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**EU-Beurteilungsbericht Isoproturon
Rechtliche Regelungen der Europäischen Union
zu Pflanzenschutzmitteln und deren Wirkstoffen
Band D 31**

Review Report Isoproturon
Legal Regulations of the European Union
for Plant Protection Products and their Active Substances
Volume D 31

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Vorwort

Für neue Wirkstoffe werden die EU-Mitgliedstaaten in den Richtlinien zur Aufnahme der Wirkstoffe in Anhang I verpflichtet, den nach Abschluss aller Prüfungen erstellten Beurteilungsbericht (Review Report) mit allen Anlagen (mit Ausnahme von vertraulichen Informationen im Sinne von Artikel 14 der Richtlinie 91/414/EWG) allen Interessierten zur Verfügung zu stellen oder auf besonderen Antrag zugänglich zu machen. Für alte Wirkstoffe ergibt sich diese Verpflichtung für die Mitgliedstaaten bereits aus Artikel 7 Absatz 6 Unterabsatz 2 der Verordnung (EWG) Nr. 3600/92.

Die Mitgliedstaaten und die Europäische Kommission haben vereinbart, dass die Beurteilungsberichte, einschließlich der zum Teil sehr umfangreichen Hintergrunddokumente, vorzugsweise beim berichterstattenden Mitgliedstaat angefordert oder eingesehen werden sollen.

Die Biologische Bundesanstalt stellt die Beurteilungsberichte als Berichte aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft als Band D in der Reihe "Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen" über den Saphir Verlag gegen Erstattung der Unkosten zur Verfügung. Das vorliegende 31. Heft dieser Reihe (Band D 31) enthält nicht die Hintergrunddokumente A, B und C des Beurteilungsberichtes. Diese können bei Bedarf bei der BBA eingesehen oder für die Wirkstoffe, für die Deutschland Berichtersteller ist, ebenfalls beim Saphir Verlag gegen Erstattung der Unkosten bezogen werden. Für Isoproturon war Deutschland Berichtersteller.

In der Reihe "Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen" sind bisher erschienen:

Heft	Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen
35/97	Band A: Richtlinie 91/414/EWG und diesbezügliche Protokolle (3. Auflage, Stand: 01. November 1997) <i>wird zur Zeit bearbeitet</i>
68/2000	Band B: Verordnungen und Protokolle zur Wirkstoffprüfung (4. Auflage, Stand 01. Juli 2000) <i>wird zur Zeit bearbeitet</i>
	Band C: <i>wird zur Zeit bearbeitet</i>

Preface

According to the Directives for the inclusion of active substances in Annex I with regard to new active substances, EU-Member States are obliged to keep available or make available on special request the review report which is prepared after completion of all evaluations including its appendices (excluding confidential information, in accordance with article 14 of Directive 91/414/EEC) to all interested parties. For existing active substance this obligation for Member States already arises from article 7 (6) subparagraph 2 of Regulation (EEC) No 3600/92.

Member States and the European Commission agreed that requests of review reports including their background documents which are partly very voluminous, shall preferably be addressed to the Rapporteur Member State.

The Federal Biological Research Centre makes available review reports as reports from the Federal Biological Research Centre for Agriculture and Forestry, Volume D of the series "Legal Regulations of the European Union for Plant Protection Products and their Active Substances" via Saphir Verlag against reimbursement of expenses. The present 31st report belonging to this series (Volume D 31) does not include background documents A, B and C of the review report. If the need arises, their inspection at the BBA is possible or they may be also obtained from Saphir Verlag against reimbursement of expenses, however, only for active substances with Germany as Rapporteur Member State. For isproturon Germany acted as Rapporteur Member State.

In the series Legal Regulations of the European Union for Plant Protection Products and their Active Substances the following Reports have been published:

Report	Legal Regulations of the European Union for Plant Protection Products and their Active Substances
35/97	Volume A: Directive 91/414/EEC and respective Protocols (3 rd Edition, date: 1 November 1997) <i>in progress</i>
68/2000	Volume B: Regulations and Protocols regarding the Evaluation of Active Substances (4 th Edition, date: 1 July 2000) <i>in progress</i>
	Volume C: <i>in progress</i>

RICHTLINIE 2002/18/EG DER KOMMISSION**vom 22. Februar 2002****zur Änderung des Anhangs I der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln zur Aufnahme des Wirkstoffs Isoproturon**

DIE KOMMISSION DER EUROPÄISCHEN GEMEINSCHAFTEN —

gestützt auf den Vertrag zur Gründung der Europäischen Gemeinschaft,

gestützt auf die Richtlinie 91/414/EWG des Rates vom 15. Juli 1991 über das Inverkehrbringen von Pflanzenschutzmitteln ⁽¹⁾, zuletzt geändert durch die Richtlinie 2001/103/EG der Kommission ⁽²⁾, insbesondere auf Artikel 6 Absatz 1,

in Erwägung nachstehender Gründe:

- (1) Die Verordnung (EWG) Nr. 3600/92 der Kommission vom 11. Dezember 1992 mit Durchführungsbestimmungen für die erste Stufe des Arbeitsprogramms gemäß Artikel 8 Absatz 2 der Richtlinie 91/414/EWG des Rates über das Inverkehrbringen von Pflanzenschutzmitteln ⁽¹⁾, zuletzt geändert durch die Verordnung (EG) Nr. 2266/2000 ⁽²⁾, sieht die Annahme einer Liste von Wirkstoffen in Pflanzenschutzmitteln vor, die im Hinblick auf ihre mögliche Aufnahme in Anhang I der Richtlinie 91/414/EWG bewertet werden sollen. Diese Liste wurde mit der Verordnung (EG) Nr. 933/94 der Kommission vom 27. April 1994 über die Festsetzung der Wirkstoffe von Pflanzenschutzmitteln und die Bestimmung der Bericht erstattenden Mitgliedstaaten zur Durchführung der Verordnung (EWG) Nr. 3600/92 ⁽³⁾, zuletzt geändert durch die Verordnung (EG) Nr. 2230/95 ⁽⁴⁾, festgelegt und enthält u. a. Isoproturon.
- (2) Die Auswirkungen von Isoproturon auf die menschliche Gesundheit und auf die Umwelt wurden gemäß den Bestimmungen der Verordnung (EWG) Nr. 3600/92 für eine Reihe von durch die Antragsteller vorgeschlagenen Anwendungen geprüft. Gemäß der Verordnung (EG) Nr. 933/94 wurde Deutschland zum Bericht erstattenden Mitgliedstaat benannt. Der Bericht erstattende Mitgliedstaat hat der Kommission seinen Bewertungsbericht und Empfehlungen am 30. Juli 1999 gemäß Artikel 7 Absatz 1 Buchstabe c) der Verordnung (EWG) Nr. 3600/92 übermittelt.
- (3) Dieser Bewertungsbericht wurde von den Mitgliedstaaten und der Kommission im Rahmen des Ständigen Ausschusses Pflanzenschutz geprüft. Die Prüfung wurde am 7. Dezember 2001 in Form des Beurteilungsberichts der Kommission für Isoproturon abgeschlossen.
- (4) Im Rahmen der Prüfung wurden keinerlei offene Fragen oder Bedenken laut, die eine Konsultation des Wissenschaftlichen Ausschusses „Pflanzen“ erfordert hätten.
- (5) Die Untersuchungen haben ergeben, dass davon ausgegangen werden kann, dass den betreffenden Wirkstoff enthaltende Pflanzenschutzmittel im Allgemeinen die Anforderungen gemäß Artikel 5 Absatz 1 Buchstaben a) und b) der Richtlinie 91/414/EWG erfüllen, insbesondere hinsichtlich der geprüften und in dem Beurteilungsbericht der Kommission behandelten Anwendungen. Daher sollte der Wirkstoff in Anhang I dieser Richtlinie aufgenommen werden, damit Pflanzenschutzmittel mit diesem Wirkstoff in allen Mitgliedstaaten gemäß den Bestimmungen der Richtlinie 91/414/EG zugelassen werden können.
- (6) Nach Aufnahme von Isoproturon in Anhang I der Richtlinie 91/414/EWG ist den Mitgliedstaaten eine Frist einzuräumen, innerhalb der sie sicherstellen, dass die Zulassungen von Pflanzenschutