

FI 2011

Mechanistic study – any study to clarify effects reported in toxicity studies	
Conclusion	Applicant's justification is acceptable.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE (specify)
Date	Give date of comments submitted
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Remarks	

# Section A6.11/01 Acute Toxicity – Studies on Other Routes of Administration (parenteral route)

Intravenous, Mouse

		Intravenous, Mouse				
		1 REFERENCE	Official use only			
1.1	Reference	(1983): Prüfung der akuten intravenösen Toxizität aktiv im Vergleich zu Formalin (Study on the Acute Intravenous Toxicity of as Compared to Formalin); Project No. ; Report No. , Doc. No. 524-001 (unpublished).				
1.2	Data protection	Yes				
1.2.1	Data owner	PAR Group				
1.2.2	Companies with letter of access	All members of PAR group				
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I.				
		2 GUIDELINES AND QUALITY ASSURANCE				
2.1	Guideline study	Not applicable, there is no OECD guideline for the conduct of acute toxicity studies following intravenous administration; the procedures employed followed OECD guideline 401 ("Acute Oral Toxicity")				
2.2	GLP	No; GLP was not mandatory by the time the study was conducted				
2.3	Deviations	Not applicable				
		3 MATERIALS AND METHODS				
3.1	Test material					
3.1.1	Lot/Batch number					
3.1.2	Specification					
3.1.3	Purity					
3.1.4	Description	Not stated				
3.1.5	Stability	Not stated				
3.2	<b>Test Animals</b>					
3.2.1	Species	Mouse				
3.2.2	Strain	CF 1				
3.2.3	Source					
3.2.4	Sex	Male				
3.2.5	Age/weight at study initiation	Age: not stated; body weight: 27 – 28 g				
3.2.6	Number of animals per group	10				
3.2.7	Control animals	None				
3.3	Administration/ Exposure					
3.3.1	Postexposure period	14 days				
3.3.2	Туре	Intravenous application				

Peracetic acid (PAA)
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3.5

3.6

Method of

 $LD_{50}$ 

determination of

**Further remarks** 

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#### **Section A6.11/01** Acute Toxicity - Studies on Other Routes of Administration (parenteral route) Intravenous, Mouse 3.3.3 Vehicle Physiological saline 158, 172, 186, 199, 251, 316, 398 mg/kg bw 3.3.4 Dose levels 3.3.5 Concentration in 15.8, 17.2, 18.6, 19.9, 25.1, 31.6, 39.8 mg/mL vehicle Total volume 3.3.6 10 mL/kg bw applied 3.3.7 Injection duration 1 minute 3.3.8 Controls None included Signs of intoxication (immediately, 1, 6 and 24 hours after 3.4 Examinations application and in intervals of 1 - 3 days until day 14). Body weight was determined after 24 hours as well as on days 7 and 14. Macroscopical examination of decedents and scheduled deaths at the end of the study period.

The intravenous LD<sub>50</sub> was determined according to the method of J.T.

Litchfield and F. Wilcoxon (J. pharm. Exptl. Ther. 96, 99-108 (1949)).

#### Peracetic acid (PAA)

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#### **Section A6.11/01**

# Acute Toxicity – Studies on Other Routes of Administration (parenteral route)

### Intravenous, Mouse

#### 4 RESULTS AND DISCUSSION

#### 4.1 Clinical signs

Signs of intoxication were notable directly after intravenous administration and recovery was seen within 24 hours after dosing. At lower dose levels only slight signs of intoxication were evident, at higher doses, however, severe signs of intoxication were evident:

- 158 mg/kg bw: moderately decreased spontaneous activity within 24 hours after treatment and moderate convulsions until 1 hour after treatment, moderate piloerection until 24 hours after treatment and slight to moderate tachypnoe until 6 hours after treatment.
- 172 mg/kg bw: moderately decreased spontaneous activity within 24 hours after treatment and moderate convulsions until 1 hour after treatment, marked piloerection until 24 hours after treatment and marked tachypnea until 1 hour after treatment (completely reversible after 6 hours).
- 186 mg/kg bw: moderately decreased spontaneous activity within 24 hours after treatment, distinct vocalisation directly after treatment, marked convulsions and moderate ataxia until 1 hour after treatment, marked piloerection and marked tachypnea within 24 hours after treatment.
- 199 mg/kg bw: markedly reduced spontaneous activity within 24 hours after treatment, distinct vocalisation and strong convulsions directly after treatment, marked ataxia within 6 hours after treatment, prone position moderate in degree directly after treatment, marked piloerection and strong tachypnea within 24 hours after treatment.
- 251 mg/kg bw: severely reduced spontaneous activity und severe ataxia within 24 hours after treatment, distinct vocalisation, marked convulsions, marked prone position and reduced ear reflex within 1 hour after treatment, slightly reduced corneal reflex directly after treatment, marked piloerection and strong tachypnea within 24 hours after treatment.
- 316 mg/kg bw markedly reduced activity and severe ataxia within 24 hours after treatment, severe vocalisation, convulsions and prone position within 1 hour after treatment, moderately decreased ear reflex, slightly reduced corneal reflex within 6 hours after treatment, marked piloerection and strong tachypnea within 24 hours after treatment
- 398 mg/kg bw: severe vocalisation directly after treatment, severe convulsions, severe prone position, severe piloerection and strong tachypnea, all animals died within 1 minute after treatment

In all dose groups, animals lost body weights until 24 hours after administration only. Thereafter, the body weight development of the surviving animals was considered to be normal.

4.2 Mortalities

After single i.v. treatment with  $\frac{1}{2}$ , death was observed 5 – 6 minutes after administration of 172 and 186 mg/kg bw, 4 – 5 minutes after administration of 199 mg/kg bw, 3 minutes after administration of 251 mg/kg bw and 2 minutes after administration of 316 mg/kg bw. A

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Section A6.11/01		Acute Toxicity – Studies on Other Routes of Administration (parenteral route)
		Intravenous, Mouse
		dose of 398 mg/kg bw caused death 20 – 30 seconds after administration.
		Please refer to Table 6.11/01-1
4.3	Pathology	There were no macroscopic findings in decedents and scheduled deaths after 14 days.
4.4	$LD_{50}$	The LD <sub>50</sub> for after a single i.v. administration to male CF 1 mice was determined to be 212 mg/kg bw (C.I: 190.9 – 235.2 mg/kg bw).
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	Materials and methods	Seven groups of 10 male CF 1 mice each received a single i.v. injection of at dose levels of 158, 172, 186, 199, 251, 316, and 398 mg/kg bw, respectively, at a constant dosing volume of 10 mL/kg bw in physiological saline as the vehicle. Animals were regularly observed for clinical signs and mortality throughout the study. Body weights were determined on the day of administration and on days 7 and 14 of the study. The study was terminated after a post-observation period of 14 days and a gross pathological examination was performed.
5.2	Results and discussion	Following single i.v. administration of to male CF 1 mice, death occurred at all dose levels except the low dose level of 158 mg/kg bw. Death was observed within 20 seconds until 6 minutes after injection. Clinical signs comprised decreased spontaneous activity, ataxia, tachypnea, vocalisation, convulsions, prone position and piloerection. The severity of clinical signs depended on the dose level given.
		There were no gross pathological findings notable after necropsy of both decedents and scheduled deaths.
5.3	Conclusion	The LD <sub>50</sub> for after a single i.v. administration to male CF 1 mice was determined to be 212 mg/kg bw (C.I: 190.9 – 235.2 mg/kg bw).
5.3.1	Reliability	1
5.3.2	Deficiencies	None

	Evaluation by Competent Authorities		
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted		
	EVALUATION BY RAPPORTEUR MEMBER STATE		
Date			
Materials and Methods			
Results and discussion			
Conclusion			
Reliability			
Acceptability	acceptable		
Remarks			

## Peracetic acid (PAA)

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Section A6.11/01 Acute Toxicity – Studies on Other Routes of Administration (parenteral route)

Intravenous, Mouse

<u></u>	COMMENTS FROM	
Date	Give date of comments submitted	
Materials and Methods	Discuss additional relevant discrepancies referring to the (sub)heading number and to applicant's summary and conclusion.  Discuss if deviating from view of rapporteur member state.	
Results and discussion	Discuss if deviating from view of rapporteur member state	
Conclusion	Discuss if deviating from view of rapporteur member state	
Reliability	Discuss if deviating from view of rapporteur member state	
Acceptability	Discuss if deviating from view of rapporteur member state	
Remarks		

Table A6.11-1: Acute Toxicity (iv.) of in Male CF 1 Mice

14010 110111 11		Tolkery (zvi) oz	in manie of I mare	
Dose [mg/kg bw]	Number of dead / number of investigated	Time of death (range)	Observations	
158	0/10	-	refer to 4.1	
172	2/10	5 – 6 minutes	refer to 4.1	
186	4/10	5 - 6 minutes	refer to 4.1	
199	6/10	4 - 5 minutes	refer to 4.1	
251	6/10	3 minutes	refer to 4.1	
316	9/10	2 minutes	refer to 4.1	
398	10/10	20 -30 seconds	refer to 4.1	
LD50 value	212 mg/kg bw (C.I:	190.9 – 235.2 mg/kg bw		

Section A6.12.1 Annex Point IIIA, 6.12	Medical surveillance on manufacturing plant personnel			
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Officia use only		
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [ ]			
Limited exposure [ ]	Other justification [ X ]			
Detailed justification:				
	<b>Evaluation by Competent Authorities</b>			
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted			
	EVALUATION BY RAPPORTEUR MEMBER STATE			
Date				
Evaluation of applicant's justification				
Conclusion	Applicant's justification is acceptable.			
Remarks				
T.	COMMENTS FROM OTHER MEMBER STATE (specify)			
Date	Give date of comments submitted			
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state			
Conclusion	Discuss if deviating from view of rapporteur member state			
Remarks				

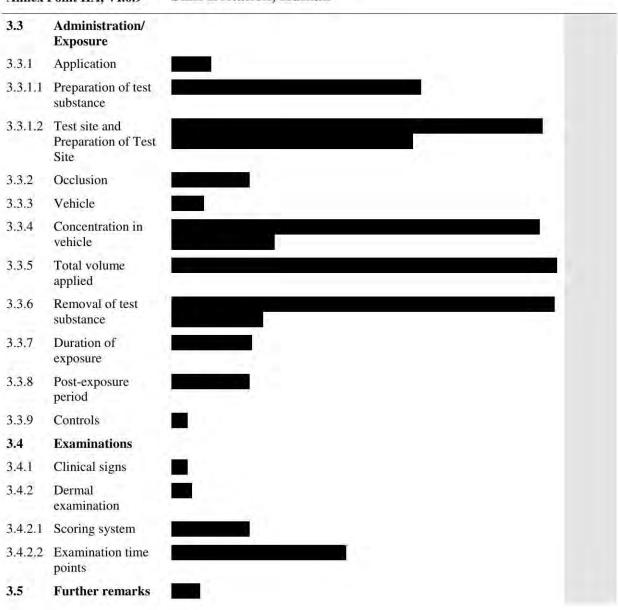
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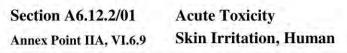
Section A6.12.2/01 Acute Toxicity

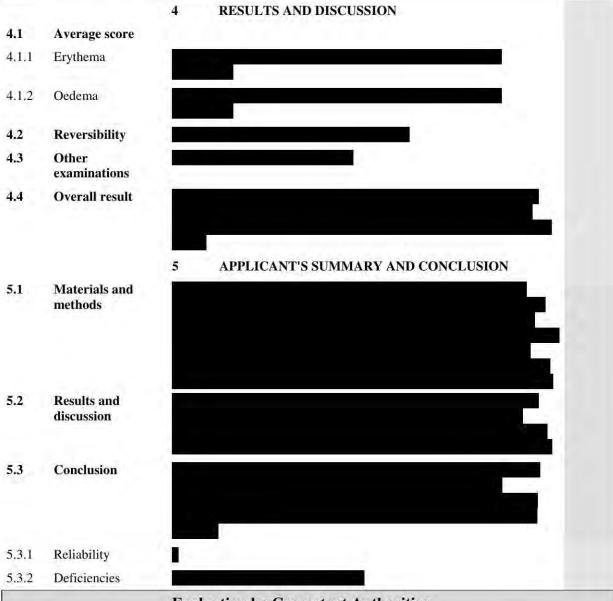
Annex Point IIA, VI.6.9 Skin Irritation, Human

key stu		are described below "all-in-one" as discussed with the RMS. Two non-summarised in IUCLID attached to Document III ( , , 1990, Doc. No. 565-013).	
		1. REFERENCE	Officia use onl
1.1	Reference	Kramer, A. et al. (1987) Toxische Risiken bei der Anwendung von Desinfektionsmitteln auf der Haut (Toxic Risks by the Use of Disinfectants on Skin); Hyg. + Med. 12, 134-142; Doc. No. 592-027 (published).	
1.2	Data protection	No, study is a publication	
1.2.1	Data owner	Not applicable, study is a publication	
1.2.2	Companies with letter of access	Not applicable, study is a publication	
1.2.3	Criteria for data protection	Not applicable, study is a publication	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	Guideline study		
2.2	GLP		
2.3	Deviations		
		3 MATERIALS AND METHODS	
3.1	Test material		
3,1.1	Lot/Batch number		
3,1.2	Specification		
3.1.3	Purity		
3.1.4	Description		
3.1.5	Stability		
3.2	<b>Test Animals</b>		
3.2.1	Species		
3.2.2	Strain		
3.2.3	Source		
3.2.4	Sex		
3.2.5	Age/weight at study initiation		
3.2.6	Number of test persons		
3.2.7	Controls		

# Section A6.12.2/01 Acute Toxicity Annex Point IIA, VI.6.9 Skin Irritation, Human







	<b>Evaluation by Competent Authorities</b>
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	Acceptable

## Peracetic acid (PAA)

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Section A6.12.2/01 Acute Toxicity

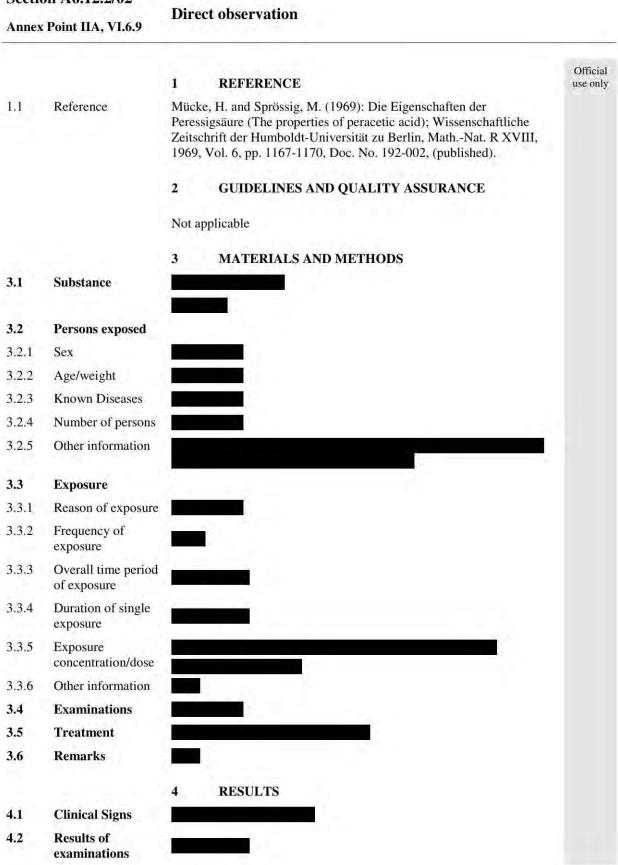
Annex Point IIA, VI.6.9 Skin Irritation, Human

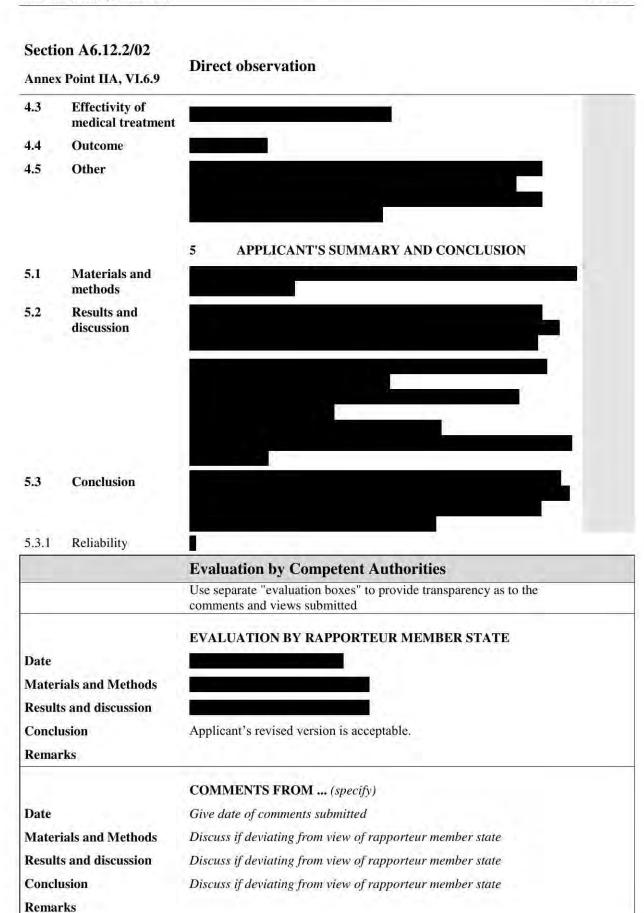
Remarks	
	COMMENTS FROM
Date	Give date of comments submitted
Materials and Methods	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.  Discuss if deviating from view of rapporteur member state
Results and discussion	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state
Remarks	

