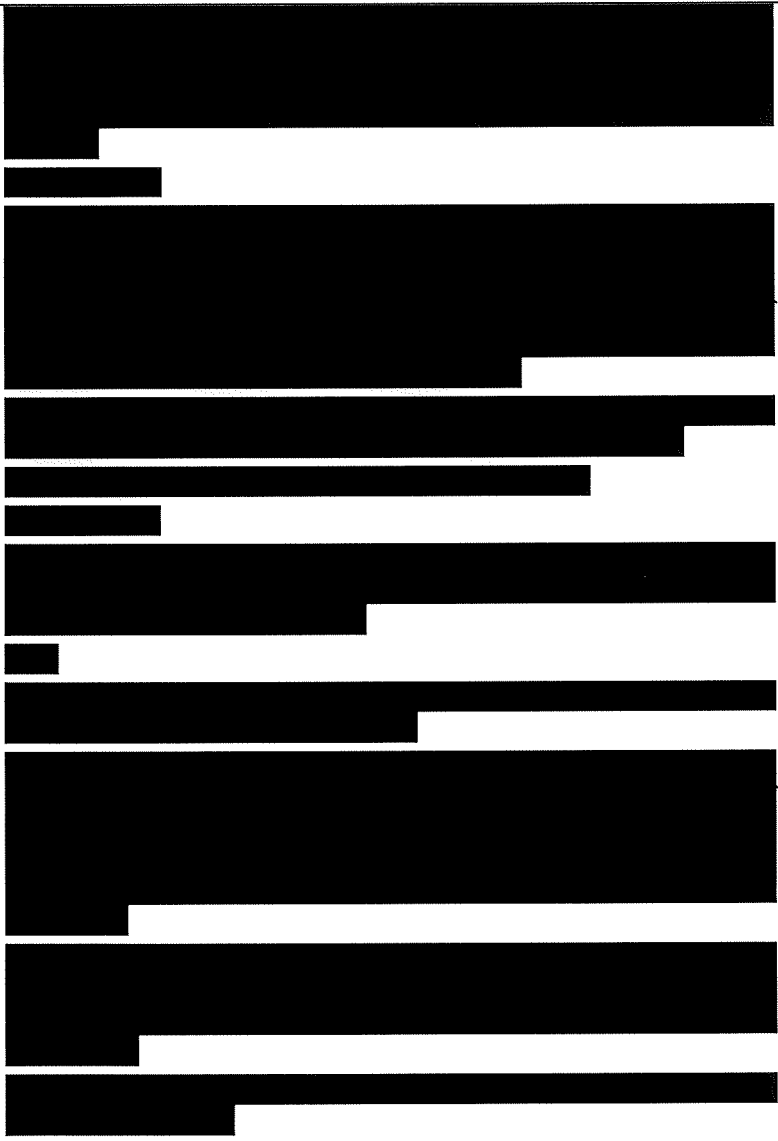



Section A6.13/01-07 Annex Point IIIA, VI.2		Toxic effects on livestock and pets In horses, cows, pigs and hens with focus on reproductive and developmental effects	
1.2.3	Criteria for data protection	[REDACTED]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	Guideline study	Not applicable [REDACTED]	
2.2	GLP	Not applicable [REDACTED]	
2.3	Deviations	Not applicable [REDACTED]	
		3 MATERIALS AND METHODS	
3.1	Test material	As given in section 2	
		4 RESULTS	
4.1	Reproductive and developmental effects of Iodine	[REDACTED]	
4.2	Case reports	[REDACTED]	

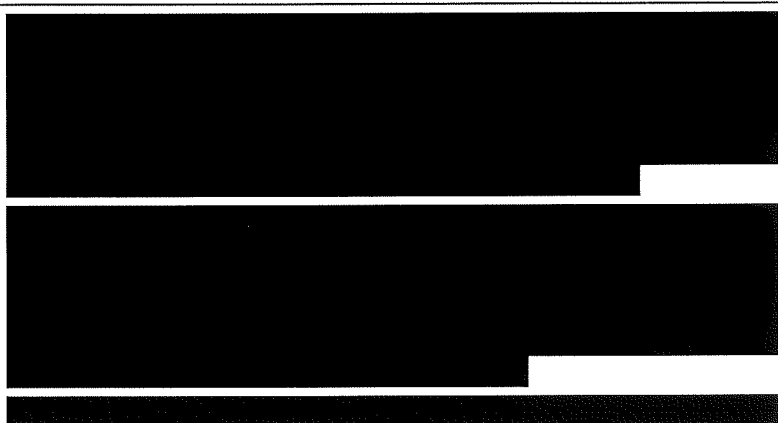
Section A6.13/01-07
Annex Point IIIA, VI.2

Toxic effects on livestock and pets
In horses, cows, pigs and hens with focus on
reproductive and developmental effects

		
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	5 APPLICANT'S SUMMARY AND CONCLUSION	
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5.1	Materials and methods	
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5.2	Results and discussion	
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<p>Section A6.13/01-07 Annex Point IIIA, VI.2</p>	<p>Toxic effects on livestock and pets In horses, cows, pigs and hens with focus on reproductive and developmental effects</p>	
	<p>[REDACTED]</p>	
<p>5.3 Conclusion</p>	<p>To avoid adverse effects on reproduction and development in livestock and pets due to deficient or excessive Iodine supply, individual recommended dietary intakes and upper intake levels for Iodine for the different species have to be considered.</p>	
<p>5.3.1 Recommended daily Intakes of Iodine</p>	<p>Cows: 0.5 mg/day</p>	
<p>5.3.1 maximal tolerable intake level of Iodine</p>	<p>Mares: 20 mg/day</p>	
<p>5.3.2 Reliability</p>	<p>[REDACTED]</p>	
<p>5.3.3 Deficiencies</p>	<p>[REDACTED]</p>	

Section A6.13/01-07 Annex Point IIIA, VI.2	Toxic effects on livestock and pets In horses, cows, pigs and hens with focus on reproductive and developmental effects
	Evaluation by Competent Authorities
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[REDACTED]
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]

Section A6.14/01-13 **Other experience related to the exposure of humans with**
Annex Point IIIA, XI.2 **focus on reproductive and developmental effects**

	1 REFERENCE	Official use only
1.1 Reference	<p>[1] World Health Organization and Food and Agriculture Organization of the United Nations (2004): Vitamin and mineral requirements in human nutrition (Second edition). Table of content: http://whqlibdoc.who.int/publications/2004/9241546123.pdf Text: http://whqlibdoc.who.int/publications/2004/9241546123_chap16.pdf Doc. No. 692-033 (published); Section A.6.14/01</p> <p>[2] TOXICOLOGICAL PROFILE FOR IODINE (April 2004); U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Public Health Service, Agency for Toxic Substances and Disease Registry http://www.atsdr.cdc.gov/toxprofiles/tp158.pdf Doc. No. 581-009 (published); Section A.6.14/02</p> <p>[3] EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, SCF, Scientific Committee on Food: Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Iodine (expressed on 26 September 2002). http://europa.eu.int/comm/food/fs/sc/scf/out146_en.pdf Doc. No. 592-031 (published); Section A.6.14/03</p> <p>[4] INCHEM: Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives: Iodine http://www.inchem.org/documents/jecfa/jecmono/v024je11.htm INCHEM: Poison Information Monograph on Iodine (PIM 280) http://www.inchem.org/documents/pims/pharm/Iodine.htm Doc. No.591-008 (published); Section A.6.14/04</p> <p>[5] Carswell F, Kerr MM, Hutchinson JH (1970). Congenital goitre and hypothyroidism after topical Iodine in pregnancy and lactation. Lancet i: 1241-1243. Doc. No. 592-042; Section A.6.14/05</p> <p>[6] Expert Group on Vitamins and Minerals (2002): Revised Review of Iodine Doc. No. 681-001 (published); Section A.6.14/06</p> <p>[7] Danziger Y, Pertzalan A, Mimouni M (1987): Transient congenital hypothyroidism after topical Iodine in pregnancy and lactation. Arch Dis Childh 62: 295-296. Doc. No. 592-048 (published), Section A.6.14/07</p> <p>[8] FNB (2001): Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium and Zinc. Food and Nutrition Board (FNB)/Institute of Medicine (IOM). National Academy Press, Washington, DC, USA. Doc. No. 692-032 (published); Section A.6.14/08</p> <p>[9] Kurt TL, Morgan ML, Hnilica V, Bost R, Petty CS. (1996). Fatal iatrogenic Iodine toxicity in a nine-week old infant. J Toxicol Clin Toxicol 34:231-234. Doc. No. 592-044 (published); Section A.6.14/09</p> <p>[10] Means LJ, Rescorla FJ, Grosfeld JL. (1990). Iodine toxicity:</p>	

Section A6.14/01-13 Annex Point IIIA, XI.2	Other experience related to the exposure of humans with focus on reproductive and developmental effects	
	<p>An unusual cause of cardiovascular collapse during anesthesia in an infant with Hirschsprung's disease. <i>J Pediatr Surg</i> 25:1278-1279. Doc. No. 592-047 (published); Section A.6.14/10</p> <p>[11] FAO/WHO (2001): Human Vitamin and Mineral Requirements; Chapter 12 Doc. No. 692-035 (published); Section A.6.14/11</p> <p>[12] (a) Stockton, L.K., Thomas, Jr., W.C. (1979): Absence of neonatal goitre during maternal use of iodinated water. <i>Clinical Research</i> 26, 536A. Only the abstract is publicly available. Doc. No. 592-069 (published); Section A.6.14/12</p> <p>[13] Iodine in Drinking-water – Background document for development of WHO <i>Guidelines for Drinking-Water Quality</i> Doc. No. 592-032 (published); Section A.6.14/13</p>	
1.2 Data protection	[REDACTED]	
1.2.1 Data owner	[REDACTED]	
1.2.3 Criteria for data protection	[REDACTED]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Not applicable, [REDACTED]	
2.2 GLP	Not applicable, [REDACTED]	
2.3 Deviations	Not applicable, [REDACTED]	
	3 MATERIALS AND METHODS	
3.1 Test material	As given in section 2	
	4 RESULTS	
4.1 Reproductive and developmental effects of Iodine	[REDACTED]	


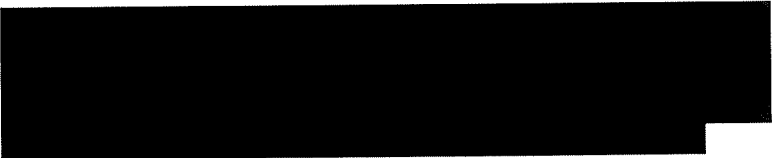



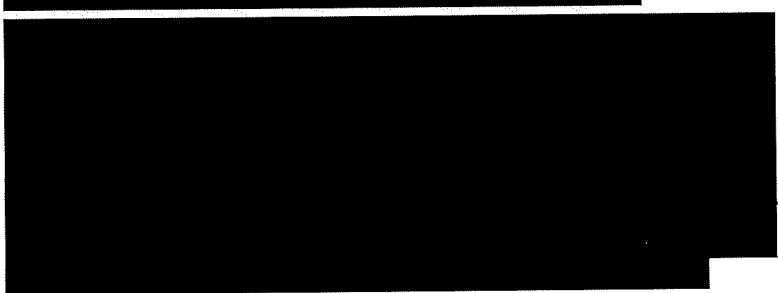





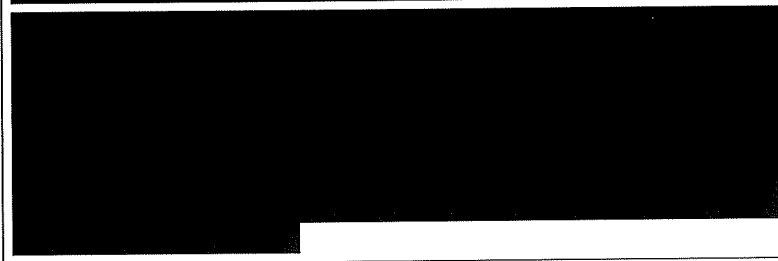
Section A6.14/01-13
Annex Point IIIA, XI.2

