value** **LC_{50}**	**Observations**	**Reference**
OECD 403, GLP **Key study**	**Male/female rat**	**Aerosol/vapour** **A mixture of hydrogen peroxide (19%), acetic acid (10%), PAA (4.7-5.4%)**	**87, 163, 185, 267 mg/m3, 4 hours.**	**204 mg/m3 calculated as pure PAA, 4080 mg/m^3, assuming 5% concentration**	**Mortalities in the 185 and 267 mg/m3 groups, increase lung weight, reduced respiratory rate, lacrimation and salivation, abnormal body gait and posture, loss of cornea and pinna reflex, cyanosis, ptosis**	**Anonymous, 1994**
Unknown guideline (FDA/GLP)	Male/female rat	Aerosol (0.2% PAA in water)	5.53 mg/l, 4 hours	>5.53 mg/l (gravimetric), 143.4 mg/l nominal (0.2% PAA)	No mortality, irregular breathing	Anonymous, 1984
Unknown guideline, GLP	Male/female rat	Aerosol (0.15% PAA)	0.15% PAA for 4 hours	> 7.669 mg/l (0.0117 mg/l PAA, nominal exposure concentration 65 mg/l)	Nasal, oral discharge, tremors, no mortality	Anonymous, 1991d
Unknown guideline, GLP	Male rat	Aerosol (35.5% PAA, 6.8% hydrogen peroxide, 39.3% acetic acid, 1.0% sulphuric acid	0.26 mg/l, 0.49 mg/l, 0.67 mg/l	0.49 mg/l of the test substance	Red nasal and ocular discharge, lethargy, laboured breathing, lung noise, loss of body weight (11-15%). During the	Anonymous, 1985

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, , form and particle size (MMAD)**	**Dose levels, duration of exposure**	**Value** **LC_{50}**	**Observations**	**Reference**
					postexposure period, 2 rats exposed to 0.49 mg/L died 1 day after exposure and 1 rat exposed to 0.67 mg/L died 2 days after exposure. Deficiencies: LC50 not determined, particle size not determined, no gross necropsy performed, range of test atmosphere concentrations relatively large.	
Unknown guideline, equivalent to OECD TG403, GLP	Male and female rat	5% PAA vapour	5 mg/l, 4 hrs exposure	> 5 mg/l of the test substance	Hyperaemia of the nasal mucosa, nasal discharge, no mortalities	Anonymous, 1992a
OECD TG403, non-GLP	Male and female rat	5% PAA vapour	50 mg/l, 4 hrs exposure	> 50 mg/l of the test substance	Piloerection, dyspnea, no mortalities, on necropsy, inflammation of the mucosa of the small intestines was evident in two male and female rats each. No other pathological findings were made on necropsy.	Anonymous, 1995c
Non-GLP, non guideline	Mice (sex unknown)	Aerosol (40% PAA in water)	100, 300, 450, 600, 800, 1000, 1300 and 1600 mg/m^3 (expressed as 100% PAA), 1h	210 mg/m3 expressed as 100% PAA	Respiratory distress, gasping, increase in respiratory rate, secretion of the eyes and the nose. Lethality in the 600 mg/m3 group	Merka, et al. 1976

Method, guideline, deviations if any	**Species, strain, sex, no/group**	**Test substance, , form and particle size (MMAD)**	**Dose levels, duration of exposure**	**Value** **LC_{50}**	**Observations**	**Reference**
Non-GLP, non guideline	Male mice	Aerosol 39%, PAA, 45% acetic acid, 6% hydrogen peroxide	1.8-24 ppm, 1h PAA vapour	Not determined	RD50 value of 17 mg/m^3 determined in mice	Gagnaire, et al, 2001
GLP, unknown guideline, no LC50 value determined	Male rat	Aerosol/vapour Test material contained 15% PAA, 14% hydrogen peroxide, 28% acetic acide, 43% water, 1% stabiliser	221.0 - 487 mg/m^3, exposure time variable, 25 minutes	Not determined	> 50% reduction in respiratory rate Histopathology: Microscopic examination of the nose, trachea and lungs revealed necrosis in the anterior parts of the nose (slight to severe necrosis of the epithelium of the lateral wall, the nasal and maxilloturbinates	Anonymous, 1990
GLP, unknown guideline, no LC50 value determined	Male rat	Aerosol/vapour Test material contained 15% PAA, 14% hydrogen peroxide, 28% acetic acide, 43% water, 1% stabiliser	0.13 – 1.45 mg/l, exposure time variable, 15-60 minutes	Not determined	Symptoms related to irritation of respiratory tract, decreased rate of respiration, statistically significant increase in lung weight. Mortalities found in the highest and second highest dose groups with long exposure times. Mortality figures increased with increasing exposure levels and increasing exposure times.	Anonymous, 1989a
GLP, unknown guideline, no LC50 value determined	Male rat	Aerosol/vapour Test material contained 15% PAA, 14% hydrogen	9.5 – 40.3 mg/l, exposure time variable, 15-60 minutes	Not determined	50% reduction in respiration rate at concentrations 21.5-24.1 mg/m^3, no other clinical	Anonymous, 1989b

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance, , form and particle size (MMAD)	Dose levels, duration of exposure	Value LC_{50}	Observations	Reference
		peroxide, 28% acetic acide, 43% water, 1% stabiliser			signs	

10.3.1 Short summary and overall relevance of the provided information on acute inhalation toxicity

There are several studies where an LC50 value has been determined, but only one of them reports being a GLP study which followed OECD TG 403. Many of the studies did not determine an LC50 but rather examined the respiratory irritation properties or the influence of peracetic acid on the respiratory rate. There is some variance in the LC50 values obtained by different studies. The LC50 value used to compare with the CLP criteria is 4.080 mg/l (5% PAA) or 0.204 mg/l expressed as 100% PAA. Although this LC50 value is not the most conservative value, his study was selected because was conducted according to GLP and OECD TG403. Peracetic acid has a harmonised classification and labelling as Skin Corr. 1A, H314, so it is likely that the mechanism of toxicity is corrosivity.

10.3.2 Comparison with the CLP criteria

According to the section 3.1.2 and the table 3.1.1. if a vapour has an LC50 (acute toxicity estimate (ATE)) value of 0.5 or lower, the substance should be classified in category 1. Although the studies often spoke of vapour, in practise aerosol was created in the experimental settings. That is, small PAA liquid droplets were created, e.g., using a nebulizer, which created PAA mixture suspended in air. Therefore, according to the table 3.1.1. for a mist an ATE of 0.05-0.5 mg/l should be classified in categy 2 for acute inhalation toxicity. An LC50 value of 4.080 mg/l (corresponding to 0.204 mg PAA/l) is used to compare to the CLP criteria.

A mixture containing 5% peracetic acid would then be classified as Acute Tox. 4; H332 (LC50 of 4.080 mg/l, assuming 5% concentration). In order to derive a correct classification/ATE value for a mixture containing peracetic acid, a 100 % substance should be classified even if the substance cannot exist in such a high concentration. Therefore, peracetic acid (100 %) should be classified as Acute Tox. 2; H330 based on the calculated LC50 values for peracetic acid in the equilibrium test substance (LC50 0.204 mg/l inhalation for 100% PAA). Based on the presented data, classification of the aforementioned formulations (PAA conc. 5-35 %) as Acute Tox. 2 with hazard statement H330: "Fatal if inhaled" in accordance with the criteria of the CLP Regulation (reference value $0.05 < ATE \leq 0.5$ mg/l for mists) is warranted when calculated for a 100% PAA.

10.3.3 Conclusion on classification and labelling for acute inhalation toxicity

Based on the available data, there is sufficient evidence to remove the asterisk from the classification, since the relevant LC_{50} value is in the range of > 0.05 and ≤ 0.5 mg/kg bw based on the CLP classification criteria. **Acute Tox. Category 2** is therefore proposed for 100 % peracetic acid, with the corresponding hazard statement **H330: Fatal if inhaled** with a ATE value of 0.204 mg PAA/l for the classification of mixtures containing peracetic acid. Data is available that indicates that the mechanism of toxicity is corrosivity, the substance or mixture should also be labelled as EUH071: ‘corrosive to the respiratory tract’.

10.4 Skin corrosion/irritation

Peracetic acid has a harmonised classification and labelling as Skin Corr. 1A, H314; Causes severe skin burns and eye damage. The hazard class is not assessed in this dossier.

10.5 Serious eye damage/eye irritation

Not assessed in this dossier.

10.6 Respiratory sensitisation

Not assessed in this dossier.

10.7 Skin sensitisation

Not assessed in this dossier.

10.8 Germ cell mutagenicity

Not assessed in this dossier.

10.9 Carcinogenicity

Not assessed in this dossier.

10.10 Reproductive toxicity

Not assessed in this dossier.