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			7

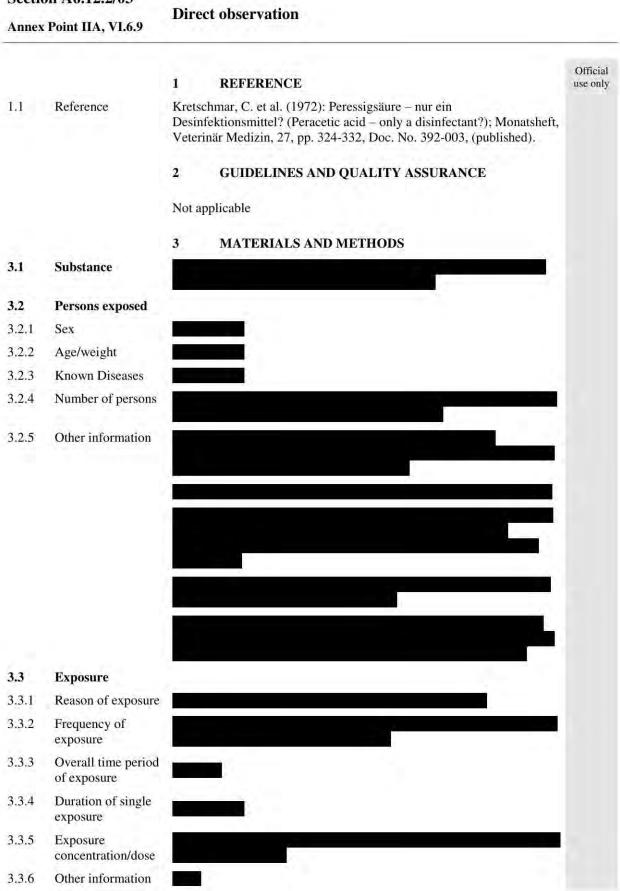
Peracetic Acid Registration Group (PAR)	Biocidal active substance:	Page 1-2
	Peracetic acid (PAA)	
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#### Section A6.12.2/02



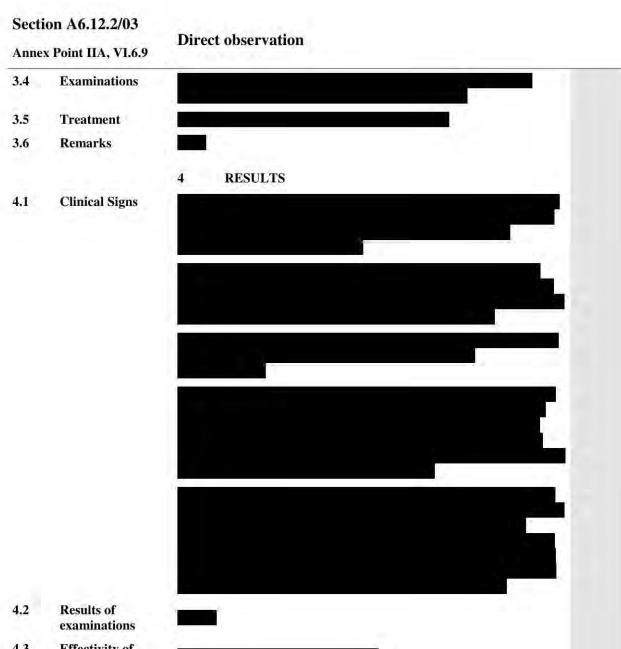


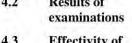
### Section A6.12.2/03



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- 4.3 Effectivity of medical treatment
- 4.4 Outcome
- 4.5 Other

#### 5.1 Materials and methods

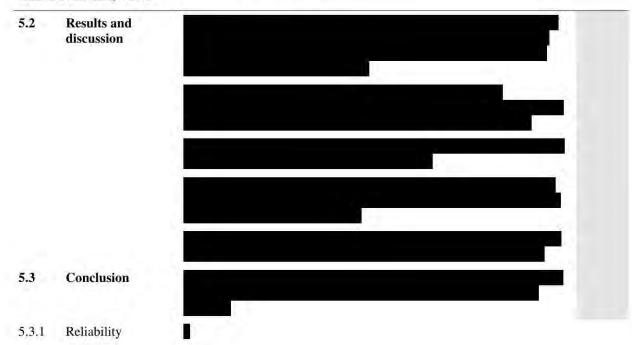


Peracetic Acid Registration Group (PAR)	Biocidal active substance:	Page 3-3
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# Annex Point IIA, VI.6.9

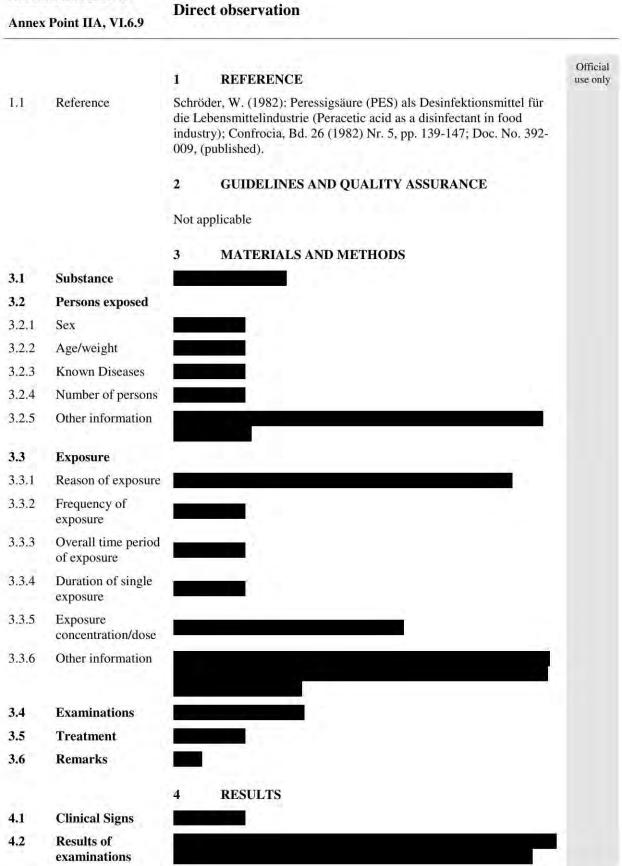
# **Direct observation**



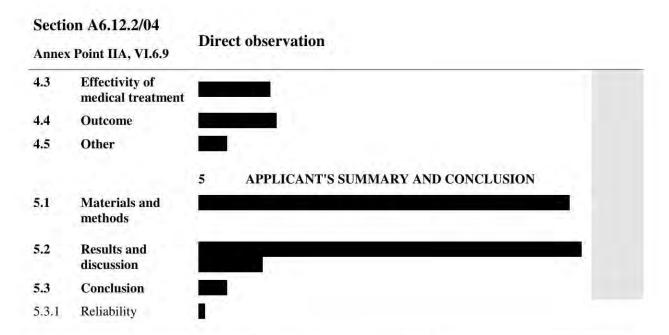
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Materials and Methods	
Results and discussion	
Conclusion	Applicant's revised version is acceptable.
Remarks	
	COMMENTS FROM (specify)
Date	Give date of comments submitted
Materials and Methods	Discuss if deviating from view of rapporteur member state
Results and discussion	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Remarks	