Other experience related to the exposure of humans with
focus on reproductive and developmental effects

	<p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p>	
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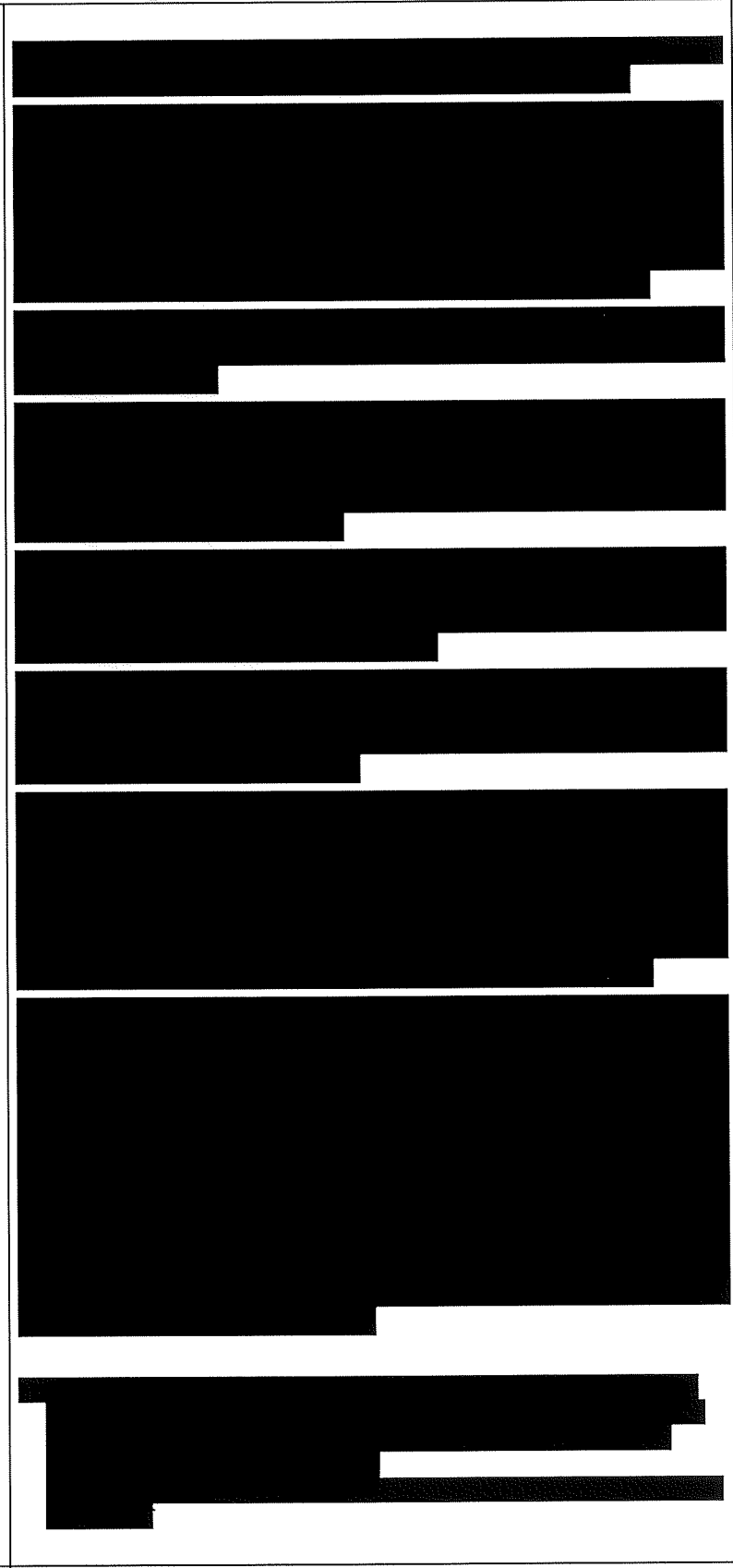

Section A6.14/01-13
Annex Point IIIA, XI.2

**Other experience related to the exposure of humans with
focus on reproductive and developmental effects**


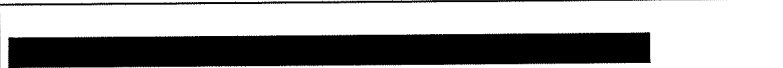

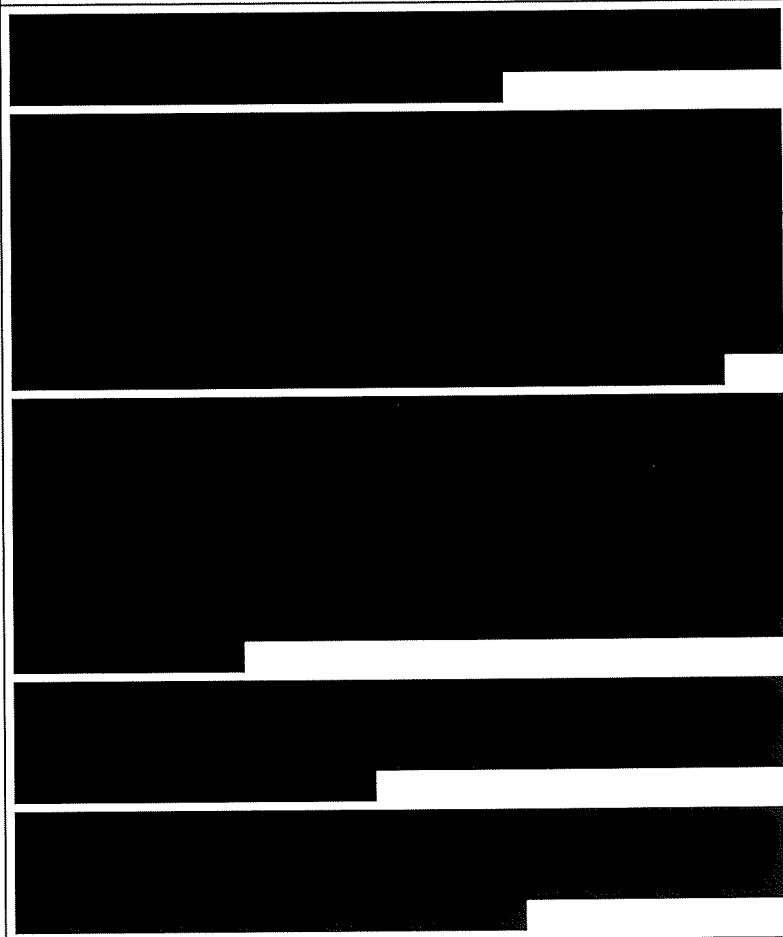
		
		
		
		
		
		
		
		
		
		
		
		

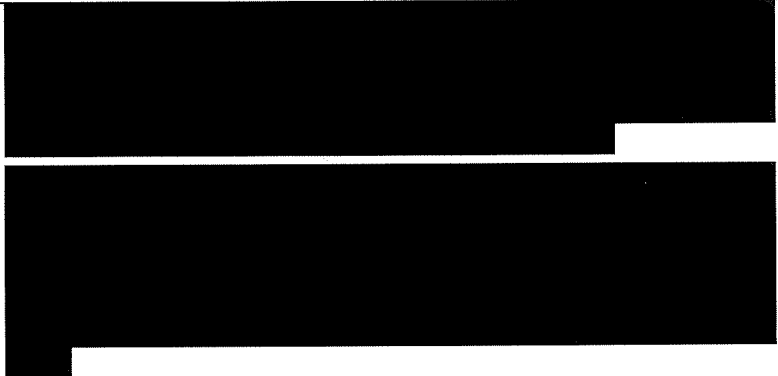









Section A6.14/01-13
Annex Point IIIA, XI.2

**Other experience related to the exposure of humans with
focus on reproductive and developmental effects**

		
4.2 Case reports		

Section A6.14/01-13 **Other experience related to the exposure of humans with**
Annex Point IIIA, XI.2 **focus on reproductive and developmental effects**

		
		
<p>5.1 Materials and methods</p>		
<p>5.2 Results and discussion</p>		

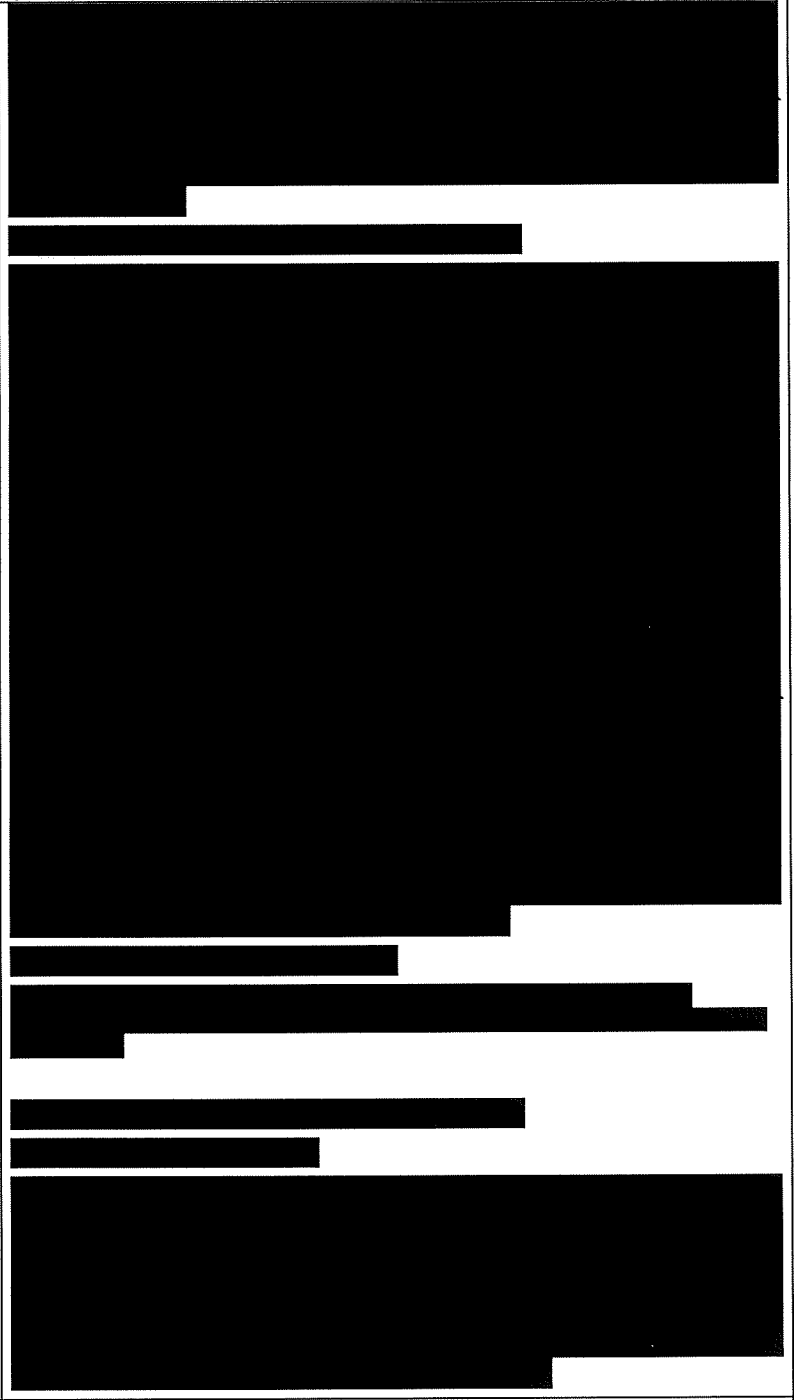
<p>Section A6.14/01-13 Annex Point IIIA, XI.2</p>	<p>Other experience related to the exposure of humans with focus on reproductive and developmental effects</p>	
		