10.11 Specific target organ toxicity-single exposure

Not assessed in this dossier.

10.12 Specific target organ toxicity-repeated exposure

Not assessed in this dossier.

10.13 Aspiration hazard

Not assessed in this dossier.

11 EVALUATION OF ENVIRONMENTAL HAZARDS

11.1 Rapid degradability of organic substances

Table 19: Summary of information on degradability

Method	Results	Remarks	Reference
Ready biodegradability			
EC Directive 92/69/EEC: Annex V, Part C: Methods for the Determination of ecotoxicity: C.4-B. Biodegradation: determination of the ready biodegradability	**Degradation** **78%** DOC removal (58% TOC removal) after 14d **66%** DOC removal(44% TOC removal) after 21d **98%** DOC removal (75% TOC removal) after 28d **96%** DOC removal (81% TOC removal) after 35d	The test substance was added in the test system stepwise from 0.395 to 15.8 mg/L within 14 days.	Anonymous (1986) Anonymous (2002)

Method	**Results**	**Remarks**	**Reference**
(1992) 40% PAA Non GLP			
OECD 301 D "Ready Biodegradability: Closed Bottle Test" test guideline (1992) Test medium containing 5.2% PAA GLP compliant	**PAA** was determined degrading **33%** (mean of two replicates) at the end of the 10-day window (11th day) and **42%** at the end of the test (day 28). The biodegradation in the **toxicity control** was **32%** after 14 days and **49%** after 28 days. These results show a slight toxic effect towards the used micro-organisms. The biodegradation of the **reference substance** (sodium acetate) reached **67%** of the ThOD within 14 days.	A closed bottle test is not suitable for the assessment of the biodegradation of PAA, because the substance liberates oxygen if it degrades abiotically. This cannot be ruled out in this case. Thus, in addition to potential inhibition of micro-organisms, the abiotically liberating oxygen could explain the apparently low oxygen consumption and low biodegradation.	Anonymous (2003b)
OECD 301 D "Ready Biodegradability: Closed Bottle Test" test guideline (1992) No information provided (presumably 40% PAA) Non GLP	PAA was observed degrading >70% at the end of the test (day 28) at concentration of 2-5 mg/L.	The result is from a test in which inoculum from a Zahn-Wellens Test preadapted to peracetic acid. Similar degradability was not obtained with non-adapted inoculum. Furthermore, the closed bottle test is not considered suitable in this case as explained above.	Gerike and Gode (1990)
Other convincing scientific evidence			
OECD 209 "Activated Sludge: Respiration Inhibition Test" test guideline (1984) 39.5% PAA GLP compliant	Half-life <**3 min** at 0.3, 1.0, 3.0, 10 and 30 mg PAA/L. Half-life ca. **15 min** at 100 mg PAA/L.	The study provides information on the primary degradation of PAA confirmed analytically by HPLC.	Anonymous (2001)
Hydrolysis			
Non-guideline study 34% PAA Non GLP	PAA in aqueous solutions can be degraded according the following reactions: 1) Spontaneous decomposition: $2\ CH_3CO_3H \rightarrow 2\ CH_3CO_2H + O_2$ 2) Hydrolysis: $CH_3CO_3H + H_2O \rightarrow CH_3CO_2H + H_2O_2$ 3) Transition metal catalysed decomposition: $CH_3CO_3H + Mn+ \rightarrow CH_3CO_2H + O_2 + Mn+$ + other products	The test was conducted to study the stability of peracetic acid in aqueous solutions under typical pulp bleaching conditions (i.e. at pH values ranging from 5.5 to 12.0 at 40°C).	Yuan et al. (1997a) Yuan et al. (1997b)

Method	Results	Remarks	Reference
EC Directive 92/69/EEC: Annex V, Part C: Methods for the Determination of ecotoxicity: C.7. Degradation: abiotic degradation: hydrolysis as a Function of pH (1992) 40% PAA Non GLP	**DT_{50}** for abiotic degradation for 0.01 mol (760 mg/L) PAA/L (748 ppm): pH 4 = **62 h (45.7 h)** pH 7 = **63 h (60.3 h)** pH 9 = **64 h (6.3 h)** **DT_{50}** for abiotic degradation for 0.001 mol (76 mg/L) PAA/L (95 ppm): pH 4 = **48 h (46.7 h)** pH 7 = **48 h (31.7 h)** pH 9 = **3.6 h (- h)**	The values in have been recalculated (2007) based on the original results using ModelMaker software with the exception of X^2 which were performed FOCUS Degradation Kinetics Report (2006). The values in brackets have been obtained using first order multi-compartment (FOMC) model for the best fit. For the nominal concentration of 0.001 mol, the value at pH 9 couldn't be re-calculated as sufficient data points were not available.	Anonymous (2000c) Anonymous (2007e) **Key study**
EU Method C.7 (Degradation: Abiotic Degradation: Hydrolysis as a Function of pH) Unknown % PAA Non GLP	**DT_{50}** for abiotic degradation for at 50°C pH 4 = **200 min** pH 7 = **97 min** pH 9 = **<15 min** **DT_{50}** for abiotic degradation for at 50°C pH 4 = **31.2h**	The values seem to be in line with the results from key study summarised above.	Anonymous (1995a)
Water, water-sediment and soil degradation data			
Water degradation data			
Non-guideline study 15% PAA non GLP	The half-life of peracetic acid at two different concentrations was analytically determined in synthetic seawater with 2 and 3.3% (w/w) salinity. At an initial concentration of 52.5 mg PAA/L, the half-life was **2 minutes**, irrespective of the salinity. At 105 mg PAA/L, the half-lives were **7** and **20 minutes** at 3.3 and 2% (w/w) salinity, respectively.	The results of the test indicate fast decomposition of peracetic acid in seawater. Increased salinity of the water resulted in enhanced decomposition. This may be explained by the high pH of the seawater.	Anonymous (2000a)
Non-guideline study 15.2% PAA non GLP	Test item was applied at a concentration which corresponded to 2 mg PAA/L and 3.2 mg H_2O_2/L. The half-life of PAA in effluent water (at 20°C) was determined to be less than 5 minutes. The half-life of H_2O_2 in the effluent water was calculated as 89 minutes at 20°C.	The degradation of peracetic acid and hydrogen peroxide in the effluent of a waste water treatment plant treating predominantly municipal waste water was tested.	Anonymous (2007d)
Non-guideline studies Unknown test media non GLP	95.1% degradation of PAA within 1 day in drinking water has been observed. PAA was observed degrading from 17% to 91% within 120 minutes in tap water. In lake water, 25.6% degradation of PAA was observed within 5 days.	Descriptions of test conditions and characteristics of the test media are not detailed.	Anonymous (1995b) Anonymous (1992b) Anonymous (1991a)

Method	Results	Remarks	Reference
			Anonymous (1991b) Anonymous (1991c)
Soil degradation data			
Non-guideline study Test media containing 15% PAA non GLP	Sandy loam was first saturated with a of 15% of PAA and 22% of H_2O_2, followed by application of 1.5% v/v solution containing 5.6% of PAA and 27% of H_2O_2. The decay profiles of the PAA and the H_2O_2 were tracked. Less than 34% of the PAA applied to the soil is recovered analytically after 1-minute contact. After 9 minutes, less than 0.2 % of the initial peracetic acid charge was detected and after 13 minutes the soil became devoid of peracetic acid. From the initial hydrogen peroxide charge of 1468 ppm, less than 1 ppm was detected after 19 minutes.	Peracetic acid decomposes rapidly in soil.	Anonymous (2003a)
Photochemical degradation			
Photodegradation in air			
Atkinson method 100% PAA non GLP	**Half-life ($t_{½}$)**: 3.969 d	The estimation of atmospheric half-life is based on the method of Atkinson. According to the incremental method of Atkinson, the OH radical rate constant was estimated to be 4.04 x 10^{-12} cm^3 $molecule^{-1s-1}$. The DT_{50} value was based on a 24-hour day assuming an OH radical concentration of 0.5 x 10^6 per cm^3.	Anonymous (2007c)

11.1.1 Ready biodegradability

The available study on ready biodegradability of peracetic acid (**Anonymous, 1986** & **Anonymous, 2002**) principally followed OECD test guideline 301E "Ready Biodegradability: Modified OECD Screening test" (1992). Although the it's stated in the OECD TG 301 that the OECD 301E is not suitable for volatile chemicals, the method is considered adequate for assessing the ready degradability as the PAA is assumed to remain in the water phase due to its high water solubility and relatively low Henry's law constant (< 1 Pa m^3/mol).

In a routine-test performed over a period of 28 days without modification of the guideline procedure (i.e. by adding the whole amount of test substance at once at the beginning of the test), the toxic effect of PAA towards the micro-organisms affected the results. For this reason, only 48% DOC removal (27% TOC removal) after 28 days was obtained. In the second test, the toxicity of PAA towards micro-organisms was taken into account. The modifications to the test method are presented below.

