Section A7.5.3-01 (PT 3) Effects on birds

Annex Point IIIA XIII 1.1

	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]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	

Section A7.5.3-01 (PT 3) Effects on birds

Annex Point IIIA XIII 1.1

	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]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	

Section A7.5.3-02 (PT 22) Effects on birds

Sections A7.5.3.1.1-A7.5.3.1.3

Annex Point IIIA XIII 1.1

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

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]

Section A7.5.3-03 (PT 1) Effects on birds

Sections A7.5.3.1.1-A7.5.3.1.3

Annex Point IIIA XIII 1.1

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

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]

Section A7.5.4.1 Acute toxicity to honeybees and other beneficial arthropods

Annex Point IIIA, XIII.3.1 *Honeybees*

	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]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	

Section A7.5.5/01-02 Bioconcentration in terrestrial organisms

Annex Point IIIAVII.7.5

[redacted]

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 A7.5.5/01.

[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 A7.5.5/02.

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 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 Bioconcentration in terrestrial plants [redacted]

[redacted]

Section A7.5.5/01-02 Bioconcentration in terrestrial organisms

Annex Point IIIAVII.7.5

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[redacted]

5.2 Results and discussion

[redacted]

5.3 Conclusion

The uptake of Iodine into terrestrial plants in combination with deposition of Iodine onto the surfaces of plants plays an important role in the transfer of Iodine through the soil-plant-cow-milk pathway.

5.3.1 Reliability

[redacted]

5.3.2 Deficiencies

[redacted]

Section A7.5.5/01-02 Bioconcentration in terrestrial organisms

Annex Point IIIAVII.7.5

EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.5.5.1 Bioconcentration, further studies

Annex Point IIIAVII.7.5

	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]	

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]

Section A7.5.6 Effects on other terrestrial non-target organisms

Annex Point IIIA, XIII.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:	[redacted]	

EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]

Section A7.5.7 Effects on mammals

Annex Point IIIA, XIII.3.4

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

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]

Section A7.6/01-10 Summary of ecotoxicological effects and fate and behaviour in the environment

[redacted]

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 A7.6/01.

[2] Merke F. (1965): The ice age as primordial cause of endemic goiter, Schweiz Med Wochenschr. 1965 Sep 4;95(36):1183-92.
Doc. No. 792-007 (published); Section A7.6/02.

[3] 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 A7.6/03.

[4] World Health Organization (1998): Iodine deficiency, Report EB103/27.
Doc. No. 592-084 (published); Section A7.6/04.

[5] IPCC/TEAP Special Report on Ozone and Climate: Safeguarding the ozone layer and the global climate system: Issues related to hydrofluorocarbons and perfluorocarbons.
Doc. No. 792-008 (published); Section A7.6/05

[6] UN Environment Programme, Environmental Effects Assessment Panel; Photochem. Photobiol. Sci., 2006, 5, 13-24.
Doc. No. 792-009 (published); Section A7.6/06

[7] FAO/WHO (2001) Chapter 12: Iodine. In: Human Vitamin and Mineral Requirements. Report of a joint FAO/WHO expert consultation Bangkok, Thailand, Food and Nutrition Division, FAO Rome, p. 185.
Doc. No. 592-035 (published); Section A7.6/07.

[8] Yuita K. 1994a. Overview and dynamics of Iodine and bromine in the environment: 1. Dynamics and Iodine and bromine in soil-plant system. JARQ 28:90-99.
Doc. No. 792-010 (published); Section A7.6/08.

[9] Kocher DC. 1981 (Abstract only). On the long-term behavior of 129I in the terrestrial environment. International Symposium on Migration in the Terrestrial Environment of Long-Lived Radionuclides from the Nuclear Fuel Cycle. IAEA-SM-257/56.
Doc. No. 792-011 (published); Section A7.6/09.

[10] 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 (published); Section A7.6/10.

Section A7.6/01-10 Summary of ecotoxicological effects and fate and behaviour in the environment

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**	Not applicable.
2.2	**GLP**	Not applicable.
2.3	**Deviations**	Not applicable.

3 MATERIALS AND METHODS

3.1	**Test material and methods**	The cited references are overview articles which do not provide detailed information on materials and methods.