<p>5.3 Conclusion</p>		
<p>5.3.1 Recommended daily Intakes of Iodine for humans (WHO)</p>	<p>Infants (0-59 months): 90 µg/day Children (6-12 years): 120 µg/day Adults, from 13 years of age through adulthood: 150 µg/day Pregnant and lactating women: 200 µg/day</p>	
<p>5.3.2 Upper Intake Level</p>	<p>Regions with mild Iodine deficiency: Adults, including pregnant and lactating women: 600 µg/day Iodine sufficient regions: Adults: 1,800 µg/day Pregnant and lactating women: 2,400 µg/day</p>	
<p>5.3.1 Reliability</p>		
<p>5.3.2 Deficiencies</p>		
<p>Evaluation by Competent Authorities</p>		
<p>EVALUATION BY RAPPORTEUR MEMBER STATE</p>		
<p>Date</p>		
<p>Materials and Methods</p>		
<p>Results and discussion</p>		
<p>Conclusion</p>		
<p>Reliability</p>		
<p>Acceptability</p>		
<p>Remarks</p>		

Section A6.14/12(b)/14 Other tests and information related to the exposure of humans as basis for LOAEL, NOAEL and Upper Intake Level deductions (Sub)chronic exposure
Annex Point IIIA, XI.2



	1 REFERENCE	Official use only
1.1 Reference	<p>[1] Stockton, L.K., Thomas, Jr., W.C. (1979): Absence of neonatal goitre during maternal use of iodinated water. Clinical Research 26, 536A. Only the abstract is publicly available. Doc. No. 592-069; Section A.6.14/12 This study has been published as an abstract only.</p> <p>[2] Freund, G. et al, (1966): Effect of Iodinated Water Supplies on Thyroid Function.; Journal of Clinical Endocrinology, 26, 619-624. Doc. No. 592-085; Section A.6.14/14</p> <p>This study / studies is / are cited by: EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, SCF, Scientific Committee on Food: Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Iodine (expressed on 26 September 2002). pp. 18, 19 http://europa.eu.int/comm/food/fs/sc/scf/out146_en.pdf Doc. No. 592-031 (published); Section A.6.14/03 Expert Group on Vitamins and Minerals (2002): Revised Review of Iodine, p. 59 Doc. No. 681-001 (published); Section A6.6.3/03 Expert Group on Vitamins and Minerals (2003): Revised Review of Iodine, p. 207 Doc. No. 592-033 (published); Section A6.6.3/04</p>	
1.2 Data protection		
1.2.1 Data owner		
1.2.3 Criteria for data protection		
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study		
	3 MATERIALS AND METHODS	
3.1 Test material	Iodide	
	4 RESULTS	
4.1 Results as citations from peer-reviewed reports		

Section A6.14/12(b)/14 Other tests and information related to the exposure of humans as basis for LOAEL, NOAEL and Upper Intake Level deductions (Sub)chronic exposure
Annex Point IIIA, XI.2

		
<p>4.2 Conclusion</p>	<p>No significant change in serum thyroxine levels was seen following the iodination of US American prison water supply at a concentration of 0.5 to 5 mg/L.</p> <p>These studies might be supportive for the deduction of the Upper Intake Level of Iodine of 600 µg/day (equivalent to about 10 µg/kg bw/day) for chronic exposure by European Commission/SCF.</p>	<p>X1</p>

Section A6.14/12(b)/14 Annex Point IIIA, XI.2 Other tests and information related to the exposure of humans as basis for LOAEL, NOAEL and Upper Intake Level deductions (Sub)chronic exposure		
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	Materials and methods	[REDACTED]
5.2	Results and discussion	[REDACTED]
5.3	Conclusion	These studies were most likely supportive for the deduction of the Upper Intake Level of 600 µg/day (SCF).
5.3.1	Reliability	[REDACTED]
5.3.2	Deficiencies	[REDACTED] X2
Evaluation by Competent Authorities		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	[REDACTED]	
Materials and Methods	[REDACTED]	
Results and discussion	[REDACTED]	
Conclusion	[REDACTED]	
Reliability	[REDACTED]	
Acceptability	[REDACTED]	
Remarks		

Table A6.14/12(b)/14-1 Results of studies in humans using iodinated drinking water

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Section A6.15.1 – Food and feeding stuffs
A6.15.6
Annex Point IIIA, XI.1.1 -
XI.1.9



Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date



Evaluation of applicant's
justification



Conclusion



Remarks

Section A6.15/01-02 **Food and feeding stuffs**
Annex Point IIIA, XI.1 **Cow's milk**

Remark: No ECB template is available. This template was supplemented based on published DAR's.

1 REFERENCE

- 1.1 Reference
- [1] Heuwieser, W. (2000): Investigation of the Efficacy of Different Dipping Procedures in the Prophylaxis of Mastitis in Lactating Dairy Cows - Study Phase I- Examination of the Safety of an Iodine-Containing Dipping Agent for Predipping; Animal Reproduction Clinic Task Force for Stock Maintenance and Quality Management FU Berlin, School of Veterinary Medicine, Reproduction Clinic of the Freie Universität Berlin, on behalf of HENKEL-Hygiene GmbH, Düsseldorf
Doc. No. 336-03024 (unpublished); A6.15/01
- [2] Falkenberg, U.; Tenhagen, B.-A.; Forderung, D.; Heuwieser W. (2002): Effect of Predipping with a Iodophor Teat Disinfectant on Iodine Content of Milk; Animal Reproduction Clinic Task Force for Stock Maintenance and Quality Management FU Berlin, School of Veterinary Medicine, Reproduction Clinic of the Freie Universität Berlin
Doc-No: 692-034 (published); A.6.15/02

1.2 Data protection

1.2.1 Data owner

1.2.2 Companies with letter of access

1.2.3 Criteria for data protection

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

2.2 GLP

2.3 Deviations

No guidelines available

Not applicable

3 MATERIALS AND METHODS

3.1 Test material and methods

3.1.1 Lot/Batch number

3.1.2 Specification in product

3.2 Test Animals

3.2.1 Species

3.2.2 Breed

Iodine

As given in section 2

Lactating cows

German Schwarzbunte and German Rotbunte

Section A6.15/01-02 **Food and feeding stuffs**
Annex Point IIIA, XI.1 **Cow's milk**

- 3.2.3 Body weight [Redacted]
- 3.2.4 Number of animals [Redacted]
- 3.2.5 Selection criteria [Redacted]
- 3.2.6 Control animals [Redacted]
- 3.3 Treatment plan [Redacted]
- 3.4 Sampling [Redacted]
- 3.5 Method of Analysis [Redacted]
- 3.6 Further remarks [Redacted]

4 RESULTS AND DISCUSSION

- 4.1 Residues in milk [Redacted]
- 4.2 Other [Redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

- 5.1 Materials and methods [Redacted]

X1

Section A6.15/01-02 Food and feeding stuffs
Annex Point IIIA, XI.1 Cow's milk

5.2 Results and discussion	[REDACTED]	X2
5.3 Conclusion	Compared to samples of control days, the residues in milk sampled on experimental days were 15 – 20 % higher. However, the overall variation in the Iodine content of milk by far exceeds the increase noted in this study.	X3 X4
5.3.1 Reliability	[REDACTED]	
5.3.2 Deficiencies	[REDACTED]	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[REDACTED]
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	

Section A6.15/03-08
Annex Point IIIA, XI.1

Food and feeding stuffs

**Residues of Iodine in Cow's milk following disinfection
of teats with dips containing Iodine**

1 REFERENCE

- 1.1 Reference**
- [1] Iwarsson, K.; Ekman, L. (1974): Iodophor Teat Dipping and the Iodine Concentration in milk; Department of Clinica Biochemistry, Royal Veterinary College, Stockholm Sweden; 01.01.1974; Doc. No. 692-002 (published); A6.15/03
 - [2] Cantor, A.; Most, S. (1976): Milk Iodides: Effects of Iodophor Teat Dipping and Under Washing, And Dietary Iodide Supplementation; West Chemical Products Inc., Long Island City, New York 11101; US; 13.01.1976; Doc. No. 692-009 (published); A6.15/04
 - [3] Terplan, G.; Grove H.-H. (1978): Rückstände von Dip-Präparaten in der Milch; Institut für Hygiene und Technologie der Lebensmittel tierischen Ursprungs (Lehrstuhl Prof. Dr. G. Terplan), Fachbereich Tiermedizin, Universität München; Doc. No. 692-011 (published); A6.15/05
 - [4] Dunsmore, D.G.; Nuzum, C.; Dettman, B. (1977): Iodophors and Iodine in Dairy Products. 3. Teat Dipping; Dairy Research Centre, Department of Agriculture, Richmond, New South Wales, Australia; 1.03.1977; Doc-No. 692-018 (published); A6.15/06
 - [5] Schuhmacher, E. (1975): Die Belastung der Milch mit Jod und Nonoxinol beim Zitzentauchen mit Lorasol@CCT; Biologische Laboratorien des Departements Biotechnische Produkte, CIBA-GEIGY AG, Basel, Switzerland, 01.01.1975; Doc. No. 692-008 (published); A6.15/07
 - [6] Galton,D.M.; Peterson, L.G.; Erb, H.N. (1986): Milk Iodine Residues in Herds PracticingIodophor Premilking Teat Disinfection, New York State Collage of Agriculture and Life Science, Department of Animal Science, Cornell University, Ithaca, NY 14863-4801, US; 01.01.1986; Doc. No. 692-026 (published); A6.15/08

1.2 Data protection

1.2.1 Data owner

1.2.2 Companies with letter of access

1.2.3 Criteria for data protection

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

2.2 GLP

2.3 Deviations Not applicable

3 MATERIALS AND METHODS

3.1 Test material Iodophor teat dipping formulations

Section A6.15/03-08
Annex Point IIIA, XI.1

Food and feeding stuffs
Residues of Iodine in Cow's milk following disinfection
of teats with dips containing Iodine

- 3.1.1 Specification [REDACTED]
- 3.1.2 Content of active substance in the application solution [REDACTED]
- 3.2 Test Animals
- 3.2.1 Species Lactating Cows
- 3.3 Further remarks [REDACTED]

4 RESULTS AND DISCUSSION

- 4.1 Residues in milk [REDACTED]
- 4.2 Other [REDACTED]

5 APPLICANT'S SUMMARY AND CONCLUSION

- 5.1 Materials and methods [REDACTED]

X1

Section A6.15/03-08
Annex Point IIIA, XI.1

Food and feeding stuffs
Residues of Iodine in Cow's milk following disinfection
of teats with dips containing Iodine

5.2 Results and discussion

[REDACTED]

5.3 Conclusion

The average increase of milk Iodine content in the publications was about 50 – 174 µg/L. This increase however is well within the natural variation of the Iodine content of milk noted in untreated animals.