Shake flasks containing mineral medium and a known concentration of the test substance as the sole source of organic carbon were inoculated with effluent of a municipal sewage treatment plant (0.5mL/L) and shaken in the dark or diffuse light at 22 ± 2 °C. The test procedure was modified as follows: the test substance was added stepwise within 14 days period until the required concentration had been reached. The modification was done in order to avoid any toxic effects on the micro-organisms: the test conducted according to the standard procedure had revealed strong inhibition of the degrading organisms as poor degradation of a well biodegradable reference substance was observed in the presence of the test substance. Furthermore, the test was performed at a temperature of 25 ± 1°C instead of 22 ± 2°C as stated in the guideline. The test period was 35 days and the samples were taken on days 14, 21, 28 and 35.

The degradation was examined by DOC analysis of test samples in weekly intervals during the 28-day period but the formation of degradation products was not investigated. The degree of biodegradation was calculated by expressing the concentration of the DOC removed (corrected for the in the blank inoculum control) as a percentage of the nominal concentration of the test substance. As a result, degradations between 66 to 98% within 14 to 28 days was measured by DOC removal method. However, it was not demonstrated in the study that a degradation sufficient to pass ready biodegradability criteria was attained within a 10-d window after the 10% degradation was reached.

Furthermore, due to study design (i.e. no abiotic control, preparation of all the test solution for a stepwise addition at once, no analytical verification of PAA concentration in the test sample solution during the 14 days period) it cannot be distinguished between a true biodegradation in the inoculated mineral medium and a potential abiotic degradation in the test sample solution prior to its addition to mineral medium. Consequently, the observed high DOC removal may be an overestimation of the biodegradation of PAA and the high degradation percentage (78%) immediately after the final stepwise addition of the test solution at day 14 suggests that some a priori abiotic degradation may have occurred. Despite the defiencies mentioned, the study is considered suitable for assessing the ready degradability of PAA.

Although not considered as ready biodegradability test, the available active sludge respiration inhibition test is considered supporting the observations of the key study. The test (**Anonymous, 2001**) followed OECD 209 “Activated Sludge: Respiration Inhibition Test” test guideline (1984) and was conducted according to GLP. It provides relevant information on the primary degradation of peracetic acid, which was followed analytically by HPLC. It was shown that PAA disappeared rapidly with a DT_{50} of < 3 minutes when applied at concentrations < 30 mg/L at pH 7. At higher concentration of 100 mg/L, the degradation in activated sludge respiration inhibition test was slowed down resulting in a DT_{50} of 15 minutes.

In addition, the degradation of PAA has also been studied by measuring the biological oxygen consumption in two closed bottle tests (**Gerike and Gode, 1990** & **Anonymous, 2003b**) conducted generally according to OECD 301 D “Ready Biodegradability: Closed Bottle Test” test guideline (1992). This test, however, is based on measurement of the biological oxygen consumption and, therefore, it is not considered suitable for the reliable biodegradation assessment of the substance since the PAA itself liberates oxygen upon decomposition and, moreover, production of oxygen is also due to the decomposition of hydrogen peroxide.

Ready biodegradability studies are among the preferred type of test data in the assessment of rapid degradability. As a general deficiency of the studies, it was noted that the formation of degradation products was not monitored. Considering the available information on ready biodegradability, no definite conclusion can be made. However, the studies available support the PAA being rapidly degradable. The endpoint is presented in Table 19 above.

11.1.2 BOD_5/COD

No studies available.

11.1.3 Hydrolysis

Two studies on hydrolytic degradation for peracetic acid are available. In open literature articles (**Yuan et al., 1997a** & **Yuan et al., 1997b)**, the metal (magnesium) catalysed and spontaneous decomposition as well as hydrolysis of PAA is studied in a pH range of 5.5 to 12.0 at 40°C. The aqueous solution containing all the required chemicals except PAA was preheated to desired temperature in 500 mL four-neck round-bottom flask immersed in constant temperature bath. The reaction was initiated by addition of the concentrated equilibrium peracetic acid (consisting about 34% of PAA, 5% hydrogen peroxide (H_2O_2), 40% acetic acid (CH_3CO_2H) and 21% water) solution to the reaction flask. The initial peracetic acid concentration was always 3.75 g/L. The pH was maintained constant by an automatic titrator with the addition of 10 mol/L

NaOH. Samples were withdrawn an analysed in accordance to iodometric method at predetermined time intervals (5, 10, 15, 20, 30, 45, 60, 90 and 120 minutes). All reported values were of at least duplicate experiments. By determining both, PAA and hydrogen peroxide concentrations, it was possible to distinguish between decomposition (no formation of hydrogen peroxide) and hydrolysis (formation of hydrogen peroxide).

As a result, in the pH range of 5.5. to 9.0, it was found out that PAA in solution may be consumed in the following three-reactions: in addition to hydrolysis (resulting in CH_3CO_2H and H_2O_2), also spontaneous decomposition as well as metal catalysed decomposition (resulting in CH_3CO_2H and O_2) is likely to contribute to the degradation of PAA. Therefore, the abiotic half-lives determined in hydrolysis studies comprise both pathways. Furthermore, the hydrolysis of PAA increases at a higher pH: between pH 5.5 and 8.2, hydrolysis is negligible and PAA consumption is mainly due to spontaneous decomposition. Between pH 8.2 and 9.0, PAA consumption is due to spontaneous decomposition and hydrolysis. Above pH 10.5, spontaneous decomposition is negligible and hydrolysis becomes dominant.

The key study (**Anonymous, 2000c**) considered valid for classification purposes basically followed the OECD 111 “Hydrolysis as a Function of pH” test guideline (1981) and was conducted at 25°C and pH 4, 7 and 9 using PAA solutions of 748 ppm (approximately 0.01M or 760 mg/L) and 95 ppm (approximately 0.01M or 76 mg/L). Peracetic acid was dissolved in buffer solutions of pH 4, 7 and 9. Samples were taken on days 0, 1, 3, 7 and 13.

However, there were several deviations from the test guideline: the hydrolysis was studied only at one temperature, the sterility of the test system was not indicated and it’s not stated in the study report whether each sample was taken from a separate vessels as recommended or from a single bulk vessel. Furthermore, only a single sample was taken at each time point instead of the minimum of two replicate samples. The need for the replicate sampling is stressed by the fact that no data are provided about the repeatability or sensitivity of the two analytical methods used: for concentrations of PAA higher than 500 ppm were determined by cerimetric analysis and for concentration of PAA lower than 500 ppm were measured by reflectometry with an RQ Merck apparatus. In addition, the formation of hydrolysis products was not studied. This, however, can be considered acceptable in this case as there is other data available on the formation of hydrolysis products.

The half-lives obtained from the study were recalculated (**Anonymous, 2007e**) using first order multi-compartment model (FOMC). At pHs 7 and 9, the model produced a slightly better fit of the curve than the pseudo first-order kinetics used in the original study report. The key values for hydrolysis were chosen firstly based on the PAA concentration and secondly the recalculated values were preferred when available (at pH 4 and 7). The recalculated DT_{50} values were 46.7h at pH 4 and 31.7h at pH 7 indicating that decomposition occurs and is faster at high pH values.

Similar results i.e. DT_{50} value of 31.2h at 25°C at pH 4 and DT_{50} values of 200, 97 and <15 minutes 50°C at pHs 4, 7 and 9, respectively, have been derived from another hydrolysis study (**Anonymous, 1995a**) following a test guideline equivalent or similar to EU Method C.7 (Degradation: Abiotic Degradation: Hydrolysis as a Function of pH). However, this study can only be regarded as supportive information as it was conducted with a mixture containing 0.35% PAA and H_2O_2 (no information on CH_3CO_2H content available) and as only the study summary is available under the REACH dossier chapter 5.1.2.

Primary degradation studies i.e. via hydrolysis combined with hazard assessment of degradation products are among the preferred type of test data in the assessment of rapid degradability. Based on the studies available, it is not possible to distinguish between hydrolysis and spontaneous decomposition of PAA as abiotic decomposition is suggested being more relevant than hydrolysis at pHs 4, 7 and 9. These studies, however, suggest the PAA being rapidly degradable. With regard the degradation products of PAA, both acetic acid (CAS 64-19-7) and hydrogen peroxide (CAS 7722-765-0) are considered being readily degradable and, therefore, no further assessment of the degradation products is needed. The endpoints are presented in Table 19 above.

11.1.4 Other convincing scientific evidence

11.1.4.1 Inherent and enhanced ready biodegradability tests

No studies available.

11.1.4.2 Water, water-sediment and soil degradation data (including simulation studies)

Aerobic aquatic degradation of peracetic acid has not been studied in a guideline compliant water or water-sediment or soil degradation tests because peracetic acid is considered to be a rapidly degradable substance.

However, there are several non-guideline studies describing the degradation and decomposition of PAA in different water types and water sources available. Especially the dissipation in seawater seems to be very rapid as indicated by the DT_{50} of 2 minutes in synthetic seawater at initial concentration of 52.5 mg/L (**Anonymous, 2000a**). Degradation of PAA was also very rapid under the conditions of effluent water from a sewage treatment plant rapid dissipation (DT_{50} < 5 minutes) was observed (**Anonymous, 2007d**) with a mixture containing 15.2% of PAA and 25.3% of H_2O_2.

Furthermore, 95.1% degradation within 1 day in drinking water has been observed (**Anonymous, 1995b**) and from 17% to 91% within 120 minutes in tap water (**Anonymous, 1992b**). The lowest degradation measured, however, was 25.6% within 5 days in lake water (**Anonymous, 1991a, Anonymous, 1991b** & **Anonymous, 1991c**). Because the test conditions and characteristics of the test media are not described, only general conclusions can be made from these tests. Therefore, despite no reliable half-lives can be calculated from the existing data for fresh water, the tests show that dissipation of PAA in tap water or natural waters support the observations made in hydrolysis studies.

One non-guideline study on degradation in soil under aerobic conditions for PAA is available (**Anonymous, 2003a**). In this test, the degradation of PAA in a loamy sand was examined. In the beginning, Californian loamy sand was saturated with solution containing 15% of PAA and 22% of hydrogen peroxide. The decay profiles of the PAA and the H_2O_2 were tracked. The same sandy loam was then saturated with 1.5% v/v solution containing 5.6% of PAA and 27% of H_2O_2. The pH and conductivity of the treated soil was monitored and compared to untreated soil for several hours. It was shown that > 66% of the initial dose was decomposed after one-minute contact time and, after 13 minutes, only trace amounts of peracetic acid were measured. Both PAA and H_2O_2 were depleted from the soil after 20 minutes.

A summary of the data is presented in Table 19 above. Since other data is available and studies with waste water or soil fate studies are not among the preferred data to be used for assessing rapid degradability according to the CLP guidance, there is no need for further investigations of the data. These results do not impact the environmental classification but can be used as supportive information.

11.1.4.3 Photochemical degradation

No studies on photochemical degradation in soil or water for peracetic acid are available. However, the PAA entering the air is not considered persistent in the atmosphere due to indirect photochemical degradation: the DT_{50} value of 3.969 days (corresponding to 95.26 hours) according the method of Atkinson (**Anonymous, 2007c**) was determined. Furthermore, the DT_{50} of 22 minutes for 25% PAA using the Fourier transfer IR spectroscopy (**Anonymous, 1997d**) has been determined. In this study, a Michelson interferometer and a mirror system were used to improve the detection limit of the closed cell under irradiation with infrared light in the gas phase under indoor conditions (workplace air).

The endpoints are presented in Table 19 above. However, since other is preceding over photolysis data for classification purposes, there is no need to investigate the data further and, therefore, detailed description of these field studies is excluded from this CLH report.

11.1.5 Conclusion on rapid degradability

Based on the degradability data available, peracetic acid is considered as rapidly degradable for classification and labelling purposes. The conclusion is based on the weight of evidence: the hydrolysis studies available are considered to demonstrate rapid abiotic degradation of the PAA. This conclusion is also supported by most of the other data available. Furthermore, the degradation products of PAA, acetic acid and hydrogen peroxide, are considered being rapidly degradable as well.

11.2 Environmental transformation of metals or inorganic metals compounds

Not relevant for this proposal.

11.3 Environmental fate and other relevant information

Table 20: Summary of relevant information on rapid environmental transformation

Method	Results	Remarks	Reference
Volatilisation			
Laboratory volatilisation studies and theoretical estimations			
Vapour pressure (test guideline not reported) highly concentrated PAA Non GLP	The vapour pressure of PAA is **14.1 hPa** at 20 °C as reported in literature.	Based on the high vapour pressure, **partitioning to air phase** is expected.	Anonymous (1970)
Henry's law constant (test guideline not reported) 100% PAA Non GLP	Aqueous solutions of peracetic acid were tested by measuring the PAA vapour pressure in a gas stream at 278°-293°K. Henry's law constant at 25 °C of **467.6 M atm^{-1}** (corresponding **0.217 Pa m^3 mol^{-1})** was determined.	Based on the calculated Henry's law constant being low, **no significant volatilisation** from water surfaces is expected.	Lind and Kok (1986)

11.3.1 Summary of data/information on environmental fate and other relevant information

There are no studies available on adsorption in soils for peracetic acid. However, the adsorption coefficient (Koc) was calculated by applying QSAR for soil. For organic acids, the QSAR equation of $\log K_{OC} = 0.60 \times \log K_{OW} + 0.32$ is given in the TGD (**European Chemicals Bureau, 2003**). With the measured log Kow of -0.60 (at pH 7), the QSAR derived adsorption coefficient K_{OC} of 1.02 L/kg was determined in the CAR. Considering the high solubility of PAA and the calculated K_{OC} value being low, it is assumed that the substance will remain in the water phase i.e. the substance is highly mobile in soil.

Despite the high vapour pressure (14.1 hPa, 20 °C) obtained in a laboratory study (**Anonymous, 1970**), volatilisation of PAA from water to air is not considered significant as the calculated (**Lind and Kok, 1986**) Henry´s law constant (0.217 Pa m^3 mol^{-1}, 25 °C) is low. Therefore, significant exposure to air is not to be expected.

The endpoints are presented in Table 20 above. These results do not impact the classification and, therefore, no further investigations of the data is needed.

11.4 Bioaccumulation

Table 21: Summary of relevant information on bioaccumulation

Method	**Results**	**Remarks**	**Reference**
Measured partition coefficient and bioaccumulation test data			
OPTTS 830.7550: Partition Coefficient (*n*-Octanol/Water): Shake Flask Method (1996) PAA GLP compliant	N-octanol/water partition coefficient of PAA at 20 °C log P_{OW} = -0.46 (pH 5) log P_{OW} = -0.60 (pH 7) log P_{OW} = -0.66 at (pH 9)	The concentration of the PAA used in the test is unknown. The log P_{OW} value of pure peracetic acid cannot be determined in an aqueous solution as peracetic acid would dissociate into acetic acid and hydrogen peroxide.	Anonymous (1998a)
Calculation using ACD/LogDSuite Program, Version 9 of Advanced Chemistry Development Toranto 100% PAA Non GLP	N-octanol/water partition coefficient of PAA at 20 °C log P_{OW} = -0.23 (pH 5) log P_{OW} = **-0.26** (pH 7) log P_{OW} = -1.20 (pH 9)	QSAR calculations were applied to determine the partition coefficient of pure PAA.	Anonymous (2007a) **Key study**

11.4.1 Estimated bioaccumulation

No studies available.

11.4.2 Measured partition coefficient and bioaccumulation test data

No bioaccumulation studies were included in the CAR or in the REACH dossier. In the absence of experimental results on BCF values, the bioaccumulation for classification purposes can be based on substances physico-chemical properties such as partition coefficients. The partition coefficient for PAA was estimated by conducting test (**Anonymous, 1998**) according to OPTTS 830.7550: Partition coefficient (n-octanol/water): Shake Flask Method (1996) guideline as well as calculated using QSAR (**Anonymous, 2007a**). The beforementioned studies on partition coefficient n-octanol/water resulted in log P_{OW} values from -0.23 to -1.20. Furthermore, the calculated BCF value of 3.162 L/Kg (program BCFBAF v3.00) available in the CAR is very low when compared to the limit value of 500 L/kg used as indicative of the potential to bioconcentrate and, therefore, PAA is not considered as bioaccumulative.

The endpoints are presented in Table 21 above.

11.5 Acute aquatic hazard

Peracetic acid (PAA) is produced in a reaction of hydrogen peroxide with acetic acid in an aqueous solution. In this process, peracetic acid is not obtained as a pure substance but in the form of aqueous equilibrium solutions containing peracetic acid, acetic acid and hydrogen peroxide: $CH3COOH + H2O2 \rightleftharpoons CH3CO(O2)H + H2O$. Pure (100 %) peracetic acid does not exist commercially, and any attempt to produce it would be prevented by the explosion risks of such a substance. Toxicity of PAA solutions is related to the PAA content, except for solutions with a relatively high ratio of hydrogen peroxide, where the toxicity is attributable to hydrogen peroxide (Ecetoc 2001). In this CLH proposal, the classification of peracetic acid is based on ecotoxicity tests on aquatic mixture of PAA, acetic acid, hydrogen peroxide and water. The aquatic toxicity results are derived based on PAA content of the test material by extrapolating the toxicity results to peracetic acid content expressed as mg PAA/L and not based on test solution mg TS/L (mixture of PAA, acetic acid, hydrogen peroxide and water). Based on the aquatic toxicity studies with variety of PAA content (0.35 – 18 %) in the Competent Authority Assessment Report (CAR) (Finland, 2015) no correlation was evident between the aquatic toxicity results and different PAA content of the test materials used. The biocidal CAR used an approach in the hazard assessment that was based on the assumption that the ecotoxicity of aqueous solution of peracetic acid is driven mainly by peracetic acid. This approach is also used in the classification proposal of peracetic acid.

Due to the rapid degradability and especially hydrolytical instability of the peracetic acid only studies with analytical monitoring and results based on measured concentrations of the test substance and with a known content of PAA are considered reliable (Klimisch score 1 & 2) for classification purposes of PAA. Discarded studies as not reliable for classification purposes without analytical monitoring can be found from the CAR annexed to this classification proposal. Validity of each study is further discussed in the respective sections.

Table 22: Summary of relevant information on acute aquatic toxicity

Method	**Species**	**Test material**	**Results**	**Remarks**	**Reference**
Fish					
U.S. EPA-FIFRA, 40 CFR, Section 158.145 Guideline 72-1 96h semi-static test GLP	*Lepomis macrochirus* (Bluegill sunfish)	Peracetic acid 5.22 % w/w	LC50 (mortality) = 1.1 mg PAA/L (mm[1])	Peracetic acid concentration analysed indirectly based on hydrogen peroxide concentrations	Anonymous (1996a) Klimisch 2
Aquatic invertebrates					
OECD 202 48h static test GLP	*Daphnia magna*	Peracetic acid 5.22 % w/w	EC50 (immobility) = 0.73 mg PAA/L (mm)	Peracetic acid concentration analysed indirectly based on hydrogen peroxide concentrations	Anonymous (1996b) Klimisch 2
Algae					
U.S. EPA-FIFRA 123-2 Comparable to OECD 201 GLP 5d static test	*Selenastrum capricornutum*	Peracetic acid 5.22 % w/w	72h EC50 = 0.16 mg PAA/L(initial) 120h EC50 = 0.18 mg PAA/L (initial) 72 EC50 = 0.050 mg PAA/L (geom. mean) 120h EC50 = 0.052 mg PAA/L (geom. mean)	The effect endpoints are based on the initial measured concentrations, which are analysed indirectly based on hydrogen peroxide concentrations. The geometric mean measured concentrations are calculated by eMSCA	Anonymous (1996c) Klmisch 2

[1] mm = mean measured concentration

11.5.1 Acute (short-term) toxicity to fish

In a semi-static (daily renewal) acute toxicity study similar to OECD TG 203 under GLP with Bluegill sunfish (*Lepomis macrochirus*), **a 96h LC50 value of 1.1 mg PAA/L** was observed based on mean measured concentrations (Anonymous, 1996a). Peracetic acid content of the test solution was 5.22 % w/w and the total peroxides content was 21.2 %. The peracetic acid concentrations were determined indirectly by measuring the hydrogen peroxide concentrations and converting them into peracetic acid concentrations. The hydrogen peroxide concentration in the test water samples was determined using a spectrometric method. Initial test concentrations were 0, 0.32, 0.54, 0.9, 1.5 and 2.5 mg PAA/L. Concentration of test substance was measured at 0 (new), 24 (old), 72 (new) and 96 (old) hours. Volume of test vessels were approximately 18 L containing 15 L of hard blended water with a volume per test animal 3 L/day. Ten test animals with a mean wet weight of 0.28 mg and a mean length of 23 mm per test vessel with one test vessel per test concentration was used. Test results are based on mean measured concentration as concentration of test substance was < 80 % of initial during the test (Table 23: Actual measured concentrations of test substance in acute fish test.). The measurements of pH, dissolved oxygen and temperature were not carried out daily but at 0, 48 and 96 hours deviating from the OECD TG 203. However, these are not considered to have an impact on the outcome of the study as validity criteria of TG 203 were otherwise met. This study was classified as reliability 2 according to evaluating Competent Authority (eCA) under Biocidal Products Regulation (EU 528/2012) and, thus, could be also considered valid and reliable for classification purposes for peracetic acid by the dossier submitter.

Table 23: Actual measured concentrations of test substance in acute fish test.

Nominal concentrations of test substance (mg/L)	**Measured concentration [mg TS/L]**					
	0 hour	**24 hour old**	**72 hour**	**96 hour old**	**Mean Measured**	**Percent of Nominal**
0.0 (control)	< MQL[b]	< MQL[b]	< MQL[b]	< MQL[b]	-	-
0.32	0.252	0.162	0.277	0.240	0.23	72
0.54	0.479	0.425	0.480	0.479	0.47	87
0.90	0.797	0.767	0.868	0.787	0.80	89
1.50	1.460	1.060	1.340	1.210	1.30	87
2.5	2.130	2.090	-	-	2.10	84
Stock solution 1.0	-	-	0.707	-	-	71

MQL[b] = Minimum Quantifiable Limit defined as: (Concentration of lowest standard.) (volume of analysis) (conversion factor) / sample volume = (0.102) x (100 mL) x (0.246)/(80.0 mL) = 0.0314 mg/L

In conclusion, the only reliable and relevant available acute fish toxicity EC50 value of 1.1 mg PAA/L based on mean measured concentration for bluegill sunfish is selected to represent acute fish toxicity for classification purposes.

11.5.2 Acute (short-term) toxicity to aquatic invertebrates

In the acute toxicity test with aquatic invertebrates, the study of Anonymous (1996b) on *Daphnia magna* with a 48h EC50 value determined as **0.73 mg PAA/L** is available (similar to OECD TG 202 and GLP compliant). The effect value was based on mean measured concentrations (analysed indirectly based on hydrogen peroxide concentrations). With the known concentration of peracetic acid and hydrogen peroxide (HP) in the original, undiluted test substance (5.22 % peracetic acid), a conversion factor (equal to content peracetic acid / content HP) was calculated for the derivation of the peracetic acid concentrations in the test medium on the basis of the hydrogen peroxide concentrations. The hydrogen peroxide concentration in the test water samples was determined using a spectrometric method. Daphnids (10 test animals per test vessel with 2 replicates per test concentration) were cultured in 1.5-L glass containers in hard blended water at 20 ± 1 °C. The light ranged from 625 to 654 lux on a 16-hour daylight photoperiod. The volume of test vessels were 250 ml containing 200 ml test solution. The mean measured test substance concentrations in the test were 0.19, 0.34, 0.56, 0.86 and 1.4 mg/L representing 100 ± 5.4 % of the nominal concentrations (Table 24: Actual concentrations of test substance in acute Daphnia test.) analysed at the beginning and the end of the test (48 h). Study followed OECD TG 202 and fulfilled the validity criteria. This study was considered acceptable for risk assessment purposes by eCA (reliability 2) and could be considered valid for classification purposes also by the dossier submitter.

Table 24: Actual concentrations of test substance in acute Daphnia test.

Nominal concentrations of test substance [mg PAA/L]	**Measured concentration [mg PAA/L]**			
	0 hour	**48 hour**	**Mean**	**Percent of Nominal**
0.0 (control)	< MQL	< MQL*	< MQL*	-
0.19	0.21	0.17	0.19	100
0.32	0.37	0.30	0.34	106
0.54	0.62	0.49	0.56	104
0.9	1.0	0.72	0.86	98
1.5	1.7	1.1	1.4	93

*MQL = Minimum quantifiable limit

In conclusion, the most reliable and only relevant aquatic invertebrate toxicity EC50 value of 0.73 mg PAA/L based on mean measured concentration for *Daphnia magna* is selected to represent acute aquatic invertebrate toxicity of peracetic acid for classification purposes.

11.5.3 Acute (short-term) toxicity to algae or other aquatic plants

For algae, the study of Anonymous (1996c) conducted under GLP and according to guideline similar to OECD TG 201 is available. The PAA content in the study was 5.22 %. The EC50 values based on cell concentrations were according to study 0.16 mg PAA/L (initial measured) after 72 hours and 0.18 mg PAA/L (initial measured) after 120 hours for *Selanastrum capricornutum*. The respective NOECs are 0.061 and 0.12 mg PAA/L. The observed algal growth is presented in Table 26. The peracetic acid concentration was determined indirectly by measuring the hydrogen peroxide concentration and converting these concentrations into peracetic acid concentrations at the beginning of the and at the end of the test (similar method to acute fish and invertebrate studies available). The hydrogen peroxide concentration in the test water samples was determined using a spectrometric method. Initial measured test concentrations were 0.061, 0.12, 0.25, 0.46, 1.1 mg PAA/L. At the end of the test, the test concentrations were under the minimum quantifiable limit (0.0314 mg PAA/L) for the three lowest test concentrations (0.061, 0.12 and 0.25 mg/L) (Table 25: Concentrations of test substance in test medium in acute algae study). In the 0.46 mg/L treatment at 120 hours, the concentration of the test item was 76 % of the nominal value. Only for the highest concentration of 1 mg PAA/L, the concentration of the test item was maintained within the 20 % range of the nominal for the whole duration of the test. The study report suggest that the 5 % peracetic acid was stable in the exposure system under the testing conditions and the degradation was related to algal density since exposure concentrations with greater than or equal to 3.6 x 10^4 cells/mL were found to be under the LOQ. Test temperature was between 22 – 24 °C and pH between 7.3 – 9.0. Three test vessels per test concentration were used in the test.