Peracetic Acid Registration Group (PAR)	Biocidal active substance:	Page 1-2
	Peracetic acid (PAA)	
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### Section A6.12.2/04



Peracetic Acid Registration Group (PAR)	Biocidal active substance:	Page 2-2
	Peracetic acid (PAA)	
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	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Materials and Methods	
Results and discussion	Applicant's version is acceptable
Conclusion	
Remarks	
	COMMENTS FROM (specify)
Date	Give date of comments submitted
Materials and Methods	Discuss if deviating from view of rapporteur member state
Results and discussion	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Remarks	

# Section A6.12.2/05

## Direct observation

Annex	Point IIA, VI.6.9	Direct	observation	
		1	REFERENCE	Official use only
1.1	Reference		M.S. (1993): Solvay internal memo – Irritancy testing of c acid to skin; Doc. No. 572-002, (unpublished).	
		2	GUIDELINES AND QUALITY ASSURANCE	
		Not app	licable	
		3	MATERIALS AND METHODS	
3.1	Substance	Peraceti	c acid (PAA)	
	150000000000000000000000000000000000000		, 5 % aqueous solution	
3.2	Persons exposed		20, 421,421,521,471,521	
3.2.1	Sex	males/fe	emales	
3.2.2	Age/weight	Not indi		
3.2.3	Known Diseases		ers with a predisposition for eczema formation	
3.2.4	Number of persons	87	P. Control	
3.2.5	Other information	out. (2500 m value sh occlusiv	was tested at dilutions of 1:33 (1500 mg/L), 1:20 mg/L) and 1:15 (3500 mg/L) according to publication, correct ould be 3300 mg/L) following a single application under the conditions for 48 h. Reading was conducted at removal at 48 h in at 96 h.	
		order to results w is in an o voluntee (accordi	ers were patients with a predisposition for eczema formation in increase the sensitivity of the test system and to allow for rapid with a relatively small test panel. Patch testing when the eczema overactive phase is avoided. In the 1500 mg/L group 16 ers, in the 2500 mg/L group 18 volunteers and in the 3500 mg/L mg to publication, correct value should be 3300 mg/L) group 53 ers attended the test procedure.	
		Scoring:		
		-	negative	
		±	erythema	
		+	erythema and infiltration	
		++	erythema, infiltration and vesicles/papules	
		+++	erythema, infiltration and coalescing vesicles	
		p/p	pustular/purpuric or follicular	
3.3	Exposure			
3.3.1	Reason of exposure	Investig	ation of dermal reactions in predisposed patients	

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# Section A6.12.2/05

Annex Poir	nt IIA, VI.6.9	Direct observation	
	equency of posure	Single	
	erall time period exposure	48 h	
	ration of single posure	48 h	
the contract of the contract o	posure ncentration/dose	1500 mg/L (1:33 dilution), 2500 mg/L (1:20 dilution), 3500 mg/L (according to publication, correct value should be 3300 mg/L, 1:15 dilution) active PAA	
3.3.6 Oth	ner information	None	
.4 Ex	aminations	Irritancy skin readings	
.5 Tre	eatment	Not indicated	
.6 Re	marks	None	
		4 RESULTS	
.1 Cli	nical Signs	Erythema and infiltration	
	sults of aminations	In the high concentration group (3500 mg/L according to publication, correct value should be 3300 mg/L), 3 volunteers showed erythema and infiltration (+ result) and 4 volunteers showed only erythema (± result). It was shown that PAA at this concentration is a mild irritant under the occlusive conditions of the patch tests.	
		In the other groups no reaction to PAA was observed. Up to 2500 mg/L PAA is non irritant.	
	fectivity of dical treatment	No medical treatment was indicated.	
1.4 Ou	tcome	Not applicable	
.5 Ot	her	None	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
	aterials and thods	For investigating the irritancy potential of PAA in the product, a Patch test (48 h, occlusive) was carried out. Dilutions of 1:33 (1500 mg/L PAA), 1:20 (2500 mg/L PAA) and 1:15 (3500 mg/L according to publication, correct value should be 3300 mg/L) were tested. Readings were conducted at 48 and 96 h.	
	sults and cussion	At concentration s of 1500 and 2500 mg/L PAA shows no irritant reaction while 3500 mg/L (correct value should be 3300 mg/L) induced mild irritant reactions in 7 out of 53 probands tested with only 3 volunteers showing distinct positive reactions.	
5.3 Co	nclusion	It can be concluded that up to 2500 mg/L PAA (corresponding to an about 0.25 % solution) is non irritant. At 3300 mg/L PAA (corresponding to an about 0.33 % solution) is a mild irritant.	
5.3.1 Re	liability	2	

Peracetic Acid Registration Group (PA)	Biocidal active substance:	Page 3-3
	Peracetic acid (PAA)	
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# Section A6.12.2/05

Annex Point IIA, VI.6.9

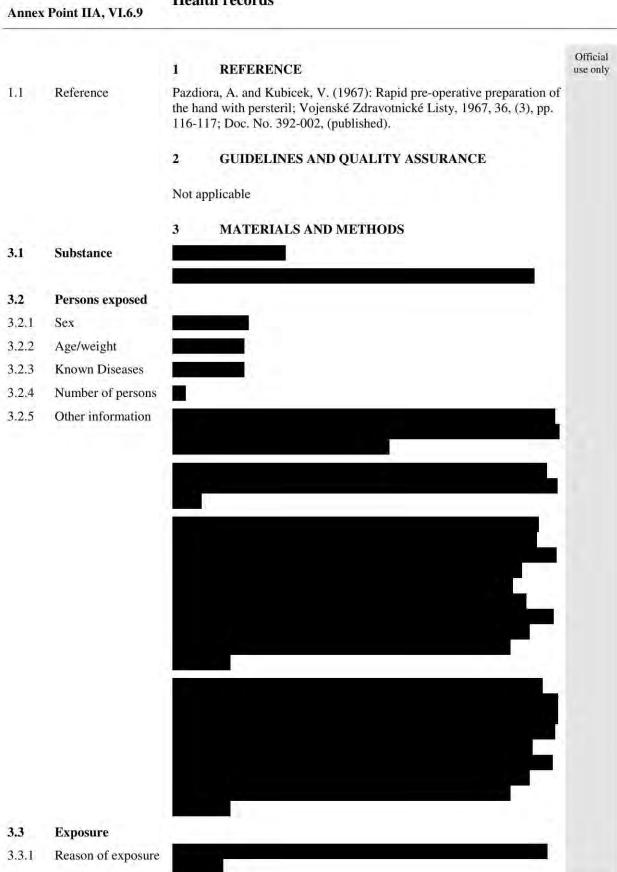
# Direct observation

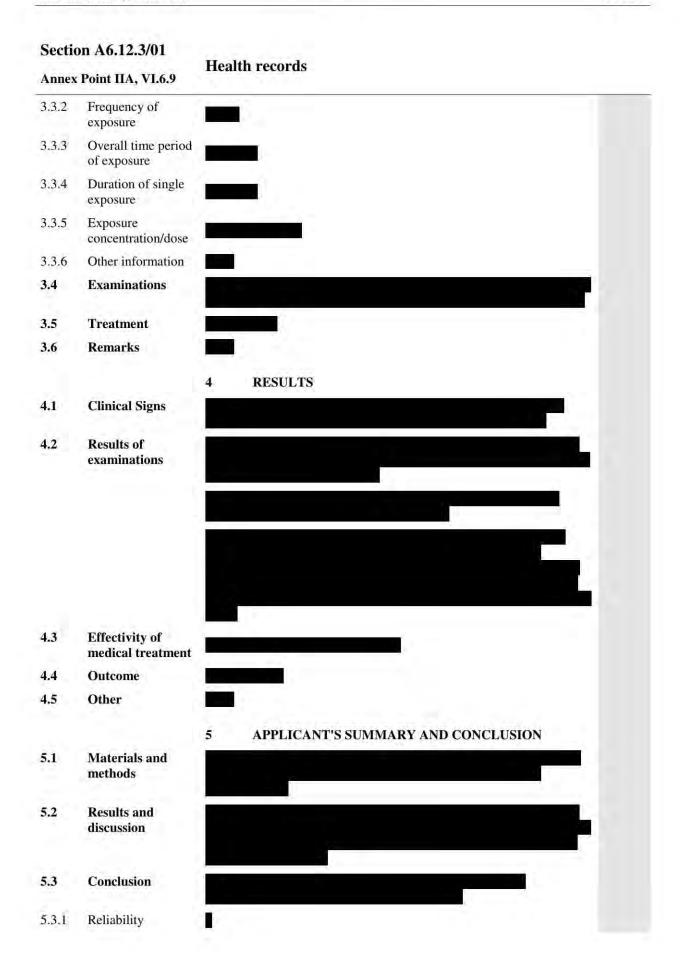
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Materials and Methods	
Results and discussion	
Conclusion	Applicant's version is acceptable.
Remarks	
	COMMENTS FROM (specify)
Date	Give date of comments submitted
Materials and Methods	Discuss if deviating from view of rapporteur member state
Results and discussion	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Remarks	

Peracetic Acid Registration Group (PA	Biocidal active substance:	Page 1-3
	Peracetic acid (PAA)	
Document IIIA, Section A6		FI 2011

# Section A6.12.3/01

# Health records





Peracetic Acid Registration Group (PAR)	Biocidal active substance:	Page 3-3
	Peracetic acid (PAA)	
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# Section A6.12.3/01

Annex Point IIA, VI.6.9

# **Health records**

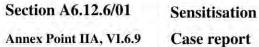
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Materials and Methods	
Results and discussion	
Conclusion	Applicant's original version is acceptable.
Remarks	
	COMMENTS FROM (specify)
Date	Give date of comments submitted
Materials and Methods	Discuss if deviating from view of rapporteur member state
Results and discussion	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Remarks	

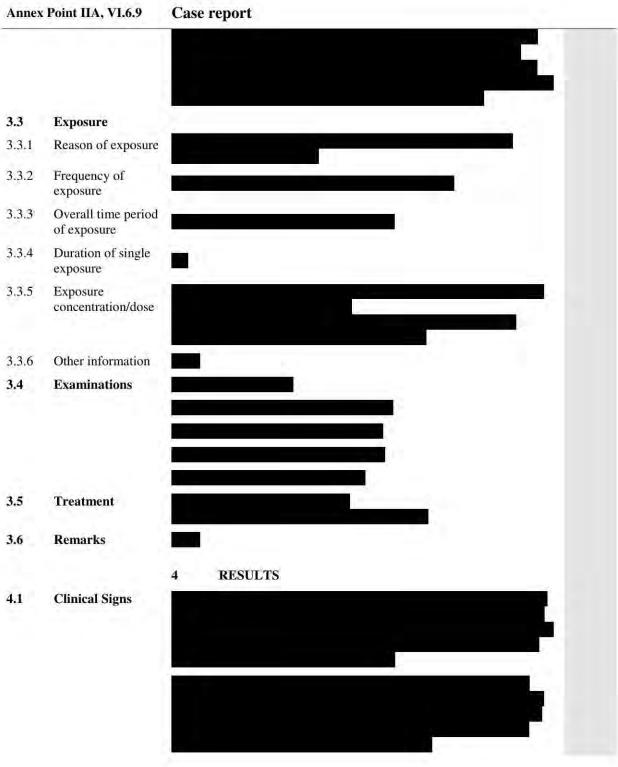
Section A6.12.4 Annex Point IIA, VI.6.9.4	Epidemiological studies on the general population		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only	
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [ ]		
Limited exposure [ ]	Other justification [X]		
Detailed justification:			
	Evaluation by Competent Authorities		
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted		
	EVALUATION BY RAPPORTEUR MEMBER STATE		
Date			
Evaluation of applicant's justification			
Conclusion	Applicant's justification is acceptable.		
Remarks			
	COMMENTS FROM OTHER MEMBER STATE (specify)		
Date	Give date of comments submitted		
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state		
Conclusion	Discuss if deviating from view of rapporteur member state		
Remarks			

