Section A6.10 Annex Point IIIA, VI.7	Mechanistic study – any study to clarify effects reported in toxicity studies	
	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:	[redacted]	X X
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	

Section A6.10 **Annex Point IIIA, VI.7**	**Mechanistic study – any study to clarify effects reported in toxicity studies**
Conclusion	Applicant's justification is acceptable. [redacted]
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

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (1983): Prüfung der akuten intravenösen Toxizität [redacted] aktiv im Vergleich zu Formalin (Study on the Acute Intravenous Toxicity of [redacted] as Compared to Formalin); Project No. [redacted]; Report No. [redacted], 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 No. 524-001 (unpublished).	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**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Purity	[redacted]	
3.1.4	Description	Not stated	
3.1.5	Stability	Not stated	
3.2	**Test Animals**		
3.2.1	Species	Mouse	
3.2.2	Strain	CF 1	
3.2.3	Source	[redacted]	
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	Type	Intravenous application	

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

3.3.3	Vehicle	Physiological saline
3.3.4	Dose levels	158, 172, 186, 199, 251, 316, 398 mg/kg bw
3.3.5	Concentration in vehicle	15.8, 17.2, 18.6, 19.9, 25.1, 31.6, 39.8 mg/mL
3.3.6	Total volume applied	10 mL/kg bw
3.3.7	Injection duration	1 minute
3.3.8	Controls	None included
3.4	**Examinations**	- Signs of intoxication (immediately, 1, 6 and 24 hours after 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.
3.5	**Method of determination of LD_{50}**	The intravenous LD_{50} was determined according to the method of J.T. Litchfield and F. Wilcoxon (J. pharm. Exptl. Ther. 96, 99-108 (1949)).
3.6	**Further remarks**	

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 [redacted], 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

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_{50} for [redacted] 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 [redacted] 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 [redacted] 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_{50} for [redacted] 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	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable
Remarks	

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

	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	

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

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
LD_{50} 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	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
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 A6.12.2/01 Acute Toxicity
Annex Point IIA, VI.6.9 Skin Irritation, Human

There are 13 studies concerning skin irritation in the rabbit available for PAA which have been selected as key studies. These are described below "all-in-one" as discussed with the RMS. Two non-key studies are presented and summarised in IUCLID attached to Document III ([redacted], 1990, Doc. No. 565-012; [redacted], 1990, Doc. No. 565-013).

Official use only

1. REFERENCE

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**	[redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.3	Purity	[redacted]
3.1.4	Description	[redacted]
3.1.5	Stability	[redacted]
3.2	**Test Animals**	
3.2.1	Species	[redacted]
3.2.2	Strain	[redacted]
3.2.3	Source	[redacted]
3.2.4	Sex	[redacted]
3.2.5	Age/weight at study initiation	[redacted]
3.2.6	Number of test persons	[redacted]
3.2.7	Controls	[redacted]

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

3.3	**Administration/ Exposure**	
3.3.1	Application	[redacted]
3.3.1.1	Preparation of test substance	[redacted]
3.3.1.2	Test site and Preparation of Test Site	[redacted]
3.3.2	Occlusion	[redacted]
3.3.3	Vehicle	[redacted]
3.3.4	Concentration in vehicle	[redacted]
3.3.5	Total volume applied	[redacted]
3.3.6	Removal of test substance	[redacted]
3.3.7	Duration of exposure	[redacted]
3.3.8	Post-exposure period	[redacted]
3.3.9	Controls	[redacted]
3.4	**Examinations**	
3.4.1	Clinical signs	[redacted]
3.4.2	Dermal examination	[redacted]
3.4.2.1	Scoring system	[redacted]
3.4.2.2	Examination time points	[redacted]
3.5	**Further remarks**	[redacted]

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

4 RESULTS AND DISCUSSION

4.1	**Average score**	
4.1.1	Erythema	[redacted]
4.1.2	Oedema	[redacted]
4.2	**Reversibility**	[redacted]
4.3	**Other examinations**	[redacted]
4.4	**Overall result**	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable [redacted]

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	

[redacted]

Section A6.12.2/02

Annex Point IIA, VI.6.9

Direct observation

Official use only

1 REFERENCE

1.1 Reference

Mücke, H. and Sprössig, M. (1969): Die Eigenschaften der Peressigsäure (The properties of peracetic acid); Wissenschaftliche Zeitschrift der Humboldt-Universität zu Berlin, Math.-Nat. R XVIII, 1969, Vol. 6, pp. 1167-1170, Doc. No. 192-002, (published).

2 GUIDELINES AND QUALITY ASSURANCE

Not applicable

3 MATERIALS AND METHODS

3.1 Substance

3.2 Persons exposed

3.2.1 Sex

3.2.2 Age/weight

3.2.3 Known Diseases

3.2.4 Number of persons

3.2.5 Other information

3.3 Exposure

3.3.1 Reason of exposure

3.3.2 Frequency of exposure

3.3.3 Overall time period of exposure

3.3.4 Duration of single exposure

3.3.5 Exposure concentration/dose

3.3.6 Other information

3.4 Examinations

3.5 Treatment

3.6 Remarks

4 RESULTS

4.1 Clinical Signs

4.2 Results of examinations

Section A6.12.2/02

Annex Point IIA, VI.6.9

Direct observation

4.3	**Effectivity of medical treatment**	[redacted]
4.4	**Outcome**	[redacted]
4.5	**Other**	[redacted]
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
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	

Section A6.12.2/03

Annex Point IIA, VI.6.9

Direct observation

Official use only

1 REFERENCE

1.1 Reference

Kretschmar, C. et al. (1972): Peressigsäure – nur ein Desinfektionsmittel? (Peracetic acid – only a disinfectant?); Monatsheft, Veterinär Medizin, 27, pp. 324-332, Doc. No. 392-003, (published).

2 GUIDELINES AND QUALITY ASSURANCE

Not applicable

3 MATERIALS AND METHODS

3.1 Substance

[redacted]

3.2 Persons exposed

3.2.1 Sex [redacted]

3.2.2 Age/weight [redacted]

3.2.3 Known Diseases [redacted]

3.2.4 Number of persons [redacted]

3.2.5 Other information [redacted]

3.3 Exposure

3.3.1 Reason of exposure [redacted]

3.3.2 Frequency of exposure [redacted]

3.3.3 Overall time period of exposure [redacted]

3.3.4 Duration of single exposure [redacted]

3.3.5 Exposure concentration/dose [redacted]

3.3.6 Other information [redacted]

Section A6.12.2/03

Annex Point IIA, VI.6.9

Direct observation

3.4	**Examinations**	[redacted]
3.5	**Treatment**	[redacted]
3.6	**Remarks**	[redacted]
	4 RESULTS	
4.1	**Clinical Signs**	[redacted]
4.2	**Results of examinations**	[redacted]
4.3	**Effectivity of medical treatment**	[redacted]
4.4	**Outcome**	[redacted]
4.5	**Other**	[redacted]
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]

Section A6.12.2/03

Annex Point IIA, VI.6.9

Direct observation

5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
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	

Section A6.12.2/04

Annex Point IIA, VI.6.9

Direct observation

Official use only

1 REFERENCE

1.1 Reference

Schröder, W. (1982): Peressigsäure (PES) als Desinfektionsmittel für die Lebensmittelindustrie (Peracetic acid as a disinfectant in food industry); Confrocia, Bd. 26 (1982) Nr. 5, pp. 139-147; Doc. No. 392-009, (published).

2 GUIDELINES AND QUALITY ASSURANCE

Not applicable

3 MATERIALS AND METHODS

3.1 Substance [redacted]

3.2 Persons exposed

3.2.1 Sex [redacted]

3.2.2 Age/weight [redacted]

3.2.3 Known Diseases [redacted]

3.2.4 Number of persons [redacted]

3.2.5 Other information [redacted]

3.3 Exposure

3.3.1 Reason of exposure [redacted]

3.3.2 Frequency of exposure [redacted]

3.3.3 Overall time period of exposure [redacted]

3.3.4 Duration of single exposure [redacted]

3.3.5 Exposure concentration/dose [redacted]

3.3.6 Other information [redacted]

3.4 Examinations [redacted]

3.5 Treatment [redacted]

3.6 Remarks [redacted]

4 RESULTS

4.1 Clinical Signs [redacted]

4.2 Results of examinations [redacted]

Section A6.12.2/04

Annex Point IIA, VI.6.9

Direct observation

4.3	**Effectivity of medical treatment**	[redacted]
4.4	**Outcome**	[redacted]
4.5	**Other**	[redacted]
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	Applicant's version is acceptable
Conclusion	[redacted]
Remarks	[redacted]
	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

Annex Point IIA, VI.6.9

Direct observation

Official use only

1 REFERENCE

1.1 Reference: French, M.S. (1993): Solvay internal memo – Irritancy testing of peracetic acid to skin; Doc. No. 572-002, (unpublished).

2 GUIDELINES AND QUALITY ASSURANCE

Not applicable

3 MATERIALS AND METHODS

3.1 Substance

Peracetic acid (PAA)

[redacted], 5 % aqueous solution

3.2 Persons exposed

3.2.1	Sex	males/females
3.2.2	Age/weight	Not indicated
3.2.3	Known Diseases	Volunteers with a predisposition for eczema formation
3.2.4	Number of persons	87
3.2.5	Other information	For investigating the irritancy potential of PAA, a Patch test was carried out. [redacted] was tested at dilutions of 1:33 (1500 mg/L), 1:20 (2500 mg/L) and 1:15 (3500 mg/L according to publication, correct value should be 3300 mg/L) following a single application under occlusive conditions for 48 h. Reading was conducted at removal at 48 h and again at 96 h. Volunteers were patients with a predisposition for eczema formation in order to increase the sensitivity of the test system and to allow for rapid results with a relatively small test panel. Patch testing when the eczema is in an overactive phase is avoided. In the 1500 mg/L group 16 volunteers, in the 2500 mg/L group 18 volunteers and in the 3500 mg/L (according to publication, correct value should be 3300 mg/L) group 53 volunteers 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	Investigation of dermal reactions in predisposed patients

Section A6.12.2/05

Annex Point IIA, VI.6.9

Direct observation

3.3.2	Frequency of exposure	Single
3.3.3	Overall time period of exposure	48 h
3.3.4	Duration of single exposure	48 h
3.3.5	Exposure concentration/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	Other information	None
3.4	**Examinations**	Irritancy skin readings
3.5	**Treatment**	Not indicated
3.6	**Remarks**	None
		4 RESULTS
4.1	**Clinical Signs**	Erythema and infiltration
4.2	**Results of examinations**	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.
4.3	**Effectivity of medical treatment**	No medical treatment was indicated.
4.4	**Outcome**	Not applicable
4.5	**Other**	None
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	For investigating the irritancy potential of PAA in the product [redacted], 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.
5.2	**Results and discussion**	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	**Conclusion**	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	Reliability	2

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	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
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	

Section A6.12.3/01

Annex Point IIA, VI.6.9

Health records

Official use only

1 REFERENCE

1.1 Reference

Pazdiora, A. and Kubicek, V. (1967): Rapid pre-operative preparation of the hand with persteril; Vojenské Zdravotnické Listy, 1967, 36, (3), pp. 116-117; Doc. No. 392-002, (published).

2 GUIDELINES AND QUALITY ASSURANCE

Not applicable

3 MATERIALS AND METHODS

3.1 Substance

[redacted]

3.2 Persons exposed

3.2.1 Sex [redacted]

3.2.2 Age/weight [redacted]

3.2.3 Known Diseases [redacted]

3.2.4 Number of persons [redacted]

3.2.5 Other information [redacted]

3.3 Exposure

3.3.1 Reason of exposure [redacted]

Section A6.12.3/01

Annex Point IIA, VI.6.9

Health records

3.3.2	Frequency of exposure	[redacted]
3.3.3	Overall time period of exposure	[redacted]
3.3.4	Duration of single exposure	[redacted]
3.3.5	Exposure concentration/dose	[redacted]
3.3.6	Other information	[redacted]
3.4	**Examinations**	[redacted]
3.5	**Treatment**	[redacted]
3.6	**Remarks**	[redacted]
	4 RESULTS	
4.1	**Clinical Signs**	[redacted]
4.2	**Results of examinations**	[redacted]
4.3	**Effectivity of medical treatment**	[redacted]
4.4	**Outcome**	[redacted]
4.5	**Other**	[redacted]
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted]

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	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
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 [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification [X]**	
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
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 Annex Point IIA, VI.6.12	Diagnosis of poisoning including specific signs of poisoning and clinical tests	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
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 A6.12.6/01 Sensitisation

Annex Point IIA, VI.6.9 **Case report**

Official use only

1 REFERENCE

1.1 Reference

Cristofari-Marquand, E. et al. (2007): Asthma caused by peracetic acid-hydrogen peroxide mixture. J. Occup. Health 2007, 49, 155-158; Doc. No. 592-094, (published).

2 GUIDELINES AND QUALITY ASSURANCE

Not applicable

3 MATERIALS AND METHODS

3.1 Substance

[redacted]

3.2 Persons exposed

3.2.1 Sex [redacted]

3.2.2 Age/weight [redacted]

3.2.3 Known Diseases [redacted]

3.2.4 Number of persons [redacted]

3.2.5 Other information [redacted]

Section A6.12.6/01 Sensitisation

Annex Point IIA, VI.6.9 **Case report**

[redacted]

3.3 Exposure

3.3.1 Reason of exposure [redacted]

3.3.2 Frequency of exposure [redacted]

3.3.3 Overall time period of exposure [redacted]

3.3.4 Duration of single exposure [redacted]

3.3.5 Exposure concentration/dose [redacted]

3.3.6 Other information [redacted]

3.4 Examinations [redacted]

3.5 Treatment [redacted]

3.6 Remarks [redacted]

4 RESULTS

4.1 Clinical Signs [redacted]

Section A6.12.6/01 Sensitisation

Annex Point IIA, VI.6.9 **Case report**

4.2 Results of examinations

[redacted]

4.3 Effectivity of medical treatment

[redacted]

4.4 Outcome

[redacted]

4.5 Other

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[redacted]

5.2 Results and discussion

[redacted]

Section A6.12.6/01 Sensitisation

Annex Point IIA, VI.6.9 **Case report**

5.3 Conclusion [redacted]

5.3.1 Reliability [redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
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 A6.12.7 **Annex Point IIIA, 6.12**	**Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment**
[redacted]	
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
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	

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)

[redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
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	

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:	[redacted]	

Section A6.13 **Annex Point IIIA, VI.2**	**Toxic effects on livestock and pets**
	[redacted]
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	Applicant's revised justification is acceptable.
Conclusion	[redacted]
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 A6.14 Annex Point IIIA, VI.3	Other tests related to the exposure of humans	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

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	[redacted]
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 A6.15 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:	[redacted]	

Section A6.15 **Annex Point IIIA, VI.4**	**Food and feeding stuffs**
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
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 A6.16 **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:	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Conclusion	[redacted]	
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 [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
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		