4 RESULTS

4.1	**Occurrence**	[redacted]

[redacted]

4.1.2 Occurrence in organisms

[redacted]

4.2 Releases into the environment

[redacted]

4.2.1 Release into the water

[redacted]

[redacted]

4.2.2 Release into the atmosphere

[redacted]

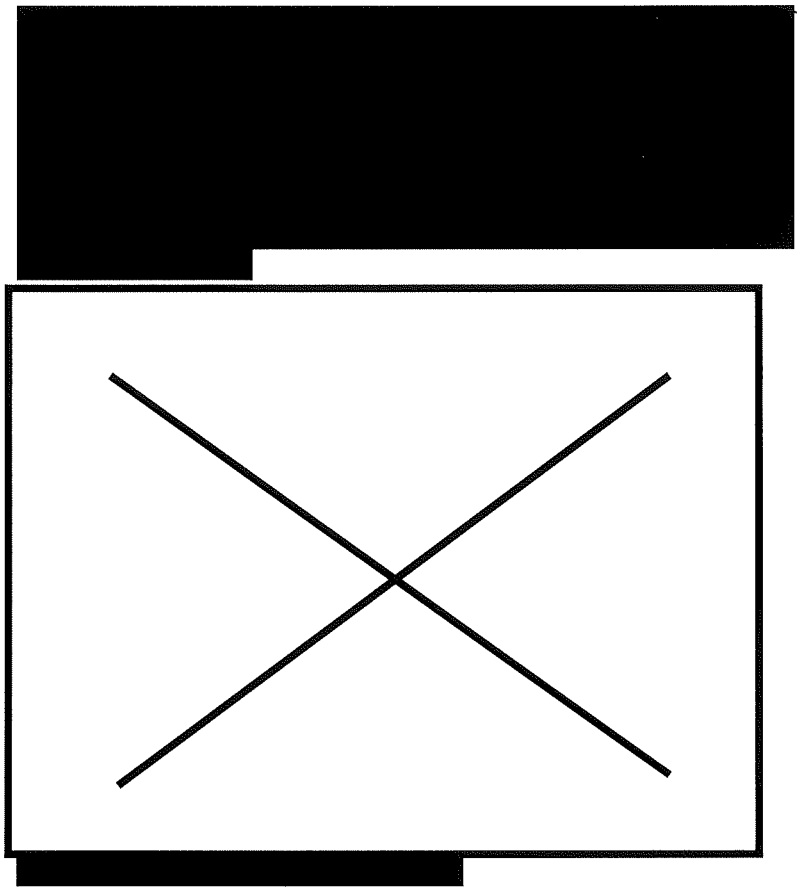
[redacted]

4.3 Release into soils

[redacted]

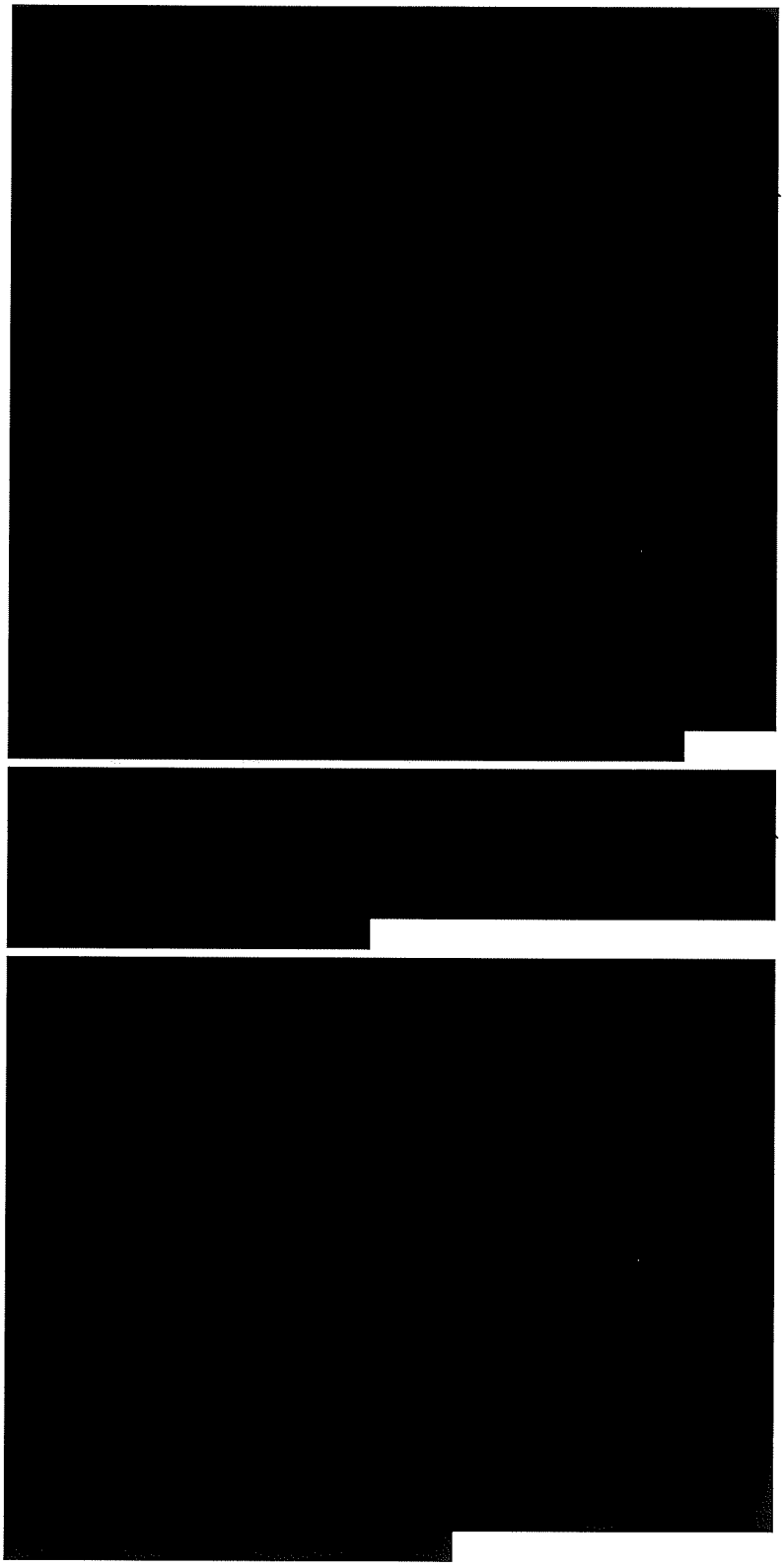
4.4 Environmental fate

[redacted]



4.4.1 Transport and Partitioning

[redacted]



[redacted]

4.4.2 Transformation and Degradation

[redacted]

[redacted]

4.5 Formation of Iodine deficiency areas

[redacted]

[redacted]

[redacted]

4.6 Impact on global warming and acid rain

[redacted]

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[redacted]

5.2 Results and discussion

[redacted]

[redacted]

5.3 Conclusion

Iodine is ubiquitous in the three main environmental compartments earth's surface ($6.3x10^{18}$ g), water ($8.1x10^{16}$ g), and air ($4x10^{7}$ g). Mean concentrations are 45-60 µg/L in water, 0.5 ppm in the earth's crust and 10-20 ng/m^3 in the air.

Iodine is present in many chemical forms as molecular Iodine (I_2), iodide (I^-), iodate (IO_3^-) and periodate (IO_4^-). The contribution and the residency time of Iodine in the compartments depends on the chemical form, its reactivity and solubility/uptake/retention in the compartment.

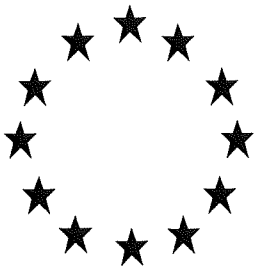
5.3.1 Reliability [redacted]

5.3.2 Deficiencies [redacted]

EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Competent Authority Report

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



IODINE

DOCUMENT III-A8 – A9

Rapporteur Member State: Sweden

Draft Final May 2013

KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

Index:

S

Section A8 Measures necessary to protect man, animals and the environment

Official use only

Subsection (Annex Point)		
8.1		**Recommended methods and precautions concerning handling, use, storage, transport or fire (IIA8.1)**
8.1.0	**Methods and precautions concerning placing on the market**	Iodine has been used in human and veterinarian disinfectants for many decades. Even if it is not produced in Europe, its methods of production and the precautions concerning handling, use, storage, transport or fire to protect man, animals and the environment are described in detail because of its use not only in disinfectants but also in pharmaceuticals, x-ray contrast media, catalysts, stabilizers, weed killer, polarizing films, feed additive and table salt.
8.1.1	**Methods and precautions concerning production, handling and use of the active substance and its formulations**	Engineering controls: COSHH (Control of Substances Hazardous to Health, UK) -Potentially exposed employees require health surveillance (medical assessment). Technical protective measures: Both local exhaust and general room ventilation are usually required. Handling: Keep away from food, drink and animal feeding stuff. Wash hands and other exposed areas with mild soap and water before eat, drink or smoke and when leaving work. Due care must be taken and any damaged packages must be isolated and repaired. Wear personal protective clothing. Respiratory protection: In case of insufficient ventilation, wear suitable respiratory equipment. Hand protection: Wearing of chemicals-resistant gloves is recommended (e.g. nitrile rubber or polyethylene gloves). Eye protection: Wearing of safety glasses is recommended. Skin and body protection: Wearing of protective clothing is recommended. Ingestion: When using, do not eat, drink or smoke. Iodine is very toxic if swallowed or inhaled. Iodine has a significant vapour pressure at room temperature which can lead to the build-up of dangerous levels of Iodine vapour. Exposure to Iodine may lead to reproductive damage. Iodine may be absorbed through the skin. Iodine should not be handled in the open lab except for very short periods. It sublimes at room temperature and exposure to the vapour is very harmful. Conditions to avoid: Heat, sunlight, poor ventilation. Upon heating toxic fumes are formed. Materials to avoid: Sulphur, reducing metals, iron, alkali metals, metal powders, phosphorous and ammonia and ammonia solutions, acetaldehyde powdered metals, metal acetylides and carbides, reducing agents and organic solvents. Doc-No. 953-003; Section A.8/01 Doc. No. 950-002; Section A.8.1.1/02

Section A8 Measures necessary to protect man, animals and the environment

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8.1.2	**Methods and precautions concerning storage of the active substance and its formulations**	Keep in tightly closed containers, in a cool, well ventilated and dry place. Protect from direct sunlight and keep away from sources of heat and/or ignition. Separate from combustible, organic or other readily oxidisable materials. Doc-No. 953-003; Section A.8/01
8.1.3	**Methods and precautions concerning transport of the active substance and its formulations**	**Transport Classification:** Miscellaneous Dangerous Substances and Articles. UN number: 3077 Description of goods: Environmentally hazardous substance, liquid, n.o.s. (Iodine) Class: 9 Packaging group: III ICAO/IATA/IMDG CLASS: 9 Risk No.: 90 ADR/RID-Labels: 9 Emergency Action Code: 2Z Doc-No. 953-003; Section A.8/01 Doc-No. 953-006; Section A8/03
8.1.4	**Methods and precautions concerning fire of the active substance and its formulations**	Suitable extinguishing media: Use water spray or fog for cooling exposed containers. Specific hazards during fire fighting: Exercise caution when fighting any chemical fire. Avoid (reject) fire-fighting water to enter environment. Special protective equipment: Normal fire protection clothing and NIOSH / MSHA respirator. Further information: use water spray to cool unopened containers. In the event of fire and/or explosion do not breathe fumes. Doc-No. 953-003; Section A.8/01 Doc. No. 950-002; Section A.8/02
8.2		**In case of fire, nature of reaction products, combustion gases, etc. (IIA8.2)** Iodine readily sublimes. Upon heating, toxic iodide fumes are formed. The substance is a strong oxidant and reacts with combustible and reducing materials. Reacts violently with metal powders, antimony, ammonia, acetaldehyde, acetylene causing fire and explosion hazards. Hazardous decomposition products: Toxic gases and vapours are released if involved in a fire. Doc-No. 953-003; Section A.8/01 Doc. No. 950-002; Section A.8/02
8.3		**Emergency measures in case of an accident (IIA8.3)**
8.3.1	**Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical**	Personal: Isolate the contaminated area and instruct others to keep away. Hazards identification: Harmful by inhalation and in contact with skin. Very toxic to aquatic organisms. Dangerous to the environment. First-aid measures:

Section A8 Measures necessary to protect man, animals and the environment

			Official use only
	treatment if available	Inhalation: Assure fresh air breathing. Keep warm and at rest. Seek medical advice. If not breathing give artificial respiration. Skin contact: Remove any contaminated clothing. Wash contaminated areas with plenty of water for at least 15 minutes. Remove Iodine stains with 5% Sodium thiosulphate solution. Call for medical aid. Eye contact: Immediately flush eye(s) with large amounts of water, occasionally lifting upper and lower lids. Continue for at least ten minutes and call for medical help. Ingestion: Do not induce vomiting. Wash out the mouth with water if the person is conscious. Never give anything by mouth to unconscious person. Administer 10 % Sodium thiosulphate solution as an antidote. Consult a doctor immediately and remove to hospital. Doc-No. 953-003; Section A.8/01 Please refer also to Section A6.12.7/01 (Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment).	
8.3.2	**Emergency measures to protect the environment**	Environmental precautions: Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters Contain and control the spillage on site. Collect and containerise as much solid Iodine as possible. Cover with weak reducing agents such as hypo, bisulphites or ferrous salts. Transfer the slurry into a large container of water and neutralise with Na_2CO_3. Sweep spilled substance into sealable containers; if appropriate, moisten first to prevent dusting. Carefully collect remainder, and then remove to safe place. Do not absorb in saw-dust or other combustible adsorbents. Do not let the product enter the environment. Personal precautions: Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection. Doc-No. 953-003; Section A.8/01	
8.4		**Possibility of destruction or decontamination following release in or on the following: (a) Air; (b) Water, including drinking water; (c) Soil (IIA8.4)**	
8.4.1	**Possibility of destruction or decontamination following release in the air**	No procedures for the destruction or decontamination of Iodine released into the air have been developed.	
8.4.2	**Possibility of destruction or decontamination following release in water, including drinking water**	A possibility maybe a neutralisation with Carbonate (see 8.3.2)	
8.4.3	**Possibility of destruction or decontamination following release in or on soil**	Pick up the product mechanically and store in suitable containers for recovery or disposal. Contain and control the spillage on site. Collect and containerise as much solid Iodine as possible. Cover with weak reducing agents such as hypo, bisulphites or ferrous salts. If appropriate, moisten first to prevent dusting. Carefully collect remainder, and then remove to safe place. Transfer the slurry into a large container of water and neutralise with Carbonate. Do not adsorb in saw-dust or other combustible adsorbents. Do not let the product enter the environment.	

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Doc-No. 953-003; Section A.8/01

8.5 Procedures for waste management of the active substance for industry or professional users e.g. possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration (IIA8.5)

8.5.1 Possibility of re-use or recycling

Recycling is preferred to disposal or incineration. If recycling is not practicable, disposal in compliance with local regulations is recommended.

8.5.2 Possibility of neutralisation of effects

A possibility maybe a neutralisation with Carbonate (see 8.3.2)

8.5.3 Conditions for controlled discharge including leachate qualities on disposal

A possibility maybe a neutralisation with Carbonate (see 8.3.2)

8.5.4 Conditions for controlled incineration

No specific conditions for controlled incineration of Iodine are known.

8.6 Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIA8.6)

If Iodine is stored and handled correctly, no undesirable or unintended side effects are expected. Iodine is very toxic to aquatic organisms (e.g. daphnia) which must be considered in case of contamination of surface water.

48h-LC50 (*Daphnia magna*) = 0.60 mg/L (water of medium hardness) or 0.16 g/L (water of low hardness)

For details see Section A.7.4.1.2/01.

96h-LC50 (*Rainbow trout*) = 1.67 mg/L (water of medium hardness) or 0.53 g/L (water of high hardness)

For details see Section A.7.4.1.1/01.

8.7 Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances (IIA8.7)

The substance Iodine falls within the scope of List 2, sub-point 2 "Biocides and their derivatives not appearing in list 1".

Reference list:
Information presented above based on the following Documents (Doc-No. as provided):

Doc. No. 953-003; Section A.8/01
Doc. No. 950-002; Section A.8/02
Doc. No. 953-006; Section A.8/03

Evaluation by Competent Authorities

Section A8 Measures necessary to protect man, animals and the environment

		Official use only
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	not relevant	
Materials and methods		
Results and discussion		
Conclusion		
Reliability		
Acceptability	*acceptable*	
Remarks		

Section A9 Classification and labelling

Current classification

Harmonised classification of iodine in Regulation (EC) No 1272/2008, Annex VI, Table 3.2 (in accordance with the criteria in Directive 67/548/EEC)

Xn; R20/21 Harmful by inhalation and in contact with skin

N; R50 Very toxic to aquatic organisms

Labelling in Annex VI, Table 3.2

Xn, N

R: 20/21-50

S: (2-)25-23- 61

Harmonised classification of iodine in Regulation (EC) No 1272/2008, Annex VI, Table 3.1 (in accordance with the criteria in that Regulation). The classification for acute toxicity is minimum classification based on a translation in accordance with Annex VII to Regulation (EC) No 1272/2008. The actual hazard class cannot be determined since no LD/LC_{50}-values are available.

Acute Tox. 4 *; H332

Acute Tox. 4 *; H312

Aquatic Acute 1; H400

M=1

Labelling in Annex VI, Table 3.1

GHS07, GHS09

Wng

H332, H312, H400

Proposed classification

Due to the experience with iodine and observed skin, eye and respiratory irritational effects, the following additional classification is proposed:

Xi

R: 36/37/38

Eye irrit. 2; H319

STOT SE 3; H335

Skin Irrit. 2; H315