5.3.2 Reliability

[REDACTED]

5.3.3 Deficiencies

[REDACTED]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date

[REDACTED]

Materials and Methods

[REDACTED]

Results and discussion

[REDACTED]

Conclusion

[REDACTED]

Reliability

[REDACTED]

Acceptability

[REDACTED]

Remarks

[REDACTED]

Section A6.15/09-12 Annex Point IIIA, XI.1	Food and feeding stuffs Dietary intake of Iodine (in particular via milk)
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Remark: No ECB template is available. This template was supplemented based on published DAR's.

	1	REFERENCE	
1.1	Reference		<p>[1] Langman, M. (2003): Safe upper Levels for Vitamins and Minerals – Expert Group on Vitamins and Minerals; Food Standard Agency, UK; 01.05.2003; Doc. No. 592-033 (published); A6.15/09</p> <p>[2] Domke, A. (2006): Use of Minerals in Foods – Toxicological and Nutritional-Physiological Aspects; BfR Wissenschaft; Germany; 01.01.2006; Doc. No. 592-080 (published); A6.15/10</p> <p>[3] Expert Group on Vitamins and Minerals (2002): Revised Review of Iodine Doc. No. 681-001 (published); A6.15/11</p> <p>[4] MAFF UK-Iodine in Milk (Sheet 198); MAFF surveillance Information sheet, UK; 23.03.2000; Doc-No. 692-031(published); A6.15/12</p>
1.2	Data protection		[REDACTED]
1.2.1	Data owner		[REDACTED]
1.2.2	Companies with letter of access		[REDACTED]
1.2.3	Criteria for data protection		[REDACTED]
	2	GUIDELINES AND QUALITY ASSURANCE	
2.1	Guideline study		[REDACTED]
2.2	GLP		[REDACTED]
2.3	Deviations		Not applicable
	3	MATERIALS AND METHODS	
3.1	Test material		Not applicable; [REDACTED]
3.2	Further remarks		[REDACTED]
	4	RESULTS AND DISCUSSION	
4.1	Residues in milk		[REDACTED]

Section A6.15/09-12
Annex Point IIIA, XI.1

Food and feeding stuffs
Dietary intake of Iodine (in particular via milk)

[REDACTED]

[REDACTED]

4.2 Other

[REDACTED]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[REDACTED]

5.2 Results and discussion

[REDACTED]

[REDACTED]

[REDACTED]

5.3 Conclusion

Iodine content in milk may contribute to the compensation of Iodine deficiency in food. If the daily dietary intake of Iodine exceeds the daily requirements up to 1000 µg/day, it is eliminated without signs of toxicity. Consequently, even very high levels of Iodine in milk are of no concern for children.

5.3.1 Reliability

[REDACTED]

5.3.2 Deficiencies

[REDACTED]

	Evaluation by Competent Authorities
Date	EVALUATION BY RAPPORTEUR MEMBER STATE [REDACTED]

Section A6.15/09-12
Annex Point IIIA, XI.1

Food and feeding stuffs
Dietary intake of Iodine (in particular via milk)

Materials and Methods

[REDACTED]

Results and discussion

[REDACTED]

Conclusion

[REDACTED]

Reliability

[REDACTED]

Acceptability

[REDACTED]

Remarks

[REDACTED]

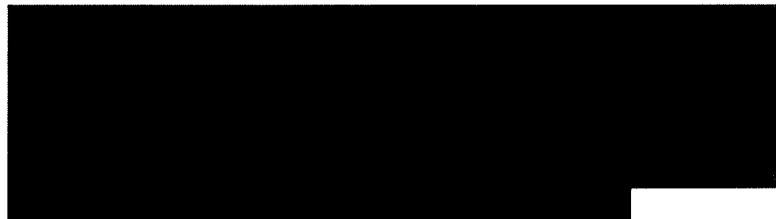
Section A6.16 **Any other tests related to the exposure of the active substance to**
Annex Point IIIA, VI.3.5 **humans, in its proposed biocidal products**

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

EVALUATION BY RAPPORTEUR MEMBER STATE

Date [REDACTED]


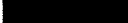


Evaluation of applicant's justification [REDACTED]

Conclusion [REDACTED]

Remarks

Section A6.17
Annex Point IIIA, VI.6

If the active substance is to be used in products for action against plants then test 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 <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification [X]	
Detailed justification:		
Evaluation by Competent Authorities		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A6.18

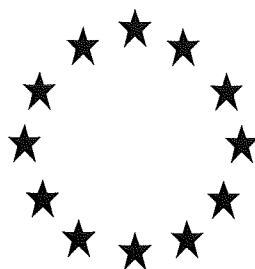
Annex Point IIA, VI.6.

Summary of toxicology

The toxicological properties of Iodine are summarised in Document IIA, Chapter 3.

Competent Authority Report

Work Programme for Review of Active Substances in Biocidal
Products Pursuant to Council Directive 98/8/EC



IODINE (PT1, PT3, PT4, PT22)

DOCUMENT III-A 7.1-7.3

Fate and behaviour in the environment

Rapporteur Member State: Sweden

Draft Final May 2013

Section A7.1.1.1.1/ 01- 13 Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA VII.7.6.2.1



- | | | |
|----------------------|---|------------------------------|
| | 1 REFERENCE | Official
use only |
| 1.1 Reference | <p>[1] TOXICOLOGICAL PROFILE FOR IODINE (April 2004); U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Public Health Service, Agency for Toxic Substances and Disease Registry http://www.atsdr.cdc.gov/toxprofiles/tp158.pdf
Doc. No. 581-009 (published); Section A7.1.1.1.1/01</p> <p>[2] INTERNATIONAL UNION OF PURE AND APPLIED CHEMISTRY; ANALYTICAL CHEMISTRY DIVISION COMMISSION OF MICROCHEMICAL TECHNIQUES AND TRACE ANALYSIS; WORKING GROUP ON SPECIATION: THE DETERMINATION OF IODINE SPECIES IN ENVIRONMENTAL AND BIOLOGICAL SAMPLES (Technical Report) 1998; Pure & Appl. Chem., Vol. 70, No. 8, pp. 1567-1584, 1998.
http://www.iupac.org/publications/pac/1998/pdf/7008x1567.pdf
Doc. No. 492-003 (published); Section A7.1.1.1.1/02</p> <p>[3] Chemistry lexicon (Roempp Lexikon)
ISBN 3-131-07830-8
Doc. No. 192-006 (published); Section A7.1.1.1.1/03</p> <p>[4] Kaplan DI, Serne RJ, Aiken, SC, Richland, WA (1999): Geochemical Data Package for the Hanford Immobilized Low-Activity Tank Waste Performance Assessment (ILAW-PA) http://www.hanford.gov/docs/gpp/fieldwork/ilaw/PNL13037.pdf
The relevant diagram cited and copied in this publication is originally published in:
Ticknor, K. V. and Y. H. Cho. 1990. "Interaction of Iodide and Iodate with Granitic Fracture-Filling Minerals." J. Radioanal. Nuclear Chem. 140:75-90.
Doc. No. 792-003 (published); ; Section A7.1.1.1.1/04</p> <p>[5] Nagy, Krisztina; Körtvélyesi, Tamás; Nagypál, István (2003): Iodine Hydrolysis Equilibrium; Journal of Solution Chemistry, Vol. 32, No. 5;
Doc. No. 792-005 (published); Section A7.1.1.1.1/05</p> <p>[6] Gottardi, W. (1978): Aqueous iodine solutions as disinfectants: composition, stability, comparison with chlorine and bromine solution (author's transl), [Article in German]; Zentralbl Bakteriol [B]. 1978 Sep;167(3):206-15.
Doc. No. 192-004 (published); Section A7.1.1.1.1/06</p> <p>[7] Gottardi, W. (1981): The formation of iodate as a reason for the</p> | |

Section A7.1.1.1.1/ 01-13 Hydrolysis as a function of pH and identification of breakdown products**Annex Point IIA
VII.7.6.2.1**

decrease of efficiency of iodine containing disinfectants (author's transl)]; Zentralbl Bakteriol Mikrobiol Hyg [B]. 1981;172(6):498-507. German.

Doc. No. 592-043 (published); Section A7.1.1.1.1/07

- [8] Gottardi, W. in DISINFECTION, STERILIZATION, AND PRESERVATION, 4th edition (1991): Iodine and iodine compounds; pp 152 - 165

Doc. No. 392-044 (published); Section A7.1.1.1.1/8

- [9] Gottardi, W. (1998): Redox-potentiometric analysis of aqueous iodine solutions

Doc. No. 492-012 (published); Section A7.1.1.1.1/9

- [10] Gottardi, W. (1999): Iodine and Disinfection: Theoretical Study on Mode of Action, Efficiency, Stability, and Analytical Aspects in the Aqueous System; Archiv der Pharmazie

Volume 332, Issue 5, Pages 151 – 157; Published Online: 26 May 1999 © 1999 WILEY-VCH Verlag GmbH, Weinheim, Fed. Rep. of Germany

Doc. No. 192-003 (published); Section A7.1.1.1.1/10

- [11] Lee, Simon K.; Zhai, Hongbo; Maibach, Howard I. (2005): Allergic contact dermatitis from iodine preparations: a conundrum; Contact Dermatitis, Volume 52; pp 184 - April 2005

Doc. No. 592-046 (published); Section A7.1.1.1.1/11

- [12] Palmer, D. A.; Ramette, R. W.; Mesmer, R. E. (1984): Potentiometric Studies of the Thermodynamics of Iodine Disproportionation from 4 to 204°C; J. Solution Chem. Vol. 13, pp 685 – 697

Doc. No. 792-006 (published); Section A7.1.1.1.1/12

- [13] Köhl, W., Kirbach, I. (2007): Expert Evaluation provided for Dossier Preparation in Accordance with Directive 98/8/EC: Aqueous specification of Iodine; SCC Scientific Consulting GmbH

Doc. No. 181-001; Section A7.1.1.1.1/13

Additional:

- [14] <http://chemfinder.cambridgesoft.com> (for evaluation of CAS No.)

1.2 Data protection

1.2.1 Data owner

1.2.2 Companies with letter of access

1.2.3 Criteria for data protection

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

Not applicable.

Section A7.1.1.1.1/ 01-13 Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA
VII.7.6.2.1

2.2 GLP Not indicated.

2.3 Deviations Not applicable

3 MATERIALS AND METHODS

3.1 Test material and methods

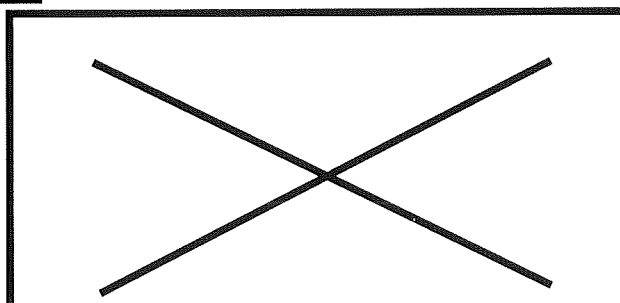
4 RESULTS

4.1 Iodine species occurring in natural waters

4.2 Solubility of elemental Iodine and hydrogen iodide

4.3 Eh-pH diagram

[Redacted text]



Section A7.1.1.1.1/ 01-13 Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA
VII.7.6.2.1

[Redacted text block]

4.4 Hydrolysis

[Redacted text block]

Section A7.1.1.1.1/ 01-13 Hydrolysis as a function of pH and identification of breakdown products

**Annex Point II A
VII.7.6.2.1**

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]



5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[Redacted]

X1

5.2 Results and discussion

[Redacted]

[Redacted]

[Redacted]

[Redacted]

X2

Section A7.1.1.1.1/ 01- 13 Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA
VII.7.6.2.1

5.3	Conclusion	<p>[REDACTED]</p> <p>Thus, in natural water, I⁻, IO₃⁻, and I₂ are coexisting whereas iodide strongly prevails.</p> <p>Degradation of these three species does not occur, only slight shifts of the equilibrium may happen, depending on the pH, potential reactions partners, and/or organisms incorporating and metabolising Iodine species.</p>
5.3.1	Reliability	[REDACTED]
5.3.2	Deficiencies	[REDACTED]

X3

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[REDACTED]
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]

Section A7.1.1.1/01-13 Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA
VII.7.6.2.1

Table A7.1.1.1/01-13-1: Relevant species of Iodine in aqueous system

No.	Specie			Source (e.g.)
1.	I ₂ (aq)			
2.	I ⁻			
3.	I ₃ ⁻			
4.	IO ₃ ⁻			
5.	HOI			
6.	H ₂ OI ⁺			
7.	HI			
8.	HIO ₃			
9.	IO ⁻			
10.	HIO ₂			

**Section
A7.1.1.1.2/01-02**

**Phototransformation in water including identity of
transformation products**

**Annex Point IIA,
VII.7.6.2.2**



			Official use only
	1	REFERENCE	
1.1	References	<p>[1] U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry (2004): Toxicological Profile for Iodine. Doc. No. 581-009 (published); Section A7.1.1.1.2/01.</p> <p>[2] Krone, C.; Kirbach, I. (2007): Expert Evaluation provided for Dossier Preparation in Accordance with Directive 98/8/EC: Occurrence, fate and behaviour of stable Iodine 127¹ in the environment including its geochemical and biochemical circulation and possible effects on global warming and contribution to acid rain. Doc. No. 781-004; Section A7.1.1.1.2/02</p>	X1
1.2	Data protection		
1.2.1	Data owner		
1.2.2	Companies with letter of access		
1.2.3	Criteria for data protection		
	2	GUIDELINES AND QUALITY ASSURANCE	
2.1	Guideline study	Not applicable.	
2.2	GLP	Not applicable.	
2.3	Deviations	Not applicable.	
	3	MATERIALS AND METHODS	
3.1	Test material		
	4	RESULTS	
4.1	Route of phototransformation		X2
	5	APPLICANT'S SUMMARY AND CONCLUSION	
5.1	Materials and		

Section A7.1.1.1.2/01-02 **Phototransformation in water including identity of transformation products**

Annex Point IIA,
VII.7.6.2.2

methods	[REDACTED]	
5.2 Results and discussion	[REDACTED]	
5.3 Conclusion	[REDACTED]	
5.3.1 Reliability	[REDACTED]	X3
5.3.2 Deficiencies	[REDACTED]	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[REDACTED]
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]

**Section
A7.1.1.1.2/03**

**Annex Point IIA,
VII.7.6.2.2**

**Phototransformation in water including identity of
transformation products**



Official
use only

1.1 References **1 REFERENCE**
Truesdale, V.W. (2007): On the feasibility of some photochemical reactions of iodide in seawater.

Doc. No. 792-013 (published); Section A7.1.1.1.2/03.

1.2 Data protection

1.2.1 Data owner

1.2.2 Companies with letter of access

1.2.3 Criteria for data protection

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study Not applicable.

2.2 GLP Not applicable.

2.3 Deviations Not applicable.

3 MATERIALS AND METHODS

3.1 Test material

3.2 Methods used

X1

**Section
A7.1.1.1.2/03
Annex Point IIA,
VII.7.6.2.2**

**Phototransformation in water including identity of
transformation products**

[Redacted]

4 RESULTS

4.1 Transformation pathways

[Redacted]

[Redacted]

[Redacted]

X2

[Redacted]

[Redacted]

5.1 Materials and methods

[Redacted]

5.2 Results and discussion

[Redacted]

**Section
A7.1.1.1.2/03**

Annex Point IIA,
VII.7.6.2.2

**Phototransformation in water including identity of
transformation products**

[Redacted]

5.3 Conclusion

Although photo-oxidation of iodide in seawater by oxygen, iodate, nitrate or a combination of nitrite and oxygen must occur, the reactions are too slow to be significant in determining the distribution of iodate and iodide in seawater. As any molecular iodine formed in seawater will be reduced rapidly by organic matter, any small production of molecular iodine, in effect, operates as a catalyst in the oxidation of organic matter by oxygen.

5.3.1 Reliability

[Redacted]

5.3.2 Deficiencies

[Redacted]

**Section
A7.1.1.1.2/03**

**Phototransformation in water including identity of
transformation products**

Annex Point IIA,
VII.7.6.2.2

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[REDACTED]
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]

Section A7.1.1.2.1 Biodegradability (ready)Annex Point IIA,
VII.7.6.1.1







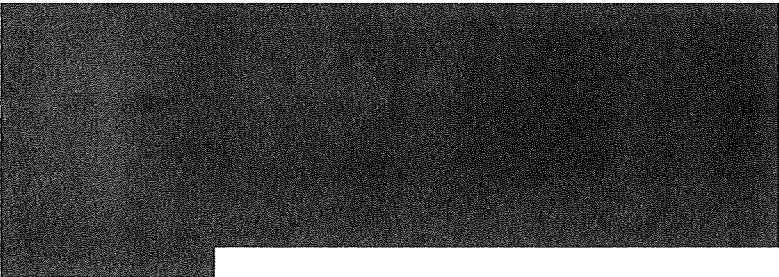
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Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input checked="" type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input type="checkbox"/>	
Detailed justification:	[REDACTED]	
Evaluation by Competent Authorities		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	[REDACTED]	
Materials and Methods	[REDACTED]	
Results and discussion	[REDACTED]	
Conclusion	[REDACTED]	
Reliability	[REDACTED]	
Acceptability	[REDACTED]	
Remarks	[REDACTED]	

Section A7.1.1.2.2 Biodegradability (inherent)

Annex Point IIA,
VII.7.6.1.2

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input checked="" type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input type="checkbox"/>	
Detailed justification:	[REDACTED]	
Evaluation by Competent Authorities		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	[REDACTED]	
Materials and Methods	[REDACTED]	
Results and discussion	[REDACTED]	
Conclusion	[REDACTED]	
Reliability	[REDACTED]	
Acceptability	[REDACTED]	
Remarks	[REDACTED]	

Section A7.1.1.2.3/01-02**Biodegradation in seawater****Annex Point IIIA, XII. 2.1**

			X1
			Official use only
	1	REFERENCE	
1.1	References	<p>[1] U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry (2004): Toxicological Profile for Iodine. Doc. No. 581-009 (published); Section A7.1.1.2.3/01.</p> <p>[2] Krone, C.; Kirbach, I. (2007): Expert Evaluation provided for Dossier Preparation in Accordance with Directive 98/8/EC: Occurrence, fate and behaviour of stable Iodine 127^I in the environment including its geochemical and biochemical circulation and possible effects on global warming and contribution to acid rain. Doc. No. 781-004; Section A7.1.1.2.3/02.</p>	
1.2	Data protection		
1.2.1	Data owner		
1.2.2	Companies with letter of access		
1.2.3	Criteria for data protection		
	2	GUIDELINES AND QUALITY ASSURANCE	
2.1	Guideline study	Not applicable.	
2.2	GLP	Not applicable.	
2.3	Deviations	Not applicable.	
	3	MATERIALS AND METHODS	
3.1	Test material		
	4	RESULTS	
4.1	Route of biotransformation		X2

Section A7.1.1.2.3/01- Biodegradation in seawater

02

Annex Point IIIA, XII. 2.1

	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.1.2.1.1 Aerobic biodegradation (PT 1)**Annex Point IIIA XII 2.1**

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data [...]	Technically not feasible []	Scientifically unjustified [X]
Limited exposure []	Other justification []	
Detailed justification:	X1	

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[REDACTED]
Evaluation of applicant's justification	[REDACTED]
Conclusion	[REDACTED]
Remarks	[REDACTED]

Iodine Registration Group (IRG)

Biocidal active substance:

Document IIIA,
Section A7.1-7.3






RMS Sweden

Iodine

Section 7.1.2.1.1

Aerobic biodegradation (PT 3)

Annex Point IIIA XII 2.1

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification [X]	
Detailed justification:		X1
Evaluation by Competent Authorities		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A7.1.2.1.1 Aerobic biodegradation (PT 22)**Annex Point IIIA XII 2.1**

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data [...]	Technically not feasible []	Scientifically unjustified [X]
Limited exposure []	Other justification []	
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Conclusion	<div style="background-color: black; width: 100%; height: 15px;"></div>
Remarks	<div style="background-color: black; width: 100%; height: 15px;"></div>

Section A7.1.2.1.2 Anaerobic biodegradation (PT 1)

Annex Point IIIA XII 2.1

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:	<div style="background-color: black; width: 100%; height: 40px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 40px;"></div>	

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
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Conclusion	<div style="background-color: black; width: 100%; height: 15px;"></div>
Remarks	<div style="background-color: black; width: 100%; height: 15px;"></div>

Section 7.1.2.1.2 Anaerobic biodegradation (PT 3)

Annex Point IIIA XII 2.1

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input checked="" type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input checked="" type="checkbox"/>	
Detailed justification:		

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

Section A7.1.2.1.2 Anaerobic biodegradation (PT 22)**Annex Point IIIA XII 2.1**

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:	<div style="background-color: black; width: 100%; height: 100%; min-height: 100px;"></div>	

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<div style="background-color: black; width: 100%; height: 15px;"></div>
Evaluation of applicant's justification	<div style="background-color: black; width: 100%; height: 40px;"></div>
Conclusion	<div style="background-color: black; width: 100%; height: 15px;"></div>
Remarks	<div style="background-color: black; width: 100%; height: 15px;"></div>

**Section A7.1.2.2.1/01-
02****Annex Point IIIA, XII. 2.1**

[REDACTED] X1

- Official
use only**
- 1 REFERENCE**
- 1.1 References**
- [1] U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry (2004): Toxicological Profile for Iodine.
Doc. No. 581-009 (published); Section A7.1.2.2.1 /01.
- [2] Krone, C.; Kirbach, I. (2007): Expert Evaluation provided for Dossier Preparation in Accordance with Directive 98/8/EC: Occurrence, fate and behaviour of stable Iodine 127^I in the environment including its geochemical and biochemical circulation and possible effects on global warming and contribution to acid rain.
Doc. No. 781-004; Section A7.1.2.2.1/02.

1.2 Data protection

1.2.1 Data owner

1.2.2 Companies with letter of access

1.2.3 Criteria for data protection

2 GUIDELINES AND QUALITY ASSURANCE**2.1 Guideline study**

Not applicable.

2.2 GLP

Not applicable.

2.3 Deviations

Not applicable.

3 MATERIALS AND METHODS**3.1 Test material**

[REDACTED]

4 RESULTS**4.1 Transformation and transfer processes in the aquatic environment**

[REDACTED]

X2

**Section A7.1.2.2.1/01- Aerobic aquatic degradation
02**

Annex Point IIIA, XII. 2.1



5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods



5.2 Results and discussion



X3

5.3 Conclusion

The predominant forms of Iodine in natural waters are iodide and iodate. At pH values between 4 and 9, iodide is the predominant species. Only under high-pH and well-oxidised conditions, iodate would occur at higher amounts.

5.3.1 Reliability



X4

5.3.2 Deficiencies



Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

**Section A7.1.2.2.1/01- Aerobic aquatic degradation
02**

Annex Point IIIA, XII. 2.1

Date	[Redacted]
Materials and Methods	[Redacted]
Results and discussion	[Redacted]
Conclusion	[Redacted]
Reliability	[Redacted]
Acceptability	[Redacted]
Remarks	[Redacted]

Section A7.1.2.2.2 Water/sediment study (PT 1)

Annex Point IIIA XII 2.1

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data [...] <input type="checkbox"/>	Technically not feasible [] <input type="checkbox"/>	Scientifically unjustified [X] <input checked="" type="checkbox"/>
Limited exposure [] <input type="checkbox"/>	Other justification [X] <input checked="" type="checkbox"/>	
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EVALUATION BY RAPPORTEUR MEMBER STATE	
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Evaluation of applicant's justification	<div style="background-color: black; width: 100%; height: 15px;"></div>
Conclusion	<div style="background-color: black; width: 100%; height: 15px;"></div>
Remarks	<div style="background-color: black; width: 100%; height: 15px;"></div>

Iodine Registration Group (IRG)

Biocidal active substance:

Document IIIA,
Section A7.1-7.3

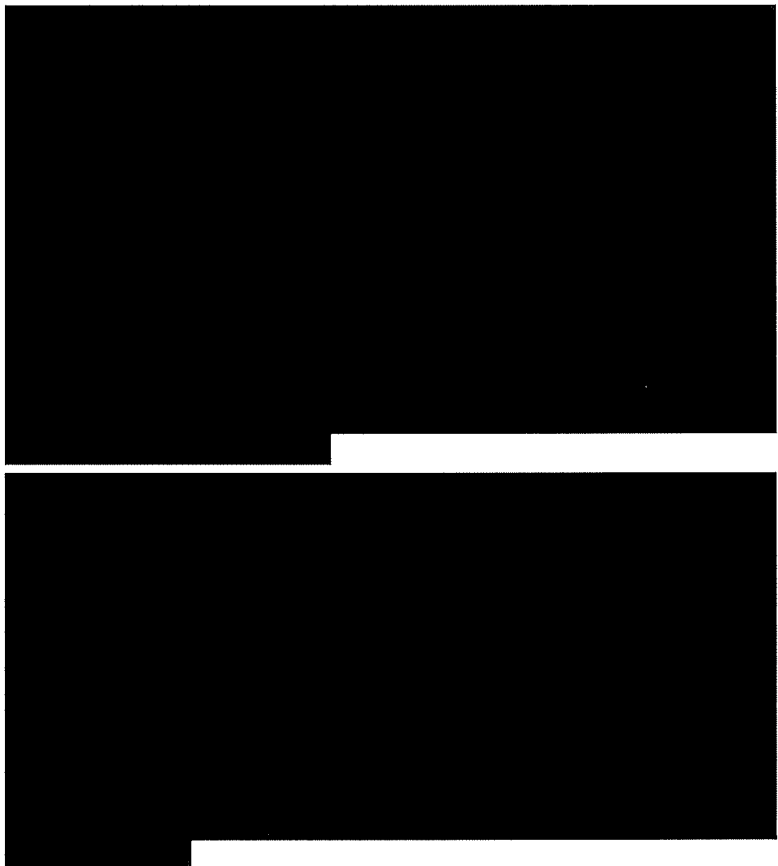
RMS Sweden


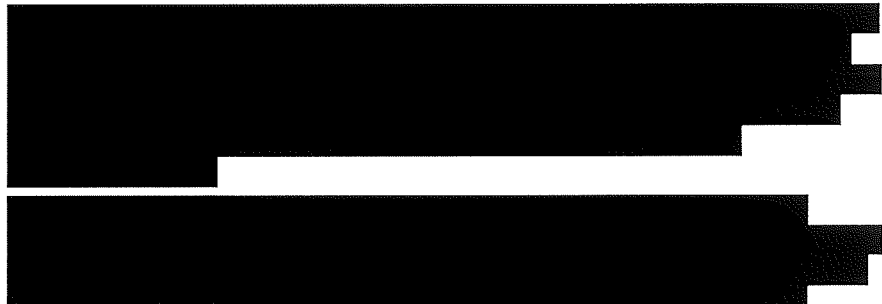
Iodine

Section 7.1.2.2.2

Water/sediment study (PT 3)

Annex Point IIIA XII 2.1

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input checked="" type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input checked="" type="checkbox"/>	
Detailed justification:		
		X1

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	
Evaluation of applicant's justification	

Section 7.1.2.2.2

Water/sediment study (PT 3)

Annex Point IIIA XII 2.1

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1 [Redacted footnote text]

Section 7.1.2.2.2

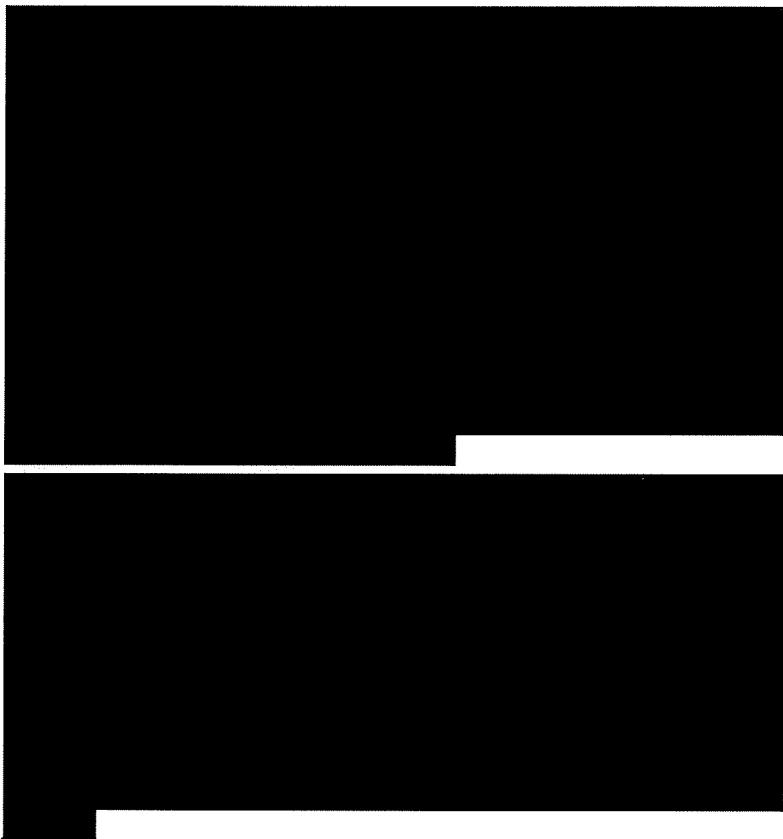
Water/sediment study (PT 3)

Annex Point IIIA XII 2.1



	
	
	
<p>Conclusion</p>	
<p>Remarks</p>	

Section A7.1.2.2.2 Water/sediment study (PT 22)

Annex Point IIIA XII 2.1

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:		

X1

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	
Evaluation of applicant's justification	

Section A7.1.2.2.2 Water/sediment study (PT 22)

Annex Point IIIA XII 2.1

	[REDACTED]
	[REDACTED]
Conclusion	[REDACTED]
Remarks	[REDACTED]

**Section A7.1.3/01
Annex Point IIA,
VII.7.7****Adsorption / Desorption screening test**Official
use only**1 REFERENCE**

- 1.1 Reference** O'Connor, B.J., Mullee, D.M. (2002): Determination of soil adsorption coefficient, Safepharm Laboratories Ltd., Derby, U.K., report no. 1580/006, report date: 18.06.2002

Doc. No. 731-001 (unpublished); Section A7.1.3/01

1.2 Data protection**1.2.1 Data owner****1.2.2 Companies with
letter of access****1.2.3 Criteria for data
protection****2 GUIDELINES AND QUALITY ASSURANCE**

- 2.1 Guideline study** OECD No.106 (2000): Adsorption – Desorption Using a Batch Equilibrium Method

2.2 GLP**2.3 Deviations****3 MATERIALS AND METHODS****3.1 Test material** Iodine**3.1.1 Batch number****3.1.2 Specification****3.1.3 Purity****3.1.4 Description of test
substance****3.1.5 Further relevant
properties****3.1.6 Method of analysis****3.2 Degradation
products****3.2.1 Method of analysis
for degradation
products****3.3 Reference
substance****3.3.1 Method of analysis**

Section A7.1.3/01
Annex Point IIA,
VII.7.7

Adsorption / Desorption screening test

for reference
substance

3.4 Soil types

[Redacted]

3.5 Testing procedure

3.5.1 Test system

[Redacted]

3.5.2 Test solution and
Test conditions

[Redacted]

[Redacted]

[Redacted]

[Redacted]

3.6 Test performance

3.6.1 Preliminary test

[Redacted]








X1

[Redacted]

[Redacted]

**Section A7.1.3/01
Annex Point IIA,
VII.7.7**

Adsorption / Desorption screening test

3.6.2	Screening test: Adsorption		X2
3.6.3	Screening test: Desorption		X3
3.6.4	HPLC-method		
3.6.5	Other test		
4 RESULTS			
4.1	Preliminary test		
		<p>The test material was classified as stable within 24 h at 25 ± 2°C as the percentage recovery was greater than 90% (defined by testing scheme of OECD 106).</p> 	
			

**Section A7.1.3/01
Annex Point IIA,
VII.7.7**

Adsorption / Desorption screening test

█	█	█
█	█	█
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█

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█

X4

- 4.2 Screening test: Adsorption See Table A7.1.3.1-2
- 4.3 Screening test: Desorption Not conducted.
- 4.4 Calculations
- 4.4.1 K_d See Table A7.1.3/01-3
- 4.4.2 K_{oc} See Table A7.1.3/01-3
- 4.5 Degradation product(s) None

5 APPLICANT'S SUMMARY AND CONCLUSION

- 5.1 Materials and methods

Testing was performed according to Tier 1 and 2 of OECD guideline 106.

The stability of the test material was investigated within 24 h at $25 \pm 2^\circ\text{C}$. The optimal soil to solution ratios were examined.

The values of mean percentage of adsorption were determined in a preliminary test for soil type 2 and 7 and in a screening test for soil types 3, 4 and 5.

The distribution coefficients (K_d) and the organic carbon normalized

Section A7.1.3/01
Annex Point IIA,
VII.7.7

Adsorption / Desorption screening test

	
	
	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7.1.3/01-2 results from screening test (together with results of preliminary tests)

time point (h)	Mean percentage adsorption (%)						
	Soil type 2	Soil type 3	Soil type 4	Soil type 5	Soil type 6	Soil type 7	
2	0.00	24.1	26.4	14.7	20.2	20.2	
4	7.95	37.8	36.3	14.7	26.6	26.6	
6	12.9	34.5	52.1	23.6	35.0	35.0	
24	54.3	70.8	85.5	53.7	54.3	54.3	
48	53.2	64.5*	96.2	54.0*	67.9	67.9	

*value calculated theoretically as experimental data was excluded due to inconsistency in soil-less controls

Table A7.1.3/01-3 results from screening test (together with results of preliminary tests)

Soil type	Mean K_d (cm ³ /g)	Mean K_{oc} (cm ³ /g)
2	1.23	51.3
3	2.09	65.2
4	124	3.65×10^3
5	1.22	76.1
7	16.2	135

K_d : calculated distribution coefficient at $25 \pm 2^\circ\text{C}$

K_{oc} : calculated organic carbon normalised adsorption coefficient at $25 \pm 2^\circ\text{C}$

Iodine Registration Group (IRG)

Biocidal active substance:

Document IIIA,
Section A7.1-7.3


RMS Sweden





Iodine

Section A7.1.4.1







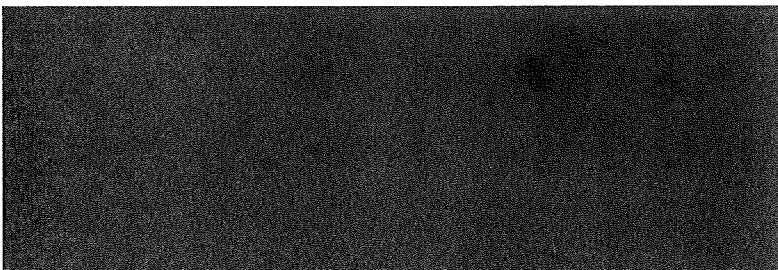
Field study on accumulation in the sediment

Annex Point IIIA, XII. 2.1

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input checked="" type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input checked="" type="checkbox"/>	
Detailed justification:		

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

Section A7.2.1/01-03 Aerobic degradation in soil, initial study**Annex Point IIIA, XII. 3**

			X1
			Official use only
	1	REFERENCE	
1.1	References	<p>[1] U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry (2004): Toxicological Profile for Iodine. Doc. No. 581-009 (published); Section A7.2.1/01.</p> <p>[2] Johanson, K.J. (2000): Iodine in soil, Technical report TR-00-21, Department of Forest Mycology and Pathology, The Swedish University of Agricultural Sciences, Uppsala. Doc. No. 781-002 (published); Section A7.2.1/02.</p> <p>[3] Krone, C.; Kirbach, I. (2007): Expert Evaluation provided for Dossier Preparation in Accordance with Directive 98/8/EC: Occurrence, fate and behaviour of stable Iodine ^{127}I in the environment including its geochemical and biochemical circulation and possible effects on global warming and contribution to acid rain. Doc. No. 781-004; Section A7.2.1/03.</p>	
1.2	Data protection		
1.2.1	Data owner		
1.2.2	Companies with letter of access		
1.2.3	Criteria for data protection		
	2	GUIDELINES AND QUALITY ASSURANCE	
2.1	Guideline study	Not applicable.	
2.2	GLP	Not applicable.	
2.3	Deviations	Not applicable.	
	3	MATERIALS AND METHODS	
3.1	Test material		
	4	RESULTS	
4.1	Transformation processes and Iodine species relevant in soils		X2

Section A7.2.1/01-03 Aerobic degradation in soil, initial study
Annex Point IIIA, XII. 3

[Redacted]

[Redacted]

X3

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[Redacted]

5.2 Results and discussion

[Redacted]

X3

5.3 Conclusion

The redox potential is considered to be an important factor with regard to the concentration of soluble Iodine as well as the ratio between iodate and iodide in the soil solution.

5.3.1 Reliability

[Redacted]

5.3.2 Deficiencies

[Redacted]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date

[Redacted]

Materials and Methods

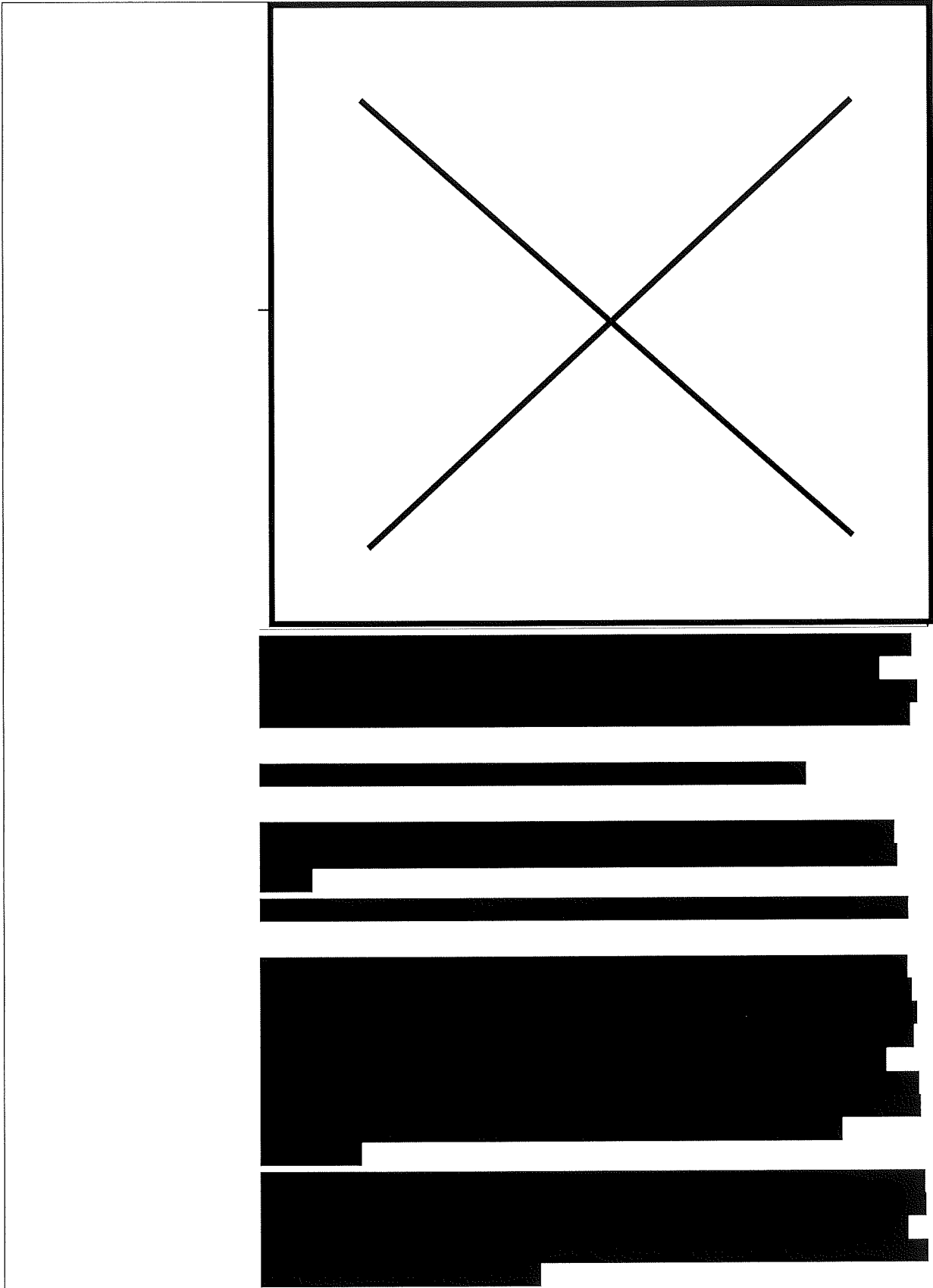
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Results and discussion

[Redacted]

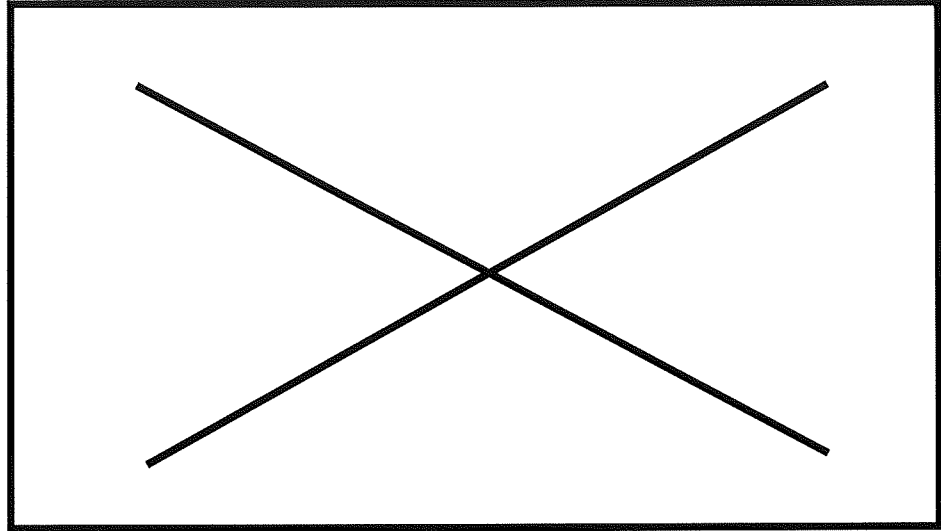
Section A7.2.1/01-03 Aerobic degradation in soil, initial study

