

Section A8.1-6		Protective measures concerning handling of the active substance	
Annex Point II A, VIII.8.1-6			
JUSTIFICATION FOR NON-SUBMISSION OF DATA			Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified [X]	
Limited exposure []	Other justification [x]		
Detailed justification:	[REDACTED]		
<i>Evaluation by Competent Authorities</i>			
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted			
EVALUATION BY RAPPORTEUR MEMBER STATE			
Date	<i>Give date of action</i>		
Evaluation of applicant's justification	<i>Discuss applicant's justification and, if applicable, deviating view</i>		
Conclusion	<i>Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g., submission of specific test/study data</i>		
Remarks			
COMMENTS FROM OTHER MEMBER STATE (specify)			
Date	<i>Give date of comments submitted</i>		
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>		
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>		
Remarks			

Peracetic acid (PAA)

Section A8.7 Annex Point IIIA, VIII.1	Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances (IIA, VIII.8.7)	Official use only
The active substance peracetic acid falls under List II point 2 of the Groundwater Directive 80/86/EEC: "Biocides and derivatives not appearing in List I".		
Evaluation by Competent Authorities		
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	<i>Give date of action</i>	
Materials and Methods	<i>State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.</i>	
Results and discussion	<i>Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers</i>	
Conclusion	<i>Adopt applicant's version or include revised version</i>	
Reliability	<i>Based on the assessment of materials and methods include appropriate reliability indicator</i>	
Acceptability	acceptable / not acceptable <i>(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)</i>	
Remarks		
COMMENTS FROM ...		
Date	<i>Give date of comments submitted</i>	
Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>	
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>	
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		

9 Classification and labelling

According to ESIS (European chemical Substances Information System), peracetic acid is officially classified and labelled as follows:

Risk phrase:	R10: Flammable
Hazard symbol:	O
Indications of danger:	Oxidising
Risk phrases:	R7: May cause fire
Hazard symbol:	Xn
Indications of danger:	Harmful
Risk phrases:	R20/21/22: Harmful by inhalation, in contact with skin and if swallowed
Hazard symbol:	C
Indications of danger:	Corrosive
Risk phrases:	R35: Causes severe burns
Hazard symbol:	N
Indications of danger:	Dangerous for the environment
Risk phrases:	R50: Very toxic to aquatic organisms
Indications of danger:	O: Oxidising C: Corrosive N: Dangerous for the environment
Safety phrases:	S1/2: Keep locked up and out of reach of children S3/7: Keep container tightly closed in a cool place S14: Keep away from ... (incompatible materials to be indicated by the manufacturer) S36/ 37/39: Wear suitable protective clothing, gloves and eye/face protection S45: In case of accident or if you feel unwell, seek medical advice immediately (show label where possible) S61: Avoid release to the environment. Refer to special instructions/Safety data sheets.





Specific concentrations limits for peracetic acid:

Concentration	Classification
$C \geq 25\%$	C, N; R20/21/22-35-50
$10\% \leq C < 25\%$	C; R20/21/22-35
$5\% \leq C < 10\%$	C; R34
$1\% \leq C < 5\%$	Xi; R36/37/38

RMS Evaluation 2015:*From Doc IIA and AR:*

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

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

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

In accordance with Directive 67/548/EEC, Annex VI Table 3.2, peracetic acid is classified and labelled as follows:

Class of danger	O Oxidising C Corrosive N Dangerous for the environment
R phrases	R7 May cause fire R10 Flammable R20/21/22 Harmful by inhalation, in contact with skin and if swallowed R35 Causes severe burns

	R50 Very toxic to aquatic organisms
S phrases	S1/2 Keep locked up and out of the reach of children S3/7 Keep container tightly closed in a cool place S14 Keep away from ... (incompatible materials to be indicated by the manufacturer) S36/37/39 Wear suitable protective clothing and gloves S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible) S61 Avoid release to the environment. Refer to special instructions / safety data sheets
Concentration Limits	Xn; R20/21/22: $C \geq 10\%$ C; R35: $C \geq 10\%$ C; R34: $5\% \leq C < 10\%$ Xi; R36/37/38: $1\% \leq C < 5\%$
Notes	B D

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

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