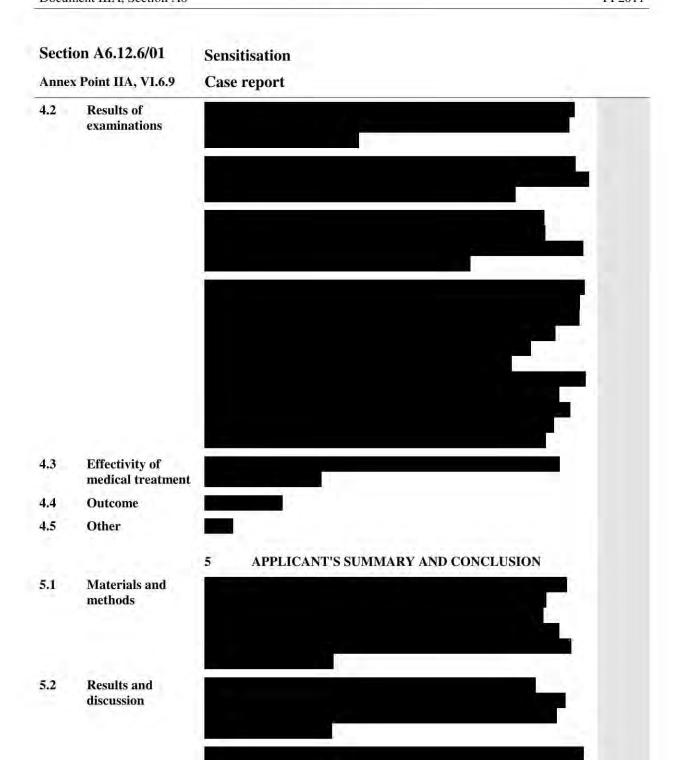
Section A6.12.5 Diagnosis of poisoning including specific signs of poisoning and clinical tests		_11
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] Limited exposure []	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [ X ]	
Detailed justification:		
	Evaluation by Competent Authorities  Use separate "evaluation boxes" to provide transparency as to the	
	comments and views submitted	
	comments and views submitted	4
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Date Evaluation of applicant's justification		
Evaluation of applicant's		
Evaluation of applicant's justification	EVALUATION BY RAPPORTEUR MEMBER STATE	
Evaluation of applicant's justification Conclusion	EVALUATION BY RAPPORTEUR MEMBER STATE	
Evaluation of applicant's justification Conclusion	EVALUATION BY RAPPORTEUR MEMBER STATE  Applicant's justification is acceptable.	
Evaluation of applicant's justification Conclusion Remarks	EVALUATION BY RAPPORTEUR MEMBER STATE  Applicant's justification is acceptable.  COMMENTS FROM OTHER MEMBER STATE (specify)	
Evaluation of applicant's justification Conclusion Remarks  Date Evaluation of applicant's	EVALUATION BY RAPPORTEUR MEMBER STATE  Applicant's justification is acceptable.  COMMENTS FROM OTHER MEMBER STATE (specify)  Give date of comments submitted	

Section A6.12.6/01	Sensitisation
Annex Point IIA, VI.6.9	Case report

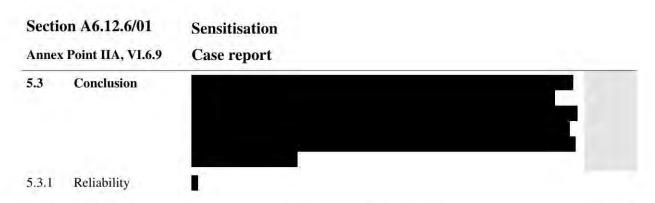
# Official 1 REFERENCE use only Cristofari-Marquand, E. et al. (2007): Asthma caused by peracetic acid-1.1 Reference hydrogen peroxide mixture. J. Occup. Health 2007, 49, 155-158; Doc. No. 592-094, (published). 2 **GUIDELINES AND QUALITY ASSURANCE** Not applicable MATERIALS AND METHODS 3.1 Substance 3.2 Persons exposed 3.2.1 Sex 3.2.2 Age/weight 3.2.3 Known Diseases Number of persons 3.2.4 3.2.5 Other information

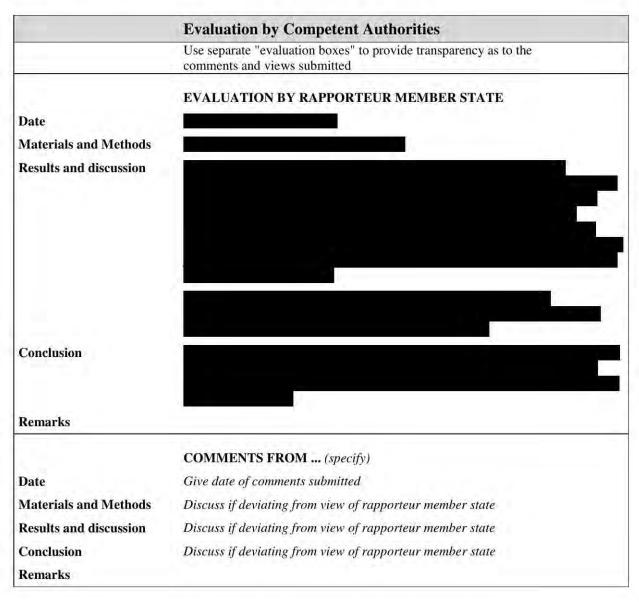






Peracetic Acid Registration Group (PAR)	Biocidal active substance:	Page 4-4
	Peracetic acid (PAA)	
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Section A6.12.7 Annex Point IIIA, 6.12	Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment
Annex Foint IIIA, 0.12	mist ard measures, annuoues and medical treatment
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Evaluation of applicant's justification	
Conclusion	Applicant's description is acceptable.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE (specify)
Date	Give date of comments submitted
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Remarks	

Peracetic acid (PAA)

Document IIIA, Section A6 FI 2011

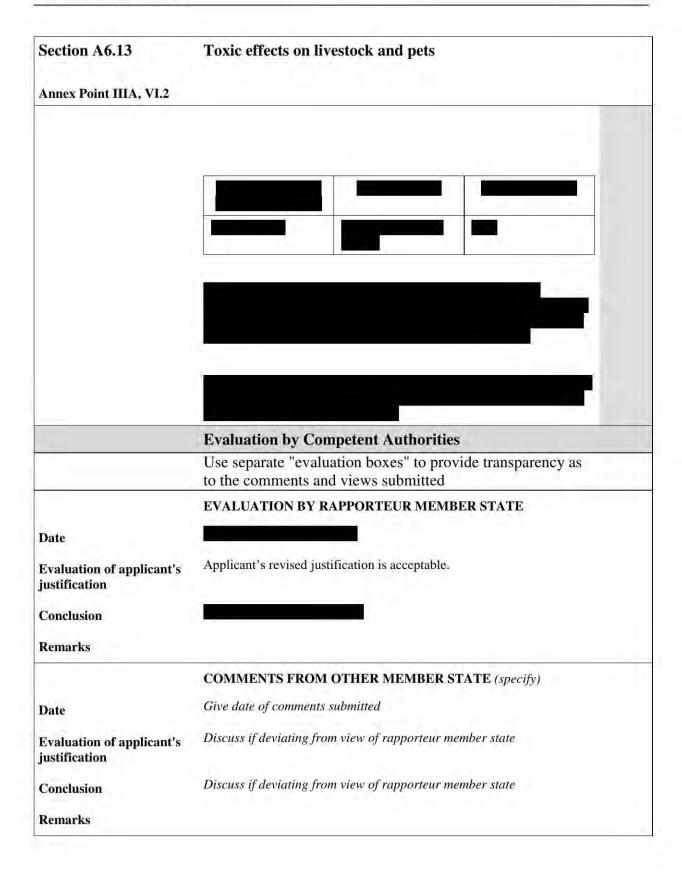
Section A6.12.8 Annex Point IIA, VI.6.9.8 Prognosis following poisoning (expected effects and the duration of these effects must be described)

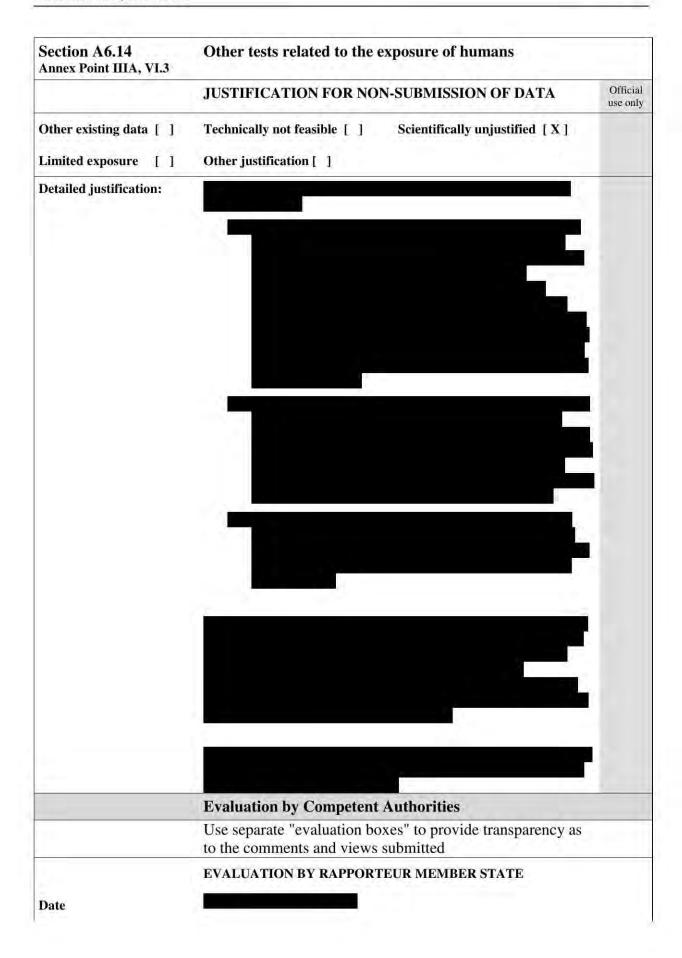


	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Evaluation of applicant's justification		
Conclusion	Applicant's revised description is acceptable.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	Give date of comments submitted	
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state	
Conclusion	Discuss if deviating from view of rapporteur member state	
Remarks		

Peracetic Acid Registration Group (PAR)	Biocidal active substance:	Page 1-2
	Peracetic acid (PAA)	
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Section A6.13	Toxic effects on livestock and pets	
Annex Point IIIA, VI.2		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	Technically not feasible [ ] Scientifically unjustified [X]	
Limited exposure [ ]	Other justification [ ]	
Detailed justification:		
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Peracetic Acid Registration Group (PAR)	Biocidal active substance:	Page 2-2
	Peracetic acid (PAA)	
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Section A6.14 Annex Point IIIA, VI.3	Other tests related to the exposure of humans
Evaluation of applicant's justification	Applicant's revised justification is acceptable.
Conclusion	
Remarks	
	COMMENTS FROM OTHER MEMBER STATE (specify)
Date	Give date of comments submitted
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state

Peracetic Acid Registration Group (PAR)	Biocidal active substance:	Page 1-2
	Peracetic acid (PAA)	
Document IIIA, Section A6		FI 2011

Section A6.15 Annex Point IIIA, VI.4	Food and feeding stuffs	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [ ]	
Limited exposure [ ]	Other justification [ X ]	
Detailed justification:		
		l,

Peracetic Acid Registration Group (PAR)	Biocidal active substance:	Page 2-2
	Peracetic acid (PAA)	
D. W. C. C. A.C.		FI 2011

Section A6.15 Annex Point IIIA, VI.4	Food and feeding stuffs
	<b>Evaluation by Competent Authorities</b>
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Evaluation of applicant's justification	
Conclusion	Applicant's justification is acceptable.
Remarks	
.11	COMMENTS FROM OTHER MEMBER STATE (specify)
Date	Give date of comments submitted
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Remarks	

Section A6.16 Annex Point IIIA, VI.5	Any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, that are considered necessary may be required	
	JUSTIFICATION FOR NON-SUBMISSION F DATA	Official use only
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [ ]	
Limited exposure [ ]	Other justification [X]	
Detailed justification:		
	Evaluation by Competent Authorities  Use separate "evaluation boxes" to provide transparency as	
	to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	Give date of comments submitted	
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state	
Conclusion	Discuss if deviating from view of rapporteur member state	
Remarks		

Section A6.17 Annex Point IIIA, VI.6	If the active substance is to be used in products for action against plants then tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals shall be required	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [ X ]	
Limited exposure [ ]	Other justification [ ]	
Detailed justification:		
	<b>Evaluation by Competent Authorities</b>	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Evaluation of applicant's justification		
Conclusion	Applicant's justification is acceptable.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	Give date of comments submitted	
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state	
Conclusion	Discuss if deviating from view of rapporteur member state	
Remarks		