In the CLP guidance (ECHA 2017) it is stated that where measured data are available for the start and end of test, the L(E)C50, for classification purposes, may be calculated based on the geometric mean concentrations of the start and end of test. Where the concentrations at the end of test are below the analytical detection limit, such concentrations shall be considered to be half that detection limit. In the study report only EC50 values based on the initial measured test concentrations are available. Based on the value of 0.0157 mg PAA/L (LOQ 0.0314 mg/L/2) set for test concentrations of 0.061, 0.12 and 0.25 mg PAA/L, the dossier submitter has calculated geometric mean concentrations using the measured concentrations at the beginning and at the end of the test. The EC50 values based on the geomean concentrations are 0.050 mg PAA/L for 72 hours and 0.052 for 120 hours. The respective NOEC values are 0.031 and 0.043 mg PAA/L based on geomean concentrations.

Deviation of the test concentrations from the measured initial concentrations were not within the range of ± 20 in the study (only at the highest test concentration). Thus, the results based on initial measured concentration are not considered valid for the classification purposes. The dossier submitter has recalculated the toxicity values based on the geometric mean concentrations. The biomass in the control cultures increased exponentially by a factor of >16 within the 72-hour test period. No information on coefficient of variation relevant for the validity criteria in OECD TG 201 is available, however, the study is still be considered valid and reliable for the classification purposes.

Table 25: Concentrations of test substance in test medium in acute algae study.

Nominal concentrations of test substance (mg/L)	**Measured concentration (mg PAA/L)**		**Geometric mean concentration (mg PAA/L)**[b]
	0 Hour	**120 Hour**	**120 hour**
Control	-	< MQL[a]	
0.065	0.061	< MQL[a]	0.031
0.13	0.12	< MQL[a]	0.043
0.25	0.25	< MQL[a]	0.063
0.50	0.46	0.38	0.42
1.0	1.1	1.0	1.05

[a] MQL = Minimum Quantifiable Limit (0.0314 mg/L)

[b] Calculcated by dossier submitter

Table 26: The mean values for algal cell concentration data of *Selenastrum capricornutum*.

Test-Substance Concentration (initial measured) [mg/L]	**Cell concentrations (mean values) [10^4 cells/mL]**											
	measured						**Percent of control**					
	0 h	**24 h**	**48 h**	**72 h**	**96 h**	**120 h**	**0 h**	**24 h**	**48 h**	**72 h**	**96 h**	**120 h**
Control	0.37	0.85	4.0	**19**	45	**120**	100	100	100	**100**	100	**100**
0.061	ND	0.93	3.7	**17**	45	**130**	ND	109.4	92.5	**89.5**	100	**108.3**
0.12	ND	0.63[a]	2.7[a]	**16[a]**	45	**120**	ND	74.1	67.5	**84.2**	100	**100**
0.25	ND	0.41[a]	0.33[a]	**0.78[a]**	1.2[a]	**3.6[a]**	ND	48.2	8.25	**4.1**	2.7	**3**
0.46	ND	0.26[a]	0.073[a]	**0.33[a]**	0.15[a]	**0.11[a]**	ND	30.6	1.8	**1.7**	0.3	**0.1**
1.1	ND	0.18[b]	0.037[b]	**0.11[b]**	0.073[b]	**0.0[b]**	ND	21.2	0.9	**0.6**	1.6	**0**

[a] Denotes a significant ($p \leq 0.05$) inhibition effect from the control as determined by using cell counts and Dunnett's test
[b] Inhibition effect from the control was determined to be biologically rather than statistically significant

In conclusion, the most reliable and only relevant algae toxicity **EC50 (72h) value of 0.050 mg PAA/L** and **EC50 (120h) value of 0.052 mg PAA/L** based on geometric measured concentrations for *Selanastrum capricornutum* are selected to represent acute algae toxicity for the classification purposes.

11.5.4 Acute (short-term) toxicity to other aquatic organisms

No data available.

11.6 Long-term aquatic hazard

Due to the rapid degradability and especially hydrolytical instability of the peracetic acid only studies with analytical monitoring and results based on measured concentrations of the test substance and with a known content of PAA are considered reliable (Klimisch score 1 & 2) for classification purposes of PAA. Discarded studies as not reliable for classification purposes without analytical monitoring can be found from the CAR annexed to this classification proposal. Validity of each study for the classification purposes is further discussed in the respective sections. Only the studies, in which the toxicity observed can be analytically confirmed to be related to the intrinsic toxicity of peracetic acid, are considered valid and reliable for the classification purposes.

Table 27: Summary of relevant information on chronic aquatic toxicity

Method	Species	Test material	Results[1]	Remarks	Reference
Fish					
OECD 210 GLP 33d flow-through test	*Danio rerio* (Zebra fish)	Peracetic acid 14,9 % w/w	NOEC = 0.00225 mg PAA/L (nominal)	Post hatch success, overall survival. Analytical verification of the test concentrations only performed for the highest test concentration. Other test concentrations of PAA below the analytical LOQ.	Anonymous (2007b) Klimisch 3
Aquatic invertebrates					
OECD 211 GLP 21d semi-static test	*Daphnia magna*	Peracetic acid 14.8 % w/w	NOEC = 0.34 mg TS/L (mortality) based on nominal concentration NOEC = 0.0121 mg PAA/L (mortality) estimated by the biocidal eCA	Invalid analytical method for the determination of PAA concentrations.	Anonymous (2000b) Klimisch 3
Algae					
OECD 201 GLP 5d static test	*Selenastrum capricornutum*	Peracetic acid 5.22 % w/w	72h NOEC = 0.061 mg PAA/L (initial) 120h NOEC = 0.12 mg PAA/L (initial) 72h NOEC = 0.031 mg PAA/L (geo	The effect endpoints are based on the initial measured concentrations, which are analysed indirectly based on hydrogen peroxide	Anonymous (1996c) Klimisch 2

			mean) 120h NOEC = 0.043 mg PAA/L (geo mean)	concentrations. The geometric mean measured concentrations are calculated by eMSCA	

11.6.1 Chronic toxicity to fish

An OECD TG 210 flow-through study under GLP for zebra fish (*Danio rerio*) (14.9 % w/w PAA) is available for peracetic acid (Anonymous 2007b). Initial nominal concentrations of 1.5, 5.0, 15, 50 and 150 µg TS/L corresponding to 0.2, 0.7, 2.2, 7.5, 22.4 µg PAA/L were used. At the start of the study 15 eggs per replicate with 4 replicates per test concentration was used. This study resulted in a 33 day NOEC value of 0.00225 mg PAA/L based on nominal concentrations for post hatch survival and overall survival. The NOEC value was based on the statistically significant effects seen on the survival at the two highest exposure concentrations, whereas no effects were seen on hatching or growth. These effects occurred during the time window of post hatch day 6 to 15. No further significant reduction of the survival rate was observed in the last third of the study. Peracetic acid concentrations were analytically monitored via LC-MS/MS (by MTSO method) at the highest treatment level only. Due to the low sensitivity of the analytical method, actual concentrations were measured only in the stock solutions (all treatments) and the test solutions of the highest concentration level. Despite using a continuous flow-through test system the measured concentrations in mixing chambers, and especially in test vessels, dropped below the limit of quantification of the method, 0.00754 mg PAA/L. Samples of the highest test concentration (150 µg TS/L) and control (mixing chamber and alternate replicates) were taken on days -1, 0 and at least weekly thereafter until end of exposure. In the mixing chambers where the stock solutions were mixed with the respective amount of tap water, no PAA could be measured during the first 15 study days (PAA < LOQ). During the first 21 days of the study the test concentration in the test solutions could not be verified (measured concentrations of PAA < LOQ). Even below LOQ for that period, the two highest test concentrations caused significant effect until day 18. On day 19 fish were transferred to bigger test vessels. In order to maintain the test solution exchange rate in the larger aquaria (approx. 10-fold per day) the flow rates were increased by 5 times. At study days 20, 21, 27 and 29 (mixing chamber) and study day 27 and 29 PAA could be measured and accounted for 49 to 95 % of the nominal concentration in the mixing chambers and was 33 to 44 % of nominal in the test vessel (Table 28).

