Common Implementation Strategy for the Water Framework Directive

Environmental Quality Standards (EQS)

Substance Data Sheet

Priority Substance No. 19

Isoproturon

CAS-No. 34123-59-6

Final version
Brussels, 31 July 2005

Disclaimer

This data sheet provides background information on the setting of the Environmental Quality Standard in accordance with Article 16 of the Water Framework Directive (2000/60/EC). The information was compiled, evaluated and used as outlined in the Manual [4] and has been discussed in a consultative process with the Expert Advisory Forum on Priority Substances and the Expert Group on Quality Standards. Furthermore, it has been peer-reviewed by the SCTEE [6]. The substance data sheet may, however, not necessarily represent the views of the European Commission.

New upcoming information was considered and included up to the date of finalisation of this data sheet. Information becoming available after finalisation of this document will be evaluated in the review process of priority substances according to Art. 16(4) of the Water Framework Directive. If necessary, the Environmental Quality Standard substance data sheets will then be revised in the light of technical and scientific progress.

1 Identity of substance

Priority Substance No: 19	Isoproturon
CAS-Number:	34123-59-6
Classification WFD Priority List*:	WFD_PSR

* PS: priority substance; PHS: priority hazardous substance; PSR: priority substance under review according to Decision 2455/2001.

2 Proposed quality standards

2.1 Overall quality standards

Ecosystem	**Quality Standard**	**Quality Standard "rounded values"**	**Comment**
AA-QS all surface waters covered by the WFD	0.32 µg/l	**0.3 µg/l**	See 8.1
MAC-QS (ECO)	1.0 µg/l	**1.0 µg/l**	See 8.1

2.2 Specific quality standards

Protection Objective	**Quality Standard**	**Comment**
Pelagic community (freshwater, transitional, coastal and territorial waters)	0.32 µg/l	See 8.1
Benthic community	not required	trigger values not met (see 8.2)
Predators (second. poisoning)	not required	trigger values not met (see 8.3)
Food uptake by man	0.91 mg/ kg (food originating from aquatic environments)	see 8.4
Abstraction of water intended for human consumption (AWIHC)	< 1 µg/l	A1-value for Σpesticides in CD 75/440/EEC; see section 8.5
Water intended for human consumption (WIHC)	0.1 µg/l	Drinking water standard set in CD 98/83/EC

3 Classification

R-Phrases and Labelling	Reference
Carc. Cat. 3; R40 - N; R50-53	[8]

4 Physical and chemical properties

Property	Value	Ref.
Vapour pressure (in Pa, state temperature)	2.8-8.1 $\times$ 10^{-6} at 20°C	[1]
Henry's law constant (Pa m^3 mol^{-1})	1.46 $\times$ 10^{-5} at 22 °C	[1]
Solubility in water (g/l or mg/l, state temperature)	70.2 mg/l (purity 1000 g/kg), no pH dependency	[1]
Dissociation constant	no dissociation	[1]

5 Environmental fate and partitioning

Property	Value	Ref.
Hydrolytic stability (DT_{50})	pH 5 (25 °C): 1210 d pH 7 (25 °C): 1560 d pH 9 (25 °C): 540 d	[1] [1] [1]
Photostability (DT_{50}) (aqueous, sunlight, state pH)	72 – 88 d (Xenon lamp, 25 °C, pH 7, irradiation corresponding to sunlight 52 °N, June) 48 d (Xenon lamp, 26.5 °C, pH 7, irradiation corresponding to sunlight 40 °N, equinox) 4.5 d (Xenon lamp, 26.5 °C, purified water, irradiation corresponding to sunlight 40 °N, equinox)	[1]
Readily biodegradable (yes/no)	no data submitted	[1]
Degradation in water/sediment - DT_{50} water - DT_{90} water - DT_{50} whole system - DT_{90} whole system	20 – 61 d (mean: 42, median: 42, n = 6) 111 – 223d (mean: 161, median: 164, n=4, DT_{90} could not be calculated in 2 studies) 44 – 276 d (mean: 149, median: 133, n = 6) 145 – 237 d (mean: 178, median: 152, n=43, DT_{90} could not be calculated in 3 studies)	[1]
Mineralization	2 – 39% AR (100 d)	[1]
Distribution in water / sediment systems (active substance)	distribution of applied radioactivity (water/sediment): max. fraction in sediment during the studies: 69.1 % AR / 32.6 % AR (30 d) 60.5 % AR / 55.8 % AR (30 d) 53.3 % AR / 53.8 % AR (60 d) 24.5 % a.s. / 69.0 % a.s. (65 d) distribution at 100 d or at the end of study: 14.6 % AR / 7.5 % AR (120 d) 61.6.% AR / 13.4 % AR (120 d) 52.0 % AR / 53.0 % AR (100 d) 47.7 % AR / 49.9 % AR (100 d) 21.6 % a.s. / 63.9 % a.s. (100 d)	[1]
Partition co-efficient (log P_{OW})	2.5 at 25°C, no pH dependency	[1]
BCF (fish)	2.6 – 3.6 (Rainbow trout, OECD 305)	[1]

6 Effect data (aquatic environment)

Table 6.1: (source: Listing of End-Points, 7 March 2001) [1]

Toxicity data for aquatic species (most sensitive species of each group) [1] (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Laboratory tests				
O. mykiss	isoproturon	Acute	mortality	18
O. mykiss	isoproturon	Long-term	growth	1
D. magna	isoproturon	Acute	immobilisation	0.58
D. magna	isoproturon	Chronic	reproduction	0.12
S. subspicatus	isoproturon	Chronic	biomass	0.021 *
N. pelliculosa	isoproturon	Chronic	biomass	0.013 *
C. riparius	isoproturon	Long-term	emergence	0.5
C. riparius	isoproturon	Long-term	emergence	0.344 calculated
L. minor	isoproturon	Chronic	content of chlorophyll	0.031
O. mykiss	N-Desmethyl-Isop.	Acute	mortality	32
D. magna	N-Desmethyl-Isop.	Acute	immobilisation	16
A. bibraianus	N-Desmethyl-Isop.	Chronic	biomass	0.32
L. gibba	N-Desmethyl-Isop	Long-term	biomass	0.081
N. pellicculosa	N-Desmethyl-Isop	Chronic	biomass	0.052
O. mykiss	Arelon (formulated product)	Acute	mortality	309-556
D. magna	Arelon	Acute	immobilisation	>1000
S. subspicatus	Arelon	Acute	biomass	0.078
Microcosm or mesocosm tests				

* The values given are no NOECs but EC50s

Table 6.2: Algae chronic NOECs (Annex B.8 Ecotoxicology, 27 July 1999[1])

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Algae NOECs				
S. subspicatus	isoproturon	Chronic (72h)		0.0032
S. capricornutum	isoproturon	Chronic (72h)	biomass	0.01

Table 6.3: Toxicity data for marine organisms

Scientific Name	Common Name	Test Duration	Endpoint	Toxicity (mg/L)	Endpoint	[Ref.]
Phaeodactylum tricornutum	Diatom (Alga)	96 hrs	NOEC EC10 EC50	0.0057 0.0081 ≥ 0.010	Growth rate	[7]
Chaetoceros calcitrans	Diatom (Alga)	21 d	EC50	0.078	population growth rate	[5]
Isochrysis galbana	Haptophyte (alga)	21 d	EC50	0.017	population growth rate	[5]
Crassostrea gigas	Pacific oyster (mollusc)	9 d	EC10	0.25	growth	[5]
Crassostrea gigas	Pacific oyster (mollusc)	9 d	LC50	0.37	mortality	[5]
Crassostrea gigas	Pacific oyster (mollusc)	48 hrs	NOEC LOEC EC10 EC50	0.098 0.150 ≥ 0.520 ≥ 0.520	Larval development	[7]
Psammechinus miliaris	Green sea urchin (echinodermata)	48 hrs	NOEC EC10 EC50	0.310 0.503 > 0.555	Larval development	[7]

6.1 Summary on endocrine disrupting potential

The endocrine disrupting potential of Isoproturon is apparently not relevant. The substance is not mentioned in reference [2].

7 Effect data (human health) [1]

Since the carcinogenic activity of isoproturon in rats is the most crucial effect, it is considered appropriate to use the NOAEL from the long-term studies in rats (NOAEL: 80 ppm, equivalent to 3.1 mg/kg bw/d) for the calculation of an ADI for consumers. In view of the carcinogenic effects of isoproturon it is considered appropriate to apply a higher assessment factor of 200.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI	0.015 mg/kg bw/d	2-year rat	200

8. Calculation of quality standards

8.1 Quality standards for water

Freshwater

Chronic NOECs are available for algae, higher plants, crustaceans and fish. The lowest chronic endpoint in the "Listing of Endpoints" for Isoproturon (tab. 6.1) is the NOEC of 10 µg/l for reproduction of Daphnia magna. However, as isoproturon is a herbicide and the chronic endpoints for algae in table 6.1 are EC50s, it was considered necessary for the reasons stated in section 8.5 of the final report [4] to extract algae NOECs from Annex B.8 of the isoproturon monograph (listed in table 6.2). As algae are the most sensitive species the lowest NOEC algae (3.2 µg/l) is divided by an assessment factor of 10 (equivalent to the long term TER trigger) in order to derive the long term quality standard for freshwater.

$QS_{freshwater}$ = $NOEC_{algae}$ (3.2 µg/l) / AF (10) = 0.32 µg isoproturon /l

The log Kow is only 2.5 and the water solubility is high. Thus the trigger criterion to calculate a corresponding $QS_{SPM.water}$ referring to the concentration of isoproturon in suspended particulate matter (SPM) is not met.

The metabolites of isoproturon exhibit a lower aquatic toxicity than the parent compound.

Transitional, coastal and territorial waters

Effect data for marine organisms are not provided in the risk assessment monograph of isoproturon as addressing the marine environment is normally not necessary in the context of the risk assessment for plant protection products. However, The Netherlands provided data of 3 short-term tests with the marine species *Phaeodactylum tricornutum* (alga), *Crassostrea gigas* (mollusca) and *Psammechinus miliaris* (echinodermata). These data are presented in table 6.3 together with some further data sets on marine algae and the mollusc *Crassostrea gigas* retrieved from the ECOTOX database of the US-EPA. These data suggest that marine invertebrates and algae species are not more sensitive to isoproturon than freshwater taxa. This is not surprising as isoproturon is a phenyl-urea herbicide with a specific mode of action, affecting photosynthesis. I.e., it interferes with the electron flux in photosystem II (inhibition), by that causing the generation of toxic oxidants. The oxidants damage pigments and membranes, resulting in cell death. Because photosynthesis is the target of toxic action, plants (and algae in particular) are by far the most sensitive aquatic organisms tested. Given the mode of action of isoproturon, it is very improbable that other marine taxa are more sensitive than algae.

The mode of action of isoproturon is known and evidence is available that marine algae are not more sensitive towards this substance than their relatives living in freshwater. Moreover, data of two additional marine groups (molluscs, echinodermata) other than fish, crustaceans and algae are available and these data indicate that the representatives of the additional groups are not more sensitive towards isoproturon than freshwater species. In line with the TGD provisions on marine risk assessment it is therefore suggested to apply an assessment factor of 10 on the lowest long-term NOEC of the combined freshwater and saltwater database. This means to set the same quality standard for transitional, coastal and territorial water as derived for inland waters.

$QS_{saltwater}$ = $QS_{freshwater}$ = 0.32 µg isoproturon /l

Quality standard accounting for transient concentration peaks (MAC-QS)

Acute toxicity data are available for fish, invertebrates and algae, see tables 6.1 & 6.3). The lowest EC50 value is 10 µg/l for the diatom *Phaeodactylum tricornutum* (tab. 6.3).

The MAC-QS is derived on the basis of the EC50 of *P. tricornutum* and the guidance given in the TGD on the effects assessment for intermittent releases (see section 4.3.6 of the Manual [4]). As isoproturon is a herbicide with a specific mode of action and the most sensitive organism is a plant it is suggested to use only a reduced assessment factor of 10 (instead of 100).

MAC-QS = 1.0 µg isoproturon /l

8.2 Quality standard for sediment

Since the log Kow is only 2.5 the calculation of sediment quality standards is not required (trigger value not met).

8.3 Secondary poisoning of top predators

Since the log Kow is only 2.5 and the BCF_{fish} obtained in a study according to OECD guideline 305 was only 2.6 – 3.6 the calculation of a quality standard referring to the protection of top predators from secondary poisoning is not required (trigger value not met).

8.4 Quality standard referring to food uptake by humans

The acceptable daily intake (ADI) for isoproturon was estimated in the risk assessment monograph (15 µg / kg bw d^{-1}) [1].

In the Manual (section 4.3.2.6) [4] it is suggested that the ADI may not be exhausted for more than 10% by consumption of food originating from aquatic sources. For a person weighing 70 kg this results in an acceptable daily intake of 105 µg isoproturon per day.

The average fish consumption of an EU citizen is 115 g d-1 (TGD [3]). Thus, 115 g edible fish tissue (or seafood) must not contain more than 105 µg isoproturon (≈ 0.91 mg/kg).

As the BCF of isoproturon is apparently very low (<10) it is not required to calculate a water concentration corresponding to the maximum acceptable level in biota (as food). The QS_{water} required to protect the aquatic community is by far lower as the concentration not to be exceeded in order to protect human health from adverse effects due to ingestion of food originating from aquatic environments. Thus a quality standard referring to food uptake by humans is not required.

8.5 Quality standard for drinking water abstraction

The imperative A1 value referring to drinking water abstraction by simple treatment is 1 µg/l for the total amount of pesticides (Council Directive 75/440/EEC). The drinking water standard (DWS) set in CD 98/83/EC is 0.1 µg/l for individual pesticides.

The DWS is a limit value never to be exceeded at the tap. The MAC-QS (ECO) derived for the protection of the freshwater community (1.3 µg/l) may therefore not suffice to allow for compliance with the DWS if only simple purification techniques (category A1 of CD 75/440/EEC, i.e. filtration

and disinfection) are used for the abstraction of drinking water from surface water bodies according to Art. 7 of the WFD.

An assessment by experts in drinking water technology with regard to the question which fraction of the amount of isoproturon present in raw water can be removed by usual simple treatment procedures might be helpful. If the respective fraction were known, this figure could be used together with the drinking water standard to set the maximum acceptable concentration in surface water bodies designated for the **a**bstraction of **w**ater **i**ntended for **h**uman **c**onsumption (AWIHC).

MAC-QS (AWIHC) = DWS (0.1 µg/l) / fraction not removable by simple treatment

8.6 Overall quality standard

The QS_{water} referring to the protection of pelagic communities may be considered as overall annual average quality standard (AA-QS) for inland waters as well as transitional, coastal and territorial waters. If the drinking water standard is exceeded in areas designated for the abstraction of water intended for human consumption in accordance with Art. 7 of the WFD, specific measures need to be taken in order to guarantee compliance with the drinking water standard at the tap.

9 References

[1] Isoproturon Monograph, 27 July 1999: Report and Proposed Decision, Annex B (Summary, Scientific Evaluation and Assessment); Listing of End-Points (7 March 2001)

[2] COM(2001)262 final: Communication from the Commission to the Council and the European Parliament on the implementation of the Community Strategy for Endocrine Disrupters – a range of substances suspected of interfering with the hormone system of humans and wildlife.

[3] Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and the Council Concerning the placing of biocidal products on the market. Part II. European Commission Joint Research Centre, EUR 20418 EN/2, © European Communities 2003. Available at the internet-site of the European Chemicals Bureau: http://ecb.jrc.it/existing-chemicals/

[4] Manual of the Methodological Framework Used to Derive Environmental Quality Standards for Priority Substances of the Water Framework Directive. Peter Lepper, Fraunhofer-Institute Molecular Biology and Applied Ecology, 15 November 2004. Available at the internet-site of the European Commission: http://europa.eu.int/comm/environment/water/water-dangersub/pri_substances.htm

[5] His, E., and M.N.L. Seaman, 1993: Effects of Twelve Pesticides on Larvae of Oysters (Crassostrea gigas) and on Two Species of Unicellular Marine Algae (Isochrysis galbana and Chaetoceros Calcitrans). Int.Counc. for the Exploration of the Sea, ICES-CM-1993/E, Copenhagen, Denmark: 22 p.

[6] Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) on "The Setting of Environmental Quality Standards for the Priority Substances included in Annex X of Directive 2000/60/EC in Accordance with Article 16 thereof", adopted by the CSTEE during the 43rd plenary meeting of 28 May 2004, European Commission Health & Consumer Protection Directorate General, Brussels. http://europa.eu.int/comm/health/ph_risk/committees/sct/documents/out230_en.pdf

[7] AquaSense (2005). Toxicity tests with priority substances in the Water Framework Directive. Sponsor: Institute for Inland Water Management and Waste Water Treatment (RIZA). Report number: 2034

[8] ESIS: European Chemicals Bureau – ESIS (European Substances Information System), July 2005. http://ecb.jrc.it/existing-chemicals/ ⇒ tick ESIS button, then enter CAS or EINECS number of substance.