



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Food Safety: plant health, animal health and welfare, international questions
E1 - Plant health

Isoproturon
SANCO/3045/99-final
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**COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY REPRESENT
THE VIEWS OF THE COMMISSION SERVICES**

Review report for the active substance *isoproturon*

Finalised in the Standing Committee on Plant Health at its meeting on 7 December 2001
in view of the inclusion of isoproturon in Annex I of Directive 91/414/EEC

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of isoproturon, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EEC) No 3600/92⁽¹⁾ laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1972/99⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Isoproturon is one of the 90 existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, Stefes Agro GmbH on 20 July 1993, Rhone-Poulenc Agro on 15 July 1993, United Phosphorus Ltd on 26 July 1993, Phytorus SA on 26 July 1993, Gharda Chemicals Ltd on 19 July 1993, Cequisa on 23 July 1993, AgrEvo GmbH on 27 July 1993, I.Pi.Ci. Industria Prodotti Chimici on 30 July 1993, Barclay Chemicals on 27 June 1993, ACI International on 30 July 1993, Chimac-Agriphar SA on 27 July 1993, SANC on 23 July 1993, Makhteshim Agan on 20 July 1993, Stefes Research GmbH on 9 July 1993, AgriChem on 15 July 1993, Portman Agrochemicals on 26 July 1993, Helm AG on 23 July 1993, Calliope SA on 21 July 1993, Industrias Afrasas on 27 July 1993 and B.V. Luxan on 21 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance isoproturon in Annex I to the Directive.

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 244, 16.09.1999, p.41.

In accordance with the provisions of Article 5 of Regulation (EEC) No 3600/92, the Commission, by its Regulation (EEC) No 933/94⁽³⁾, as last amended by Regulation (EC) No 2230/95⁽⁴⁾, designated Germany as rapporteur Member State to carry out the assessment of isoproturon on the basis of the dossiers submitted by the notifiers. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for isoproturon this deadline was 31 October 1995.

Rhone-Poulenc Agro on behalf of the isoproturon task force (comprising Rhone-Poulenc Agro and AgrEvo), Phytorus SA, Gharda Chemicals Ltd, Barclay Chemicals, ACI International and Makhteshim Agan submitted each a dossier to the rapporteur Member State. The isoproturon task force was considered as main data submitter, with a dossier which did not contain substantial data gaps, taking into account the supported uses. Phytorus SA, Gharda Chemicals Ltd, Barclay Chemicals, ACI International and Makhteshim Agan did not submit complete dossiers.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Germany submitted on 30 July 1999 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of isoproturon in Annex I to the Directive. Moreover, in accordance with the same provisions, the Commission and the Member States received also the summary dossier on isoproturon from the isoproturon task force, on 23 September 1999.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States as well as to Aventis being the main data submitter, on 20 September 1999.

The Commission organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines:

- identity and physical /chemical properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Pesticide Safety Directorate (PSD) in York, United Kingdom, from November 1999 to July 2000.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 12 January 2001 for comments and further clarification.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the Standing Committee on Plant Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from February to December 2001, and was finalised in the meeting of the Standing Committee on 7 December 2001.

The present review report contains the conclusions of this final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the peer review as basic information for the final examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

The review did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, have been developed and finalised in support of the Directive 2002/18/EC⁵ concerning the inclusion of isoproturon in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing isoproturon they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 7(6) of Regulation (EEC) No 3600/92, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request. Moreover the Commission will send a copy of this review report (not including the background documents) to all operators having notified for this active substance under Article 4(1) of this Regulation.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

⁵ OJ L 55, 26.02.2002 p.29

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing isoproturon will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each isoproturon containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the following uses which were proposed and supported by the main data submitter:

- herbicide against weeds in cereals

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) for a 60 kg adult is 6 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water and products of animal origin are not expected to give rise to intake problems.

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4 (1) (b) (iv) and (v) of Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 6 of this report.

4. Identity and Physical/chemical properties

The identity and the main physical/chemical properties of isoproturon are given in Appendix I. The active substance shall comply with the FAO specification (AGP: CP/250) and there seem not to be reasons for deviating from that specification; the FAO specification is given in Appendix I of this report.

The review has established that for the active substance notified by the main data submitter Aventis, none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

In accordance with the provisions of Article 13(5) of Directive 91/414/EEC, Germany is also satisfied, on the basis of the information currently available, that the substances notified by the

other data submitters (Phytorus SA, Gharda Chemicals Ltd, Barclay Chemicals, ACI International and Makhteshim Agan) do not, in the meaning of Article 13(2) and (5) of the Directive, differ significantly in degree of purity and nature of impurities from the composition registered in the dossier submitted by the main data submitter.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints as identified during the re-evaluation process are set out under point 1 above. These endpoints are listed in Appendix II.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing isoproturon

On the basis of the proposed and supported uses (maximum application rate 1.5 kg isoproturon/ha, single application), the following particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- Leaching to groundwater: Particular attention should be given to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions and risk mitigation measures should be applied where appropriate.
- Surface water: Member States must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.

7. List of studies to be generated

No further studies were identified which were at this stage considered necessary in relation to the inclusion of isoproturon in Annex I under the current inclusion conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions.

8. Information on studies with claimed data protection

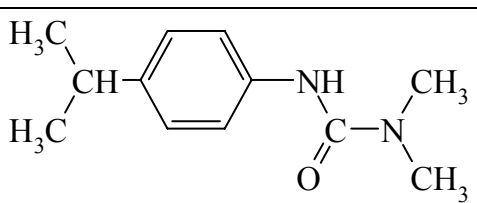
For information of any interested parties, Appendix III gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available to the Commission services at the

time this review report was prepared; but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC neither does it commit the Commission.