Annex Point IIIA, XII. 3

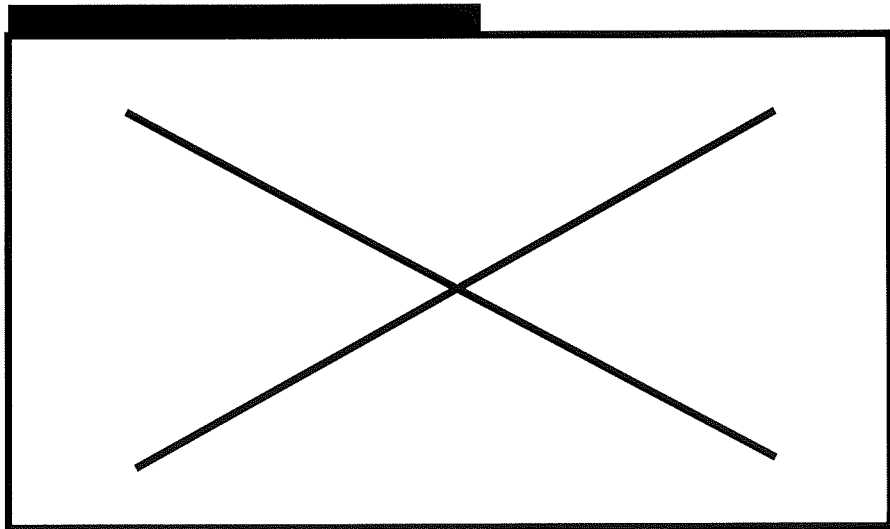


Section A7.2.1/01-03 Aerobic degradation in soil, initial study

Annex Point IIIA, XII. 3



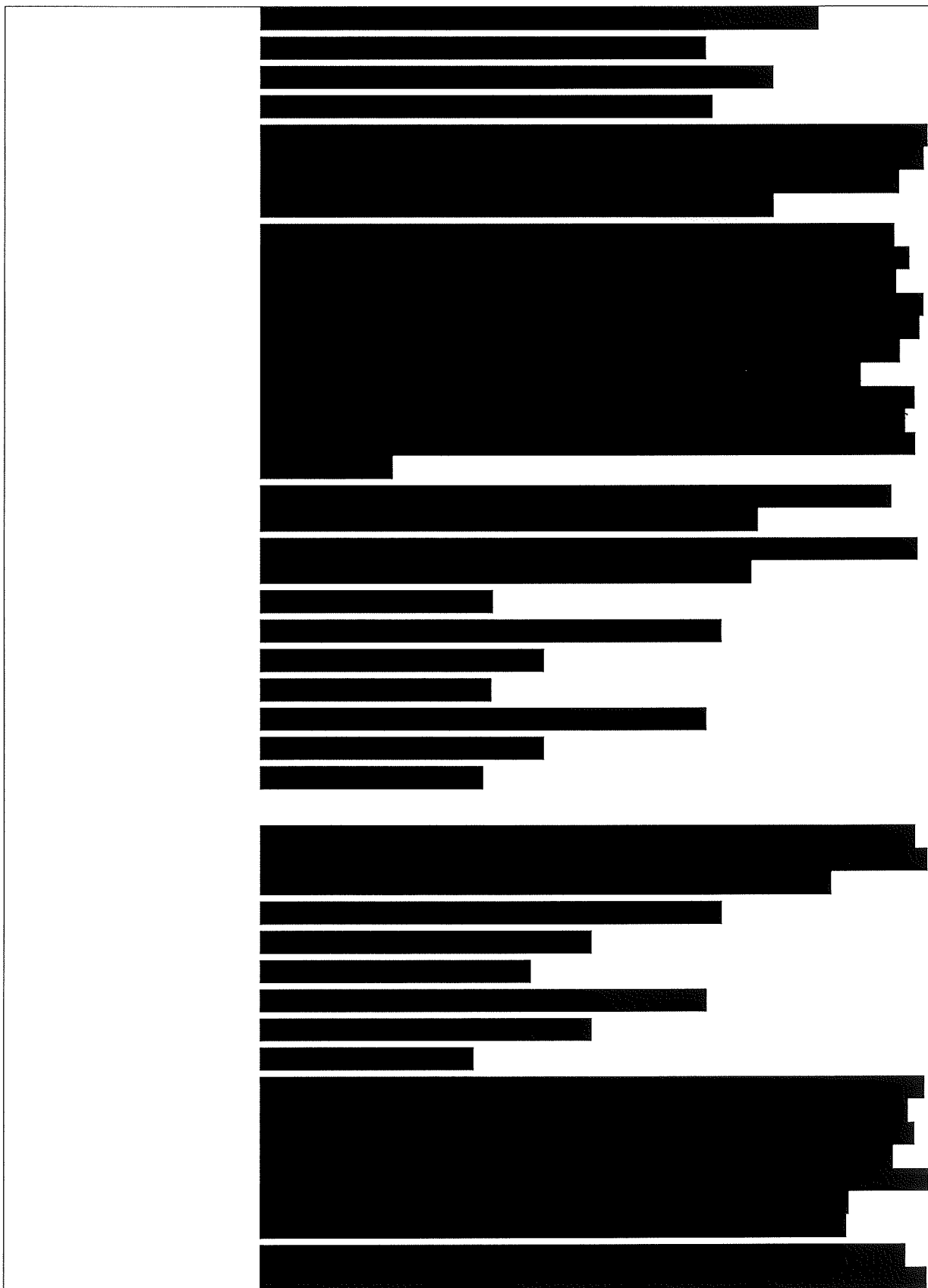
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Section A7.2.1/01-03 Aerobic degradation in soil, initial study

Annex Point IIIA, XII. 3



Section A7.2.1/01-03 Aerobic degradation in soil, initial study

Annex Point IIIA, XII. 3



Section A7.2.1/01-03 Aerobic degradation in soil, initial study

Annex Point IIIA, XII. 3

	[Redacted]
	[Redacted]
	[Redacted]
	[Redacted]
Conclusion	[Redacted]
	[Redacted]
	[Redacted]
	[Redacted]
	[Redacted]
	[Redacted]
Reliability	[Redacted]
	[Redacted]
	[Redacted]
Acceptability	[Redacted]
	[Redacted]
Remarks	[Redacted]

Iodine Registration Group (IRG)

Biocidal active substance:


Document IIIA,
Section A7.1-7.3





RMS Sweden

Iodine

Section A7.2.2.1-4 Aerobic degradation in soil, further studies

Annex Point IIIA, XII.1.1,
XII.1.4

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input checked="" type="checkbox"/>	
Detailed justification:		

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

Section A7.2.3/01

Annex Point IIIA, XII.1.2

Adsorption and mobility in soil, further studies:

Adsorption and desorption in at least three soil types and, where relevant, the adsorption and desorption of metabolites and degradation products

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification [X]	
Detailed justification:		

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

Section A7.2.3.2 Mobility in soil: outdoor confirmatory study (PT 1)

Annex Point IIIA, XII.1.3

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data [...]	Technically not feasible []	Scientifically unjustified []
Limited exposure []	Other justification [X]	
Detailed justification:	<div style="background-color: black; width: 100%; height: 100%; min-height: 150px;"></div>	

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<div style="background-color: black; width: 100%; height: 15px;"></div>
Evaluation of applicant's justification	<div style="background-color: black; width: 100%; height: 15px;"></div>
Conclusion	<div style="background-color: black; width: 100%; height: 15px;"></div>
Remarks	<div style="background-color: black; width: 100%; height: 15px;"></div>

Section A7.2.3.2 Mobility in soil: outdoor confirmatory study (PT 3)

Annex Point IIIA, XII.1.3

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input checked="" type="checkbox"/>	
Detailed justification:	<div style="background-color: black; width: 100%; height: 40px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 40px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 40px;"></div>	
X1		
Evaluation by Competent Authorities		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	<div style="background-color: black; width: 100%; height: 15px;"></div>	
Evaluation of applicant's justification	<div style="background-color: black; width: 100%; height: 80px;"></div>	
Conclusion	<div style="background-color: black; width: 100%; height: 15px;"></div>	
Remarks	<div style="background-color: black; width: 100%; height: 15px;"></div>	

**Section A7.2.3.2
Annex Point IIIA,
XII.1.3**

**Mobility in at least three soil types and where relevant
mobility of metabolites and degradation products
Mobility in soil: outdoor confirmatory study (PT 22)**

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data [...]	Technically not feasible []	Scientifically unjustified []
Limited exposure []	Other justification [X]	
Detailed justification:	<div style="display: flex; justify-content: space-between;"> <div style="width: 80%; height: 150px;"></div> <div style="width: 15%; text-align: center;">X1</div> </div>	

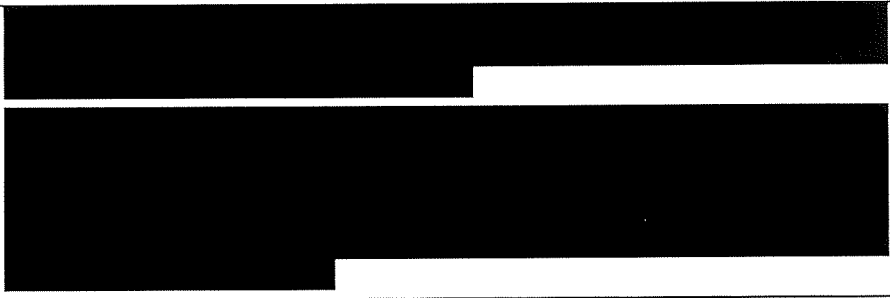
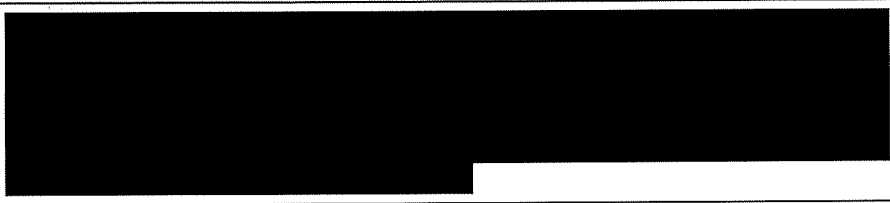
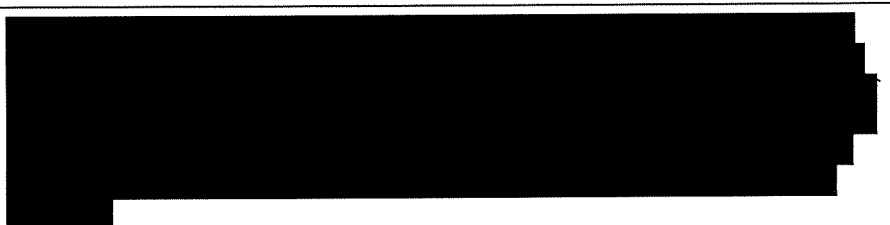

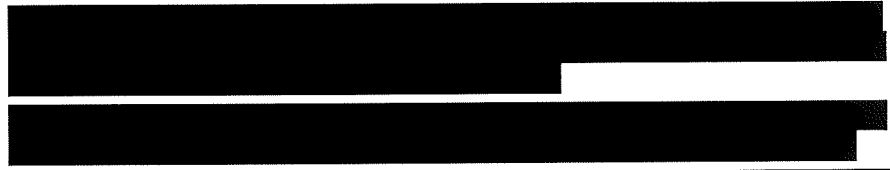


Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

Section A7.3.1/01 Phototransformation in air (estimation method)**Annex Point IIIA, VII.5**

	1 REFERENCE
1.1 Reference	<p>Saiz-Lopez, A. et al., 2004: Absolute absorption cross-section and photolysis rate of I₂, School of Environmental Sciences, University of East Anglia, Norwich, UK, Atmos, Chem. Phys. Discuss. Vol. 4: 2379-2403.</p> <p>Doc. No. 192-007 (published); Section A7.3.1/01 X1</p>
1.2 Data protection	[REDACTED]
1.2.1 Data owner	[REDACTED]
1.2.3 Criteria for data protection	[REDACTED]
	2 GUIDELINES AND QUALITY ASSURANCE
2.1 Guideline study	<p>Methods used were comparable to the US EPA guideline § 161-4 with the exception that temperature during the test was held at 22°C instead of 30°C.</p> <p>X2</p>
2.2 GLP	Not indicated [REDACTED]
2.3 Deviations	Not ascertainable [REDACTED]
	3 MATERIALS AND METHODS
3.1 Test material	Iodine I ₂ crystals [REDACTED]
3.1.1 Lot/Batch number	[REDACTED]
3.1.2 Specification	[REDACTED]
3.1.3 Purity	[REDACTED]
3.1.4 Description of test substance	[REDACTED]
3.1.5 Composition of Product	[REDACTED]
3.1.6 Further relevant properties	[REDACTED]
3.2 Cross-section determination	[REDACTED]
3.3 Rate of photolysis of I₂	
3.3.1 Experimental set-up	[REDACTED]

Section A7.3.1/01 Phototransformation in air (estimation method)

Annex Point IIIA, VII.5

	
3.3.2 Photolysis rate measurement	
	4 RESULTS
4.1 I ₂ absorption cross-section	
4.2 I ₂ route of photolysis	
4.3 I ₂ rate of photolysis	
	5 APPLICANT'S SUMMARY AND CONCLUSION
5.1 Materials and methods	
5.2 Results and	

Section A7.3.1/01 Phototransformation in air (estimation method)

Annex Point IIIA, VII.5

discussion	[REDACTED]
5.3 Conclusion	Photolysis appears to be a dominant loss process for I ₂ during daytime, and hence an important source of iodine atoms in the lower atmosphere. X3
5.3.1 Reliability	[REDACTED]
5.3.2 Deficiencies	[REDACTED]
Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[REDACTED]
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]