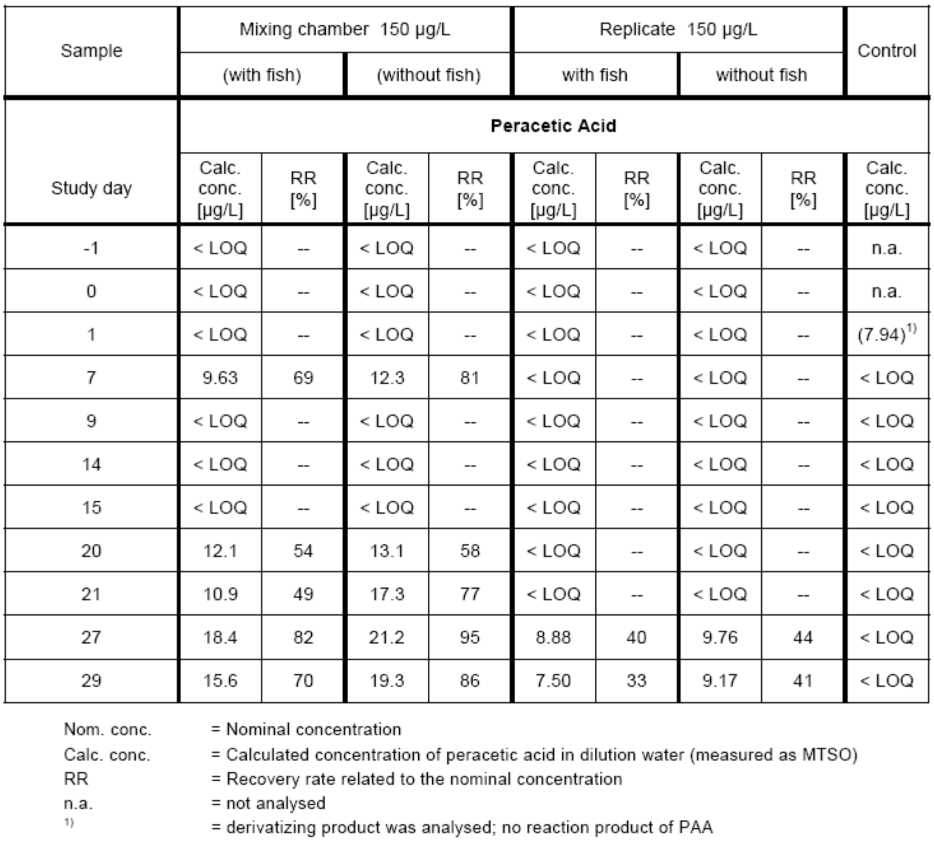
The number of hatched eggs was determined daily until day 8. On day 7 of the study, 98 % of all fertilized and living embryos in the control groups had hatched. At the end of exposure (after 33 days) the total length of all survivors was measured to the nearest 0.5 mm. No statistically significant adverse effect on the sublethal parameters hatching time, hatching success, swim-up of larvae and growth of surviving animals could be observed up to the highest tested concentration level. Post hatch success and survival of fish were statistically reduced at the end of the study at the two highest test concentrations (50 and 150 µg/L TS). Analytical measurement of the test concentration in the test vessels have been performed only for the highest test concentration, but otherwise the OECD TG 210 validity criteria were met.

The analytical verification of test concentration coud not be performed during the sensitive early-life stages of the study as concentrations of PAA was consistently below LOQ. According to the OECD test guideline 210 when the measured concentrations do not remain within 80-120% of the nominal concentration, the effect concentrations should be determined and expressed relative to the arithmetic mean concentration for flow-through tests. The arithmetic mean exposure concentration in the study can not be determined, because the concentrations in test vessels have been analytically determined only at the highest treatment level. During the first 21 days the concentrations of PAA were below LOQ. Also the CLP guidance states that when the measured concentrations do not remain withing 80 - 120 % of the nominal, the effects concentrations cannot be based on initial measured concentrations. NOEC value of 2.25 µg PAA/L based on the nomimal concentration is below the analytical limit of quantification (7.54

µg/L for PAA). Thus, the analytical verification of the test concentration of PAA was only possible for the highest test concentration.

This study was given a reliability score of 2 by eCA but due to lack of analytical verification and/or quantification of the test concentrations of peracetic acid during the test the study is not considered reliable and valid for the classification purposes by the dossier submitter. No peracetic acid was quantified during the first 21 days of the study (PAA concentrations below LOQ). Based on the results of the study Anonymous 2007b, it is not possible to derive a NOEC value representing the intrinsic toxicity of peracetic acid from the test solution mixute. Thus, this study is not considered reliable and relevant for the classification purposes of peracetic acid.

Table 28: The analytical measurements of PAA concentration at the highest nominal test concentration of 150 µg/L in the mixing chamber and in the test vessels in a flow-through system.



Sample	Mixing chamber 150 µg/L				Replicate 150 µg/L				Control
	(with fish)		(without fish)		with fish		without fish		
	Peracetic Acid								
Study day	Calc. conc. [µg/L]	RR [%]	Calc. conc. [µg/L]	RR [%]	Calc. conc. [µg/L]	RR [%]	Calc. conc. [µg/L]	RR [%]	Calc. conc. [µg/L]
-1	< LOQ	--	< LOQ	--	< LOQ	--	< LOQ	--	n.a.
0	< LOQ	--	< LOQ	--	< LOQ	--	< LOQ	--	n.a.
1	< LOQ	--	< LOQ	--	< LOQ	--	< LOQ	--	(7.94)[1)]
7	9.63	69	12.3	81	< LOQ	--	< LOQ	--	< LOQ
9	< LOQ	--	< LOQ	--	< LOQ	--	< LOQ	--	< LOQ
14	< LOQ	--	< LOQ	--	< LOQ	--	< LOQ	--	< LOQ
15	< LOQ	--	< LOQ	--	< LOQ	--	< LOQ	--	< LOQ
20	12.1	54	13.1	58	< LOQ	--	< LOQ	--	< LOQ
21	10.9	49	17.3	77	< LOQ	--	< LOQ	--	< LOQ
27	18.4	82	21.2	95	8.88	40	9.76	44	< LOQ
29	15.6	70	19.3	86	7.50	33	9.17	41	< LOQ

Nom. conc. = Nominal concentration
Calc. conc. = Calculated concentration of peracetic acid in dilution water (measured as MTSO)
RR = Recovery rate related to the nominal concentration
n.a. = not analysed
1) = derivatizing product was analysed; no reaction product of PAA

11.6.2 Chronic toxicity to aquatic invertebrates

A 21d semi-static chronic toxicity study for *Daphnia magna* according to OECD TG 211 is available for peracetic acid (14.8 % PAA w/w) by Anonymous 2000b. Initial test concentration used were 0.034, 0.11, 0.34, 1.1 and 3.4 mg TS/L. No mortality in the control was observed. The mean number of live young per surviving adult after 21 days was 104 in the controls. The coefficient of variation for the control group was 18%. Parental mortality in terms of immobility was observed at nominal test concentrations of 1.1 mg TS/L (100 % mortality by day 19) and 3.4 mg TS/L (100 % mortality by day 3), but no mortality occurred at the 0.034, 0.11 and 0.34 mg TS/L test concentrations. No deviations from the TG was observed for physico-chemical measurements. Test media was renewed on days 0, 2, 5, 9, 12, 14, 16 and 19 with analytical monitoring of test concentrations on days 0 (fresh test media), 2, 5, 7, 9, 12, 14, 16, 19 and 21 (old test media days 2-21). On day 0, measured concentrations of peracetic acid ranged from 81% to 124% of nominal values, while analysis on days 2, 5, 7, 9, 12, 14, 16, 19 and 21 showed concentrations of peracetic acid ranging from 4% to 785% of nominal values. Peracetic acid concentration was indirectly determined from methyl-p-tolylsulfoxide (MTSO) resulting from oxidation of methyl-p-tolylsulfide (MTS) by PAA. The study report suggested that the low measured concentrations were considered to be due to possible losses due to instability of the component in the test diluent. The enhanced levels of peracetic acid were explained by an unknown component in the culture medium which was also able to produce the reaction from MTS to MTSO. A range of pre-study test samples showed that peracetic acid is unstable during a period equivalent to media renewal period in the definitive test. In the definitive test at nominal test concentrations of 0.034, 0.11 and 0.34 mg TS/L, the concentrations analysed from the expired test solutions gave recoveries of 166-782 %, 71-651 % and 19-598 %, respectively. Culture medium taken from the Daphnia stock cultures was analysed to confirm that the presence of methyl-p-tolylsulphoxide in the control samples and excessively high concentrations in the test samples was due to culture medium containing uknown component oxidising MTS to MTSO and not the presence of PAA. Analytical detection method of PAA in the study assumed that MTS is oxidised to MTSO by peracetic acid. This analytical verification method for PAA was not considered reliable due to the presence of another unknown component. Thus, the effect concentrations based on the nominal are not considered acceptable for the classification purposes and they do not reflect the initial toxicity of PAA.

The NOEC was recalculated by biocidal eCA using a geomean approach with background correction for supposed PAA concentration in the control samples. At the start of the study, instead of 0.34 mg/L the concentration of 0.403 mg/L corresponding to 119% recovery were measured. However, the nominal concentration was used by the eCA instead of the measured value for the calculation of the geomean. In addition, at the start of each exposure period the concentrations were assumed to be 0.34 mg/L as the fresh test media was not analytically measured. The NOECgeomean was calculated with a background (control) correction. The LOQ/2 was applied when a concentration was not reliably quantified. The LOQ was 0.00050 mg/L, thus LOQ/2=0.0003 mg/L*. The study resulted in a NOEC value of 0.0121 mg PAA/L for parental mortality and reproduction based on geometric mean measured concentrations (**Table 29: Measured and corrected concentrations of nominal concentration 0.34 mg TS/L by biocidal eCA.**).

Table 29: Measured and corrected concentrations of nominal concentration 0.34 mg TS/L by biocidal eCA.

Days	Nominal conc. at the start of the exposure period at day 0 (mg/L)	Measured conc. in test vessel at the end of the exposure period (mg/L)	Measured conc. in test vessel at the end of the exposure period in control (mg/L)	Corrected conc. at the end of the exposure period (background correction from the control) (mg/L)	Geometric mean of the exposure period (correted conc.) (mg/L)
0-2	0.34	0.111	< LOQ	0.111	0.194
2-5	0.34	0.262	0.00320	0.259	0.297
5-7	0.34	0.189	< LOQ	0.189	0.254
7-9	0.34	0.179	0.103	0.076	0.161
9-12	0.34	0.132	0.0932	0.039	0.115
12-14	0.34	0.0919	0.154	(-0.0621) 0.0003*	0.010
14-16	0.34	0.0636	0.0247	0.039	0.115
16-19	0.34	0.0650	0.0556	0.009	0.055
19-21	0.34	(2.03) 0.0003*	0.105	0.0003*	0.010

*LOQ/2

A geomean concentration of the 0.34 mg TS/L treatment over all 9 exposure periods of "Fennosan peracetic acid" is 0.08223 mg/L (with background correction). The proportion of peracetic acid in "Fennosan peracetic acid" is 14.8 %. Thus, NOECmeasured of 12.1 µg/l was estimated by the eCA. This study fulfils the validity criteria in OECD TG 211. The study was assigned a reliability score 2 by eCA, however due to the invalid analytical method for the verification of PAA concentrations during the test, this study was not considered valid for the classification purposes by the dossier submitter. Thus, the Klimisch score of 3 was assigned by the dossier submitter due to the uncertainties related to the analytical verification of the test concentrations. Based on this study it was not possible to conclude the intrinsic long-term toxicity of peracetic acid to *Daphnia magna*.

11.6.3 Chronic toxicity to algae or other aquatic plants

Algal toxicity study is already discussed in the section 11.5.3. The representing NOEC values in the study were **the 72h NOEC value of 0.031 mg/L and the 120h NOEC value of 0.043 mg/L** based on geometric mean measured concentration calculated by the dossier submitter (Anonymous, 1996c).

11.6.4 Chronic toxicity to other aquatic organisms

No data available.

11.7 Comparison with the CLP criteria

11.7.1 Acute aquatic hazard

Acute aquatic toxicity data for peracetic acid are available for fish, aquatic invertebrates and algae. Algae are the most sensitive taxonomic group and green alga *Selenastrum capricornutum* can be considered as the most sensitive species tested. The 72h toxicity value of 0.050 mg PAA/L by Anonymous (1996c) (based on the geometric mean measured concentrations) is proposed as the lowest and the most reliable acute endpoint.

For acute aquatic hazards, on the basis of this acute aquatic alga endpoint being in the range 0.01 mg/l < L(E)C50 ≤ 0.1 mg/l, peracetic acid should be classified as Aquatic Acute 1 (H400) with M-factor of 10. Peracetic acid has already an existing harmonised acute classification of Aquatic Acute 1 (H400). It is now proposed to add M-factor of 10 to the existing acute aquatic classification of peracetic acid.

11.7.2 Long-term aquatic hazard (including bioaccumulation potential and degradation)

Bioaccumulation

No experimental BCF studies on peracetic acid are available. The study on partition coefficient n-octanol/water (generally according to OECD test guideline 107 “Shake Flask Method”) as well as the calculated partition coefficients, however, resulted in log POW values from -0.23 to -1.20. These are less than the trigger value of 4 given in the CLP Regulation. Therefore, the substance is considered to have low potential to bioaccumulate for the classification purposes.

Rapid degradation

Based on a ready biodegradability test (generally following the OECD test guideline 301E “Ready Biodegradability: Modified OECD Screening test”), degradation of peracetic acid was measured being between 66 to 98% within 14 to 28 days by DOC removal method. However, it was not demonstrated in the study that a degradation sufficient to pass ready biodegradability criteria (i.e. 70% of DOC removal within 28 days) was attained within a 10-d window beginning after a 10% degradation was reached. Therefore, the result cannot be used for a definite conclusion of the PAA being rapidly degradable for purposes of classification. However, the data on ready biodegradability can be considered as supporting information on rapid degradation of the PAA.

There are no surface water simulation tests available for the PAA.

According to a hydrolysis test (generally following to OECD test guideline 111 “Hydrolysis as a Function of pH”) peracetic acid is hydrolytically instable as DT_{50} values of 46.7h at pH 4 and 31.7h at pH 7 were obtained. According to the criteria in CLP guidance, the substance can be considered as rapidly degradable for classification purposes when the longest half-life determined within the pH range of 4-9 is shorter than 16 days (corresponding to a degradation of > 70% within 28 days) and when the hydrolysis products formed do not fulfil the classification criteria as hazardous for aquatic environment. PAA fulfils this criteria of rapid degradatation as the degradation products, acetic acid and hydrogen peroxide, do not have harmonised classifications as hazardous to aquatic environment under CLP.

Furthermore, there are several non-guideline studies available supporting the observations of peracetic acid being rapidly degradable. With regard to the CLP criteria, the degradation information from the hydrolysis test available provides sufficient data on peracetic acid of having a half-life of less than 16 days. Therefore, peracetic acid is considered being rapidly degradable according to the CLP criteria.

Toxicity

Reliable and valid long-term aquatic toxicity data for peracetic acid is only available for algae. Long-term aquatic toxicity data available in fish and aquatic invertebrate studies can not be considered valid for the classification purposes due to the analytical deficiencies to monitor peracetic acid concentrations. The effects seen in those studies could not be verified to be related to the intrinsic toxicity of peracetic acid. The 72h NOEC value of 0.031 mg PAA/L by Anonymous (1996c) based on the geometric mean measured concentration is the only reliable chronic endpoint for PAA.

Since there are adequate chronic toxicity data available for only one trophic level, PAA should be classified according to the Figure 4.1.1 in the CLP based on the most stringent outcome (surrogate method):

(a) according to the criteria given in Table 4.1.0(b)(i) or 4.1.0(b)(ii) (depending on information on rapid degradation), and

(b) (if for the other trophic level(s) adequate acute toxicity data are available) according to the criteria given in Table 4.1.0(b)(iii).

Based on the lowest toxicity value of the 72h NOEC 0.031 mg PAA/L for algae, peracetic acid can be classified according to the criteria set out in CLP in Table 4.1.0(b)(ii). In this case classification of Aquatic Chronic 2 is applicable for peracetic acid based on the lowest NOEC value of 0.031 mg PAA/L (≤ 0.1 mg/l).

Since peracetic acid is rapidly degradable and the log Pow ≤ 4 it will not be classified according to the criteria given in Table 4.1.0(b)(iii). Thus, peracetic acid is classified according to the available valid and reliable long-term aquatic toxicity data for algae.

For long-term aquatic hazards, peracetic acid should be classified according to Regulation EC 1272/2008 as Aquatic Chronic 2 (H411).

11.8 CONCLUSION ON CLASSIFICATION AND LABELLING FOR ENVIRONMENTAL HAZARDS

Conclusions on classification and labelling for environmental hazards of peracetic acid.

Hazard Class and Category code(s)	M factor	Hazard Statement
Aquatic Acute Category 1, H400	10	Very toxic to aquatic life
Aquatic Chronic Category 2, H411	-	Toxic to aquatic life with long lasting effects

12 EVALUATION OF ADDITIONAL HAZARDS

The hazard class “Hazardous to the ozone layer” has not been assessed in this dossier.

13 ADDITIONAL LABELLING

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15 ANNEXES

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