9. Updating of this review report

The technical information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations will be examined and finalised in the Standing Committee on Plant Health, in connection with any amendment of the inclusion conditions for isoproturon in Annex I of the Directive.

APPENDIX I**Identity, physical and chemical properties****ISOPROTURON**

Common name (ISO)	Isoproturon
Chemical name (IUPAC)	3-(4-isopropylphenyl)-1,1-dimethylurea
Chemical name (CA)	<i>N,N</i> -dimethyl- <i>N'</i> -[4-(1-methylethyl)phenyl]urea
CIPAC No	0336
CAS No	34123-59-6
EEC No	251-835-4
FAO SPECIFICATION	AGP:CP/250 (1990)
Minimum purity	970
Molecular formula	C ₁₂ H ₁₈ N ₂ O
Molecular mass	206.3
Structural formula	

Melting point	156.5-158 (992-996 g/kg)
Boiling point	Not required.
Appearance	slightly yellowish powder (995 g/kg)
Relative density	1.161-1.187 (996-995 g/kg)
Vapour pressure	$2.8 - 8.1 \times 10^{-6}$ at 20°C
Henry's law constant	1.46×10^{-5} at 22 °C
Solubility in water	70.2 mg/l (purity 1000 g/kg), no pH dependency
Solubility in organic solvents	n-heptane < 0.1 g/l; methanol 70 g/l; methanol 40 g/l; acetone 30 g/l; xylene 2 g/l; 1,2-dichloroethane 46 g/l
Partition co-efficient (log P_{ow})	2.5 at 25°C, no pH dependency
Hydrolytic stability (DT₅₀)	pH 5 (25 °C): 1210 d
	pH 7 (25 °C): 1560 d
	pH 9 (25 °C): 540 d
Dissociation constant	no dissociation
Quantum yield of direct photo-transformation in water at $\epsilon > 290$ nm	$2.1 - 2.6 \times 10^{-6}$ (polychromatic light, 25 °C, pH 7) 3.57×10^{-6} (polychromatic light, 26.5 °C, pH 7) 3.33×10^{-5} (polychromatic light, 26.5 °C, purified water) 3.9×10^{-3} (304 nm)
Flammability	not highly flammable
Explosive properties	Not explosive.
UV/VIS absorption (max.)	Max.: 207.8 nm ($\epsilon = 32512 \text{ l mol}^{-1} \text{ cm}^{-1}$), 241.5 nm ($\epsilon = 1972 \text{ l mol}^{-1} \text{ cm}^{-1}$) ϵ (295 nm) = $550 \text{ l mol}^{-1} \text{ cm}^{-1}$
Photostability in water (DT₅₀)	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)

APPENDIX II**END POINTS AND RELATED INFORMATION****ISOPROTURON****1 Toxicology and metabolism****Absorption, distribution, excretion and metabolism in mammals**

Rate and extent of absorption:	90% based on urinary excretion in 24 h
Distribution:	Widely and evenly distributed
Potential for accumulation:	No accumulation
Rate and extent of excretion:	Completely within 3 days, mainly via urine (> 85%)
Toxicologically significant compounds:	Parent compound and metabolites
Metabolism in animals:	Completely metabolised Oxidation of the isopropyl group, N-demethylation No aniline derivatives detected in urine and faeces

Acute toxicity

Rat LD ₅₀ oral:	>2000 mg/kg bw
Rat LD ₅₀ dermal:	>2000 mg/kg bw
Rat LC ₅₀ inhalation:	>1.95 mg/l (4h, whole body exposure, aerosol)
Skin irritation:	Non-irritant.
Eye irritation:	Non-irritant.
Skin sensitization (test method used and result):	Non-sensitising (M&K).

Short term toxicity

Target / critical effect:	Red blood cells (haemolytic effects, methaemoglobin formation, haemosiderin deposition), liver (degeneration of hepatocytes)
Lowest relevant oral NOAEL / NOEL:	3 mg/kg bw/d (50 ppm); 30-day & 90-day dog studies
Lowest relevant dermal NOAEL / NOEL:	1000 mg/kg bw/d: 90-day rabbit study
Lowest relevant inhalation NOAEL / NOEL:	>0.25 mg/l; 14-day rat study

Genotoxicity

Negative in standard <i>in vitro</i> and <i>in vivo</i> assays
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Long term toxicity and carcinogenicity

Target / critical effect:

Red blood cells (haemolytic effects), liver (pre-neoplastic foci, hepatocellular tumours and cholangiocarcinoma)
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Lowest relevant NOAEL:

3.1 mg/kg bw/d (80 ppm); 2-year rat study

Carcinogenicity:

Hepatocellular tumours and cholangiocarcinomas in rats.

Reproductive toxicity

Target / critical effect - Reproduction:

Reduced litter size and pup weight at maternally toxic doses
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Lowest relevant reproductive NOAEL / NOEL:

10 mg/kg bw/d (100 ppm); 2-generation rat study

Target / critical effect - Developmental toxicity:

Developmental retardation at maternally toxic doses No evidence of teratogenicity
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Lowest relevant developmental NOAEL / NOEL:

40 mg/kg bw/d; rabbit study

Delayed neurotoxicity

No indications of delayed neurotoxicity in the hen or standard tests
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Other toxicological studies

Mechanistic studies indicate enzyme induction and foci-promoting/foci-initiating activity in rat liver. Metabolite desmethylisoproturon: LD50, rat, oral = 541 mg/kg bw; no mutagenic activity in bacteria (<i>S. typhimurium</i> , <i>E. coli</i>).
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Medical data

No toxic effects reported in manufacturing plant personnel
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Summary

	Value	Study	Safety factor
ADI:	0.015 mg/kg bw/d	2-year rat	200
AOEL systemic:	0.015 mg/kg bw/d	90-day dog	200
ARfD (acute reference dose):	Not allocated - not necessary		

Dermal absorption

17% used for operator exposure assessment (supported by comparison of dermal and oral toxicity)

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

10 - 22 % AR (ring label)

Non-extractable residues after 100 days:

56 – 68 % AR (ring label)

Major metabolites above 10 % of applied active substance: name and/or code
% of applied rate (range and maximum)

Desmethylisoproturon (M1):
max. 14 % AR (8 d, ring label)

Supplemental studies

Anaerobic:

stable under anaerobic conditions (92 %
remained in the system after 119 days)

Soil photolysis:

stable to photolysis (90 % remained after 30
days)

Remarks:

None.

Rate of degradation

Laboratory studies

DT_{50lab} (20 °C, aerobic):

DT_{50lab} (20°C, aerobic):
7.2 – 18.2 d (1st order, n = 14, mean: 12.6 d,
median: 11.9 d, ring label)

Metabolite Desmethylisoproturon (M 1):

DT_{50lab} (20°C, aerobic):
22 - 40 d (best fit, n = 4, mean: 32, median 33,
ring label),
22 - 65 d (1st order, mean: 47, median: 50)

DT_{90lab} (20 °C, aerobic):

DT_{90lab} (20°C, aerobic): 23.8-111.1 d (n = 14,
mean: 45.8 d, median: 39.2 d)

DT_{50lab} (10 °C, aerobic):

DT_{50lab} (10°C, aerobic): 27-53 d (n = 4)

DT_{50lab} (20 °C, anaerobic):

DT_{50lab} (20°C, anaerobic): no significant
degradation

Field studies (country or region)

DT_{50f} from soil dissipation studies:

DT_{50f}: 12 – 33 d (n = 4), Germany

DT_{90f} from soil dissipation studies:

DT_{90f}: 34 – 68 d (n = 4), Germany

Soil accumulation studies:

Not relevant.

Soil residue studies:

Not relevant.

Remarks:

e.g. effect of soil pH on degradation rate

None.

Adsorption/desorption K_f / K_{oc} :isoproturon:
 K_f : 0.26 – 27.1 / K_{oc} : 36 – 241 (mean: 122,
median: 104, n = 22)
no pH dependence K_d

pH dependence:

metabolite Desmethylisoproturon (M1):
 K_f : 1.07-4.4 / K_{oc} : 84 – 232 (mean: 147, median:
136, n = 4)
no pH dependence**Mobility****Laboratory studies:**

Column leaching:

< 0.5 – 37 % AR (isoproturon), up to 5
unidentified metabolites

Aged residue leaching:

< 0.8 – 1.5 % AR (isoproturon), over 2 days
9.4 % AR (total; contains up to 21.8 %
isoproturon + up to 26.5 % of 6 unidentified
metabolites), over 12 days**Field studies:**

Lysimeter/Field leaching studies:

autumn application: 1.5 kg as/ha, 2 lysimeters
over 2.5 years, metabolites M 1 and M 3 have
been determined during the second year only
average annual concentration of a.s.: 0.02, 0.25,
0.14 and 0.06 µg/l
average annual concentration of M 1 + M 3
(combined): 0.051 and 0.022 µg/l
spring application: 1.5 kg as /ha, 2 lysimeters
over 2 years, metabolites M 1 and M 3 have
been determined during the second year only
average annual concentration of a.s.: 0.20, 0.08,
0.02 and 0.01 µg/l.
average annual concentration of M 1 + M 3
(combined): 0.000 and 0.016 µg/l**Remarks:**

None.

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

pH 5 (25 °C): 1210 d
pH 7 (25 °C): 1560 d
pH 9 (25 °C): 540 d

Major metabolites:

None

Photolytic degradation:

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)

Major metabolites:

No data

Biological degradation

Readily biodegradable:

Not readily biodegradable.

Water/sediment study:

20 – 61 d (mean: 42, median: 42, n = 6)
111 – 223d (mean: 161, median: 164, n=4, DT₉₀ 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, DT₉₀ could not be calculated in 3 studies)

DT₅₀ water:

DT₉₀ water:

DT₅₀ whole system:

DT₉₀ whole system:

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)

Distribution in water / sediment systems
(Major metabolite)

Desmethylisoproturon (M1)
Up to 19.2 % AR in the water phase (60 d)
Up to 6.8 % AR in sediment (60 d)
All other metabolites < 10 % AR, unknown compounds in water max. 16 % AR (120 d)

Accumulation in water and/or sediment:

Not relevant

Degradation in the saturated zone

No data.

Remarks:

None.

2.3 Fate and behaviour in air**Volatility**

Vapour pressure:

2.8 - 8.1 X 10⁻⁶ at 20°C

Henry's law constant:

1.46 x 10⁻⁵ at 22°C**Photolytic degradation**

Direct photolysis in air:

No data.

Photochemical oxidative degradation in air
DT₅₀:DT₅₀ = 3 – 4.7 h (24h-day, 5.0*10⁵ OH/cm³)
calculated from UV absorption coefficient and
quantum yield (according to Frank & Klöpffer)

Volatilisation:

from plant surfaces: 0.4 % AR
from soil: 0.04 – 0.25 % AR

Remarks:

None.

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD ₅₀ 1826 mg/kg bw
Acute toxicity to birds:	LD ₅₀ 1401 mg/kg bw
Dietary toxicity to birds:	LC ₅₀ > 5000 ppm
Reproductive toxicity to birds:	NOEC 130 ppm
Short term oral toxicity to mammals:	LD ₅₀ > 2000 mg/kg bw (rat)
Long-term toxicity mammals	NOEL 100 ppm (rat, 2-generation study)

Aquatic Organisms

Acute toxicity fish:	18 mg/L (mortality)
Long term toxicity fish:	1 mg/L (growth)
Bioaccumulation fish:	Not relevant.
Acute toxicity invertebrate:	0.58 mg/L (immobilisation)
Chronic toxicity invertebrate:	0.12 mg/L (reproduction, <i>D. magna</i>)
Acute toxicity algae:	0.013 mg/L (<i>N. pelliculosa</i>)
Chronic toxicity sediment dwelling organism:	0.344 mg/L (emergence; calculated)
Acute toxicity aquatic plants:	0.031 mg/L (<i>L. minor</i>)
Acute toxicity fish (N-Desmethyl-IPU)	32 mg/L (<i>O. mykiss</i>)
Acute toxicity invertebrates (N-Desmethyl-IPU)	16 mg/L (<i>D. magna</i>)
Chronic toxicity algae (N-Desmethyl-IPU)	0.052 mg/L (<i>N. pelliculosa</i>)
Long-term toxicity aquatic plants (N-Desmethyl-IPU)	0.081 mg/L (<i>L. gibba</i>)

Honeybees

Acute oral toxicity:	LD ₅₀ 195 µg/bee
Acute contact toxicity:	LD ₅₀ 200 µg/bee

Other arthropod species

Test species	Stage/application rate/test substance	% Effect
<i>Typhlodromus pyri</i>	nymph 2.5 kg as/ha 500g as/l SC	16 (mortality) 27 (fertility)
<i>Typhlodromus pyri</i>	nymph	3 (mortality)

Test species	Stage/application rate/test substance	% Effect
	0.12 kg as/ha 500g as/l SC	16 (fertility)
<i>Aphidius rhopalosiphi</i>	adult 2.5 kg as/ha 500g as/l SC	7 (mortality) 30 (fertility)
<i>Aphidius rhopalosiphi</i>	adult 1.8 kg as/ha 500g as/l SC	21 (mortality) 22 (fertility)
<i>Aphidius rhopalosiphi</i>	adult 0.12 kg as/ha 500g as/l SC	0 (mortality) 1 (fertility)
<i>Chrysoperla carnea</i>	larvae 1.5 kg as/ha 500g as/l SC	10 (mortality) 0 (fertility)
<i>Aleochara bilineata</i>	adult 1.5 kg as/ha 500g as/l SC	0 (parasitism capacity)
<i>Aleochara bilineata</i>	cyclus 2.0 kg as/ha 500g as/l SC	0 (parasitism capacity)
<i>Aleochara bilineata</i>	cyclus 2.16 kg as/ha 500g as/l SC	57 (parasitism capacity)
<i>Poecilus cupreus</i>	adult 1.5 kg as/ha 500g as/l SC	0 (mortality) 0 (food uptake)
<i>Poecilus cupreus</i>	adult 2.0 kg as/ha 500g as/l SC	0 (mortality) 0 (food uptake)
<i>Poecilus cupreus</i>	adult 2.16 kg as/ha 500g as/l SC	4 (mortality) 3 (food uptake)
<i>Pardosa spp.</i>	immature 1.8 kg as/ha 500g as/l SC	10 (mortality) 0 (food uptake)

Earthworms

Acute toxicity:

Acute toxicity (N-Desmethyl-IPU)

Reproductive toxicity:

LC ₅₀ > 1000 mg as/kg dry soil
LC ₅₀ 180 mg/kg dry soil
Not relevant

Soil micro-organisms

Nitrogen mineralization:

No chronic effect up to 3.0 kg as/ha (Isoproturon) No effect up to 12.5 kg as/ha (Formulation)
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Carbon mineralization:

No effect up to 3.0 kg as/ha (Isoproturon) No effect up to 12.5 kg as/ha (Formulation)

APPENDIX IIIA

ISOPROTURON

List of studies for which the main submitter has claimed data protection and which during the re-evaluation process were considered as essential for the evaluation with a view to Annex I inclusion¹.

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
AIIA, 4.2.1	LeBrun, G.	2000	Independent laboratory validation of analytical method AR-118-95 for the determination of isoproturon in animal products C010029 MET2000-408	2000-08-09
AIIA-1.10; AIIA-1.11	Baccaini, S., J.Cousin, R., Reynaud and M.H. Valcarce	1994	Technical Isoproturon- analysis and certification of product ingredients, Owner: RPA Unpublished report from Rhone- Poulenc Ref. R&D/CRLD/AN/9416281, September 9, 1994 (Description of the method „watwe“, „Volatile“ and „Chlorids) (See Document J) CHE96-00957	
AIIA-1.11	Challis,B.C. and U. Howell	1994	Total nitrosamine assays of Rhone- Poulenc Isoproturon-samples DA901-905, Unpublished report Ref. R&D/CRLD/AN/9416486 from Open University Chemistry Department, Walton Hall, Milton Keynes, MK7 6AA, UK, September 1994 (Submitted with Document J) Owner: RPA CHE96-00958	

¹ List based on a detailed analysis from the Rapporteur Member State.

² Reports received from Member States at the date of finalisation of the present review report (not exhaustive).
Dates referring to Germany indicate the submission for the national authorization

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports² on previous use in granting national authorizations
AIIA-1.11	Reynaud, R. and Cousin, J.	1994	Technical Isoproturon - HPLC determination of Fenuron and LS 700682. Owner:RPA R&D/CRLD/AN/9416284 not GLP, unpublished CHE96-00956	
AIIA-1.11	Reynaud, R. and Cousin, J.	1994	Technical Isoproturon - HPLC determination of RPA 406350 and RPA 408743. Owner: RPA R&D/CRLD/AN/9416283 not GLP, unpublished CHE96-00955	
AIIA-1.11	Reynaud, R. and Cousin, J.	1994	Technical Isoproturon - HPLC determination of LS 710670 and LS 700917. Owner: RPA R&D/CRLD/AN/9416282 not GLP, unpublished CHE96-00954	
AIIA-2.1; AIIA-2.2; AIIA-2.4	Cousin, J. and Baccaini, S.	1994	Isoproturon active ingredient, physical characteristics and stability. Owner: RPA R&D/CRLD/AN/9415563 GLP, unpublished CHE96-00917	
AIIA-2.10; AIIA-7.2.1.2	Maestracci, M.	1994	Isoproturon - Estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions. Owner: RPA R&D/CRLD/AN/9415502 GLP, unpublished LUF95-00135	1995-04-21
AIIA-2.11	Fillion, J.	1996	Determination of the relative self-ignition temperature of Isoproturon. Owner: RPA 95-081-SEC GLP, unpublished CHE96-00931	
AIIA-2.13	Francois, J.M.	2000	Isoproturon- Flammability, explosives and oxidizing properties. Doc number 447930 CHE2000-1198	WA1004278 09.08.00

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports² on previous use in granting national authorizations
AIIA-2.14	Cousin, J.	1998	Isoproturon active ingredient-surface tension Unpublished Report RD/CRLD/AN/9815251 from Rhone-Poulenc Agro, March 20, 1998 Owner: RPA CHE2000-1197	
AIIA-2.6	Certon, A. and Cousin, J.	1995	Isoproturon active ingredient, Water and solvent solubility. Owner: RPA 9516539 GLP, unpublished CHE96-00924	
AIIA-2.8	Guillot, J. and Cousin, J.	1995	Isoproturon active ingredient, n-Octanol/Water partition coefficient. Owner: RPA 9516538 GLP, unpublished CHE96-00928	
AIIA-2.9	Cousin, J.	1994	Isoproturon - Dissociation constant. R&D/CRLD/AN/9416872 Owner: RPA not GLP, unpublished WAS95-00196	1995-04-21
AIIA-2.9; AIIA-7.2.1.2	Bürkle, W.L.	1992	Direct photolysis of the 14C-labelled active ingredient in aqueous solution, degradation kinetics and quantum yield. Owner: RPA A50359 GLP, unpublished WAS95-00197	1995-04-21
AIIA-3.0; AIII 6.6	Rosinger C.	2000	Selectivity threshold for Isoproturon in various crops ED10 values in soil. Aventis CropScience Frankfurt C009673, 12.09.00	NL 043183 10.10.00
AIIA-3.4.2	Turner, M. T. F.	1999	The herbicidal activity of the monomethyl metabolite of isoproturon (LS 700682), compared to the parent material (isoproturon): Glasshouse test – UK 1999 202282 BIO2000-456	2000-03-20

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ² on previous use in granting national authorizations
AIIA-4.2.1	Martial, F., Venet, C. and Simonin, B.	1996	Analytical method for the determination of residues in animal products; Ref. AR 118-95 Owner: ROP. unpublished MET96-00214	
<i>This method will be considered provided MRL's will be proposed by the residue group.</i>				
AIIA-4.2.1	Müller, M.A.	1996	Determination of isoproturon residues in cereals ; Ref. RI 3785, 1985, 30 January 1996 ; Addendum recalculation of recovery experiments, Ref. PA/AM/96/02. Owner: ROP unpublished MET96-00180	
AIIA-4.2.1	Müller, M.A.	1996	Determination of isoproturon residues in cereals ; Ref. RI 3685, 1985, 30 January 1996 ; Addendum recalculation of recovery experiments, Ref. PA/AM/96/01. Owner: ROP unpublished MET96-00179	
AIIA-4.2.1	Müller, M.A.	1996	Determination of Isoproturon residues in cereals. Unpublished report from Rhone Poulenc Ref. PA/AM/01/96 30 January 1996 MET9600179	1996-01-31
AIIA-4.2.2	Wrede, A.	1995	Residue analysis of Isproturon in irrigation and drainage water and soil smples (Drainage study) Unpublished report from AgrEvo (addendum Recalculation of recovery experiments) Internal Hoechst Ref. No. A55919), 19.12.1995 MET9600183	1996-01-31
AIIA-4.2.2	Zimmermann, U.J.	2000	Enforcement method and validation for soil by GC. Isoproturon (AE F016410). Doc no.: C009023 MET2000-409	WA1004278 09.08.00
AIIA-4.2.3	Müller, M.A.	1996	Analytical method for the determination of isoproturon residues in waters, Ref. method AR87-91E; Addendum recalculation of recovery experiments, Ref. PA/AM/96/03. Onwer: ROP unpublished MET96-00184	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports² on previous use in granting national authorizations
AIIA-4.2.3	Neuss, B.	2000	Enforcement Method and Validation for Surface and Drinking Water by GC/NPD Isoproturon (AE F016410) C008854 MET2000-410	2000-08-09
AIIA-4.2.3	Royer, A. and Le Brun, G.	1999	Development and Validation of a Method of Analysis for the Determination of Monomethyl Isoproturon in Waters Owner: ROP Study 99-120, Method AR 216-99. unpublished MET2000-122	
AIIA-4.2.3	Royer, A. and LeBrun, G.	1999a	Development and validation of a method of analysis for the determination of monomethyl isoproturon in soils 446818 MET2000-121	2000-03-10
AIIA-4.2.4	LeBrun, G.	2000	Development of a confirmatory method for the determination of isoproturon in air C010027 MET2000-407	2000-08-09
AIIA-4.2.4	Reichert, N.	1993	Methodenvalidierung zur Bestimmung von Isoproturon (Hoe 016410) und Monolinuron (Hoe 002747) in Luft; Internal Hoechst Ref A 51490 Owner: ROP RCC Projekt 413504. unpublished MET96-00190	

B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
All, 5.1	Filaquier	1996	Isoproturon: Adsorption, Distribution, Metabolism and Excretion in the rat Document Rhone-Poulenc Agrochimie, Centre de Recherches de Sophia Antipolis SA94452 31 May 1996 TOX9651262	1996-06-24
AIIA-5.8.1	<i>Kitching, J., Bouvier, G. and Katchadourian, P.</i>	1999	<i>Monomethyl-Isoproturon: Bacterial Mutation Assay Rhône-Poulenc Agro Doc. No. 604420 GLP, unpublished WAT2000-115</i>	2000-03-10
All, 5.8.1	Dange, M.	2000	Monomethyl-Isoproturon (LS 700683) Acute oral toxicity in the rat <i>Rhône-Poulenc Agro Doc. No. 604290 GLP, unpublished TOX2000-1280</i>	2000-03-10
All, 5.10	Urtizberrea, M.	1998	Isoproturon Operator Exposure Study for Groundboom application of Strong 500 in cereal Fields Unpublished report Rhone Poulenc Agro SA 946477 April 10, 1998 TOX2000-9	1999-11-19

B.7 Residue data

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AIIA-6.0	Schneider, E.	1995	Isoproturon –HOE 016410 00 ZB99 0004: Stability of Isoproturon in grain during deep frozen storage. 07.06.1995 Report No. PR 92/038	ZA 004505-00 28.02.1997 RIP9700630

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
All, 7.1.1.2.1	McMillan-Staff, S.	1999	¹⁴ C-Monomethyl-Isoproturon: Rate of Degradation in Four Soils at 20° C RPA Document 202056 GLP, unpublished BOD2000-486	2000-03-20
AIIA- 7.1.1.1.1	McMillan Staff and Knight, S.J.	1999	(14C)-Isoproturon Aerobic soil metabolism. RPA Doc. 201938 Owner: ROP GLP, unpublished BOD1999-782	1999-11-25
AIIA- 7.1.1.1.2	Burr, C.M.	1999	[14C]-Isoproturon Anaerobic soil degradation RPA Document 201797 Owner: ROP GLP, unpublished BOD 1999-783	1999-11-25
AIIA- 7.1.1.1.2	Clarke, D.E. and Metcalf, D.J.	1999	[14C]-Isoproturon: Photodegradation on soil. RPA Document 201894 Owner: ROP GLP, unpublished BOD 1999-784	1999-11-25
AIIA- 7.1.1.2.1	Eißel, H.	1992	The degradation of ¹⁴ C-Isoproturon in soil under aerobic conditions at an application rate of 2.0 mg/kg. Owner: ROP LLFA Neustadt/Weinstraße, Doc No. A48118, not GLP, unpublished BOD2000-472	1999-07-01
AIIA- 7.1.1.2.1	McMillan-Staff, S.L. and Knight, S.J.	1999	[¹⁴ C]-Isoproturon aerobic soil metabolism. RPA Document 201938, Owner: ROP GLP, unpublished BOD 1999-782	1999-11-25
AIIA-7.1.2	Burr, C.M.	1999	[¹⁴ C]-Monomethyl isoproturon Adsorption/desorption to and from four soils. Owner: ROP Study No. 15735, Doc. No. 201897 GLP, unpublished BOD2000-485	2000-03-20

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AIIA-7.1.2	McMillan-Staff, S.L.	1998	[14C]-Isoproturon Aged desorption from four soils Owner: ROP RPA Document 201919 GLP, unpublished BOD 1999-780	1999-07-01
AIIA-7.1.3	Erzgräber, B.	2000	Risk analysis for leaching to ground water of Isoproturon used under different pedo-climatic conditions relevant in major use areas in Europe. Owner: AVD OE00/042, C008435 not GLP, unpublished BOD2000-599	2000-05-25
AIIA-7.1.3	Wicks, R.J.	1998	Isoproturon: Computer simulation of the potential for mobility in soil using the PELMO 2.01 Model. Owner: ROP Rep.No. 16582 not GLP, unpublished BOD1999-277 (BOD1999-44)	1998-11-19
AIIA-7.1.3.3	Idstein, H., Junker, H. and Merz, H.D.	1994	Investigating the Isoproturon discharge by runoff following pre-emergence application of Arelon flüssig in winter wheat. Owner: RPA A51779 ! ER91DEU420 GLP, unpublished BOD95-00462	1995-04-21
AIIA-7.1.3.3	Idstein, H., Junker, H. and Merz, H.D.	1994	Investigating the Isoproturon discharge by runoff following post-emergence application of Arelon flüssig in winter wheat. Owner: RPA A51778 ! ER92DEU420 GLP, unpublished BOD95-00460	1995-04-21
AIIA-7.1.3.3	Idstein, H., Wolf, R. and Merz, H.D.	1994	Investigating IPU drainflows following pre-emergence application of Arelon flüssig in winter wheat. Owner: RPA A52545 ! ER91DEU410 GLP, unpublished BOD95-00458	1995-04-21

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AIIA-7.1.3.3	Neuß, B. and Junker, H.	1999	Untersuchungen zur Verlagerung von Isoproturon in bindigen Freilandböden unter gesonderter Berücksichtigung drainierter Flächen an Standorten in Deutschland – Endbericht. Owner: ROP Report IF-96/15333-00 from Institut Fresenius GLP, unpublished BOD 1999-811	1999-11-24
AIIA-7.1.3.3	Schmitt, B.	1999	Investigations on the leaching behaviour of isoproturon in compact outdoor soils under consideration of drained areas on different sites in Germany – Final Report 1999 Owner: ROP English translation (without appendices) Report IF-96/15333-00 from Institut Fresenius GLP, unpublished BOD 1999-788	1999-11-25
AIIA-7.1.3.3	Whale, U.	1994	Investigating IPU drainflows following post emergence application of Arelon flüssig in cereal. Owner: RPA A52605 ! HOE-009/7-23 GLP, unpublished BOD95-00459	1995-04-21
AIIA-7.1.3.3	Wicks, R.J. and Jones, R.L.	1992	Herbicides: Isoproturon: Surface water research study in the UK. Owner: RPA P91/269 ! A 50361 not GLP, unpublished BOD95-00461	1995-04-21
AIIA-7.2.1.3.2	Bürkle, W.L. and Mehler, I.	1993	Degradation of the 14C-labelled test compound in two water/sediment systems. Owner: RPA A51489 GLP, unpublished WAS95-00193 (WAS9400172)	1994-10-20
AIIA-7.2.1.3.2	Fischer, H.	1995	Isoproturon - Fate and behaviour in water/sediment. Owner: ROP Report from A & M, Study A & M 016/94 GLP, unpublished WAS 1999-274 (WAS9500141)	1994-11-29

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AIIIA 9.2.1	Erzgräber, B. and Feyerabend, M.	1999	Evaluation of the influence of organic carbon content on the leaching of Isoproturon. Owner: ROP Report No OE99/127 not GLP, unpublished BOD 1999-786	1999-11-25
AIIIA 9.2.1	Erzgräber, B., Gatzweiler, E. and Feyerabend, M.	1999	Leaching risk assessment of Isoproturon following application in winter cereal crops on sandy soils. Owner: ROP Report No OE99/072 not GLP, unpublished BOD 1999-781	1999-07-01
AIIIA 9.2.1	Granitza, E.	1998	Mathematical simulation of four field trials to assess the risk of ground water contamination by isoproturon using the MACRO model. Owner: ROP English translation Report OE98/088 not GLP, unpublished BOD2000-1060	2000-08-11
AIIIA 9.2.1	Jene, B.	1999	Simulationsrechnungen mit dem Modell MACRO zur Beurteilung des Versickerungsverhaltens von Isoproturon auf vier Feldstandorten mit bindigen Böden. Owner: ROP Report OE99/087 not GLP, unpublished BOD 1999-778	1999-08-16
AIIIA 9.2.1	Reinken, G.	2000	Isoproturon: Computer simulation of the potential mobility of the metabolite monomethyl isoproturon in soil after application of isoproturon to winter cereals using the PELMO 3.0 model. Owner: ROP Study No. 17403, Doc. No. 202525 not GLP, unpublished BOD2000-487	2000-03-20

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AIIA-8.1.1	Cameron, D.M. and Gillham, A.M.	1998	Isoproturon: Acute oral toxicity (LD50) to bobwhite quail. Owner: ROP RNP 563/982775 GLP, unpublished AVS98-00205	1998-08-23
AIIA-8.2.1	Jonas, W.	1995	Acute toxicity test on the Rainbow trout (Oncorhynchus mykiss); Semistatic Test Procedure Test Substance: I.P.U. Monomethyl. Owner: ROP NA 95 9411/3 GLP, unpublished WAT95-00604	1995-04-21
AIIA-8.2.1	Peters, A.	1993	Acute Toxicity of Isoproturon tech. on Carps (Cyprinus carpio L). Owner: ROP 07/93/361 GLP, unpublished WAT94-00680	1993-11-05
AIIA-8.2.2	McElligott	1998	Isoproturon: Fish, Juvenile Growth Test 28 Days Under Flow-Through Conditions Unpublished report SA 98307 from Rhone Poulenc Agro 18 December 1998 WAT1999-911	1999-11-19
AIIA-8.2.3	Jonas, W.	1995	Acute immobilisation Test on Daphnia magna Test Substance IPU Monomethyl. Owner: ROP NA 95 9411/2 GLP, unpublished WAT95-00603	1995-04-21
AIIA-8.2.4	Mc Elligott, A.	1999	Isoproturon Daphnia magna Acute Immobilisation Test at the Limit of Solubility owner: ROP, GLP, unpublished Report-No.: sa 99184 WAT1999-912	1999-11-19

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AIIA-8.2.5	Jonas, W.	1995	Determination of the growth inhibition on <i>Pseudokirchneriella subcapitata</i> (former name: <i>Ankistrodesmus bibraianus</i>) Test Substance: I.P.U. Monomethyl. Owner: ROP NA 95 9411/1 GLP, unpublished WAT95-00602	1995-04-21
AIIA-8.2.6	Hoberg, J.	1999a	Monomethyl-Isoproturon (IPU monomethyl) -Toxicity to the Freshwater Diatom, <i>Navicula pelliculosa</i> C006596 WAT2000-113	2000-03-10
AIIA-8.2.6	Hoberg, J.R.	1998	Isoproturon - Toxicity to the freshwater diatom, <i>Navicula pelliculosa</i> . Owner: ROP 98-5-7319 not GLP, unpublished WAT98-00544	1998-09-09
AIIA-8.2.6	Mc Elligott, A.	1999	EXP31655 C: Freshwater algal growth inhibition study (72 hours) (<i>Scenedesmus subspicatus</i>) Unpublished report from Rhone-Poulenc Report ref. SA 99118 of 03 June, 1999 WAT1999-913	1999-11-19
AIIA-8.2.6	Wenzel, A.	1999	Algal growth inhibition study: Effects of EXP 31655 on the growth of five different alga species Unpublished report from Fraunhofer Report + 1 st amendment Ref. RPS-002/04-30 of September 1999 WAT2000-44	1999-11-19
AIIA-8.2.7	Suteau, P.	1997	Isoproturon Toxicity to the Sediment dwelling Chironomid Larvae (<i>Chironomus riparius</i>) 28 days. Owner: ROP SA 96316 not GLP, unpublished WAT97-00042	1997-03-06
AIIA-8.2.8	Hoberg, J.	1999b	Monomethyl-Isoproturon (IPU-monomethyl) – Toxicity to the Duckweed, <i>Lemna gibba</i> C006635 WAT2000-114	2000-03-10

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AIIA-8.2.8	Hoberg, J.R.	1998	Isoproturon - Toxicity to the duckweed, Lemna gibba. Owner: ROP 98-5-7326 not GLP, unpublished WAT98-00545	1998-09-09
AIIA-8.3.1.1	Schmitzer, S.	1998	Laboratory Testing for Toxicity (Acute Contact and Oral LD50) of ISOPROTURON on Honey Bees (<i>Apis mellifera</i> L.)(Hymenoptera, Apidae). Owner: ROP 3170036 GLP, unpublished BIE98-00114	1998-09-09
AIIA-8.3.2	Nienstedt, K.M.	2000	Arelon Fluid: Acute toxicity test with the parasitic wasp, <i>Aphidius rhopalosiphii</i> (Hymenoptera: Braconidae). Springborn Laboratories (Europe) AG, Switzerland, study #: 1067.001.270, 22.08.00 GLP ANA2000-1019	NL 43183 10.10.00
AIIA-8.3.2	Petto, R.	1993	Effects of EXP 3808 (Tolkan Flo) on <i>Poecilus cupreus</i> L. (Coleoptera, Carabidae) in laboratory. Unpublished Report from RCC Umweltchemie GmbH Ref. No. 421920, GLP ANA95-00009	1993-11-01
AIIA-8.3.2	Petto, R.	1993	Effects of EXP 3808 (Tolkan Flo) on <i>Aleochara bilineata</i> Gyll. (Coleoptera, Staphilinidae) in laboratory. Unpublished report from RCC Umweltchemie GmbH Ref. No. 421918, GLP ANA95-00008	1993-11-01
AIIA-8.3.2 AIIIA-10.5.1	Candolfi, M.P.	1996	Arelon flüssig: Laboratory toxicity test with the predacious mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) based on the IOBC approved method of Overmeer (1986). Owner: ROP 96-030-1013 GLP, unpublished ANA97-00093	

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AIIA-8.3.2 AIIIA-10.5.1	Candolfi, M.P.	1996	Arelon flüssig: Laboratory toxicity test with the parasitic wasp <i>Aphidius rhopalosiphi</i> (hymenoptera, braconidae) based on the IOBC approved method of Polgar (1988). Owner: ROP 95-029-1013 GLP, unpublished ANA97-00092	
AIIA-8.3.2; AIIIA-10.5.1	Engelhard, E.K.	1998	Arelon flüssig (EXP 03808H) at a 5 % drift rate: A laboratory contact toxicity test with the predacious mite, <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae) based on the IOBC approved method of Overmeer (1988). Owner: ROP 97-061-1013 GLP, unpublished ANA98-00401	
AIIA-8.3.2; AIIIA-10.5.1	Engelhard, E.K.	1998	Arelon flüssig (EXP 03808H) at a 5 % drift rate: A laboratory toxicity test with the parasitic wasp, <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) based on the IOBC approved method of Polgar (1988). Owner: ROP 98-062-1013 GLP, unpublished ANA98-00402	
AIIA-8.3.2; AIIIA-10.5.1	Moll, M., Klepka, S.	1998	Effects of EXP03808H on the Lacewing <i>Chrysoperla carnea</i> Steph. (Neuroptera, Chrysopidae) in the Laboratory. Owner: ROP 3210046 GLP, unpublished ANA98-00403	
AIIA-8.3.3	Wetton, P. M.	1999	Monomethyl-Isoproturon: Acute Toxicity to Earthworms (<i>Eisenia Foetida</i>) 603691 ARW2000-78	2000-03-10
AIIA-8.5	Forster, J.	1994	Isoproturon – A laboratory assessment of the effects of Isproturon on soil microflora respiration and nitrogen transformations according to EPPO bulletin 24, 1 – 16 (1994) International, Chemex reference ENV3069; GooD 15232, 04.01.1999 BMF2000-10	ZA 004071 26.03.1999 DE 1999-11-19

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports on previous use in granting national authorizations
AIIA-8.6, AIIIA-10.8	Gaus, I.	2000	Biotest zur Bewertung der Auswirkung des Herbizides IP FLO (Wirkstoff Isoproturon) auf terrestrische Pflanzen owner: ROP, Rep-No.OC0002 unpublished PFL2000-183	2000-10-10
AIIA-8.7	Mead, C.	1998	Isoproturon Assessment of the inhibitory effect on the respiration of activated sewage sludge. Owner: ROP 282/503 not GLP, unpublished WAT98-00547	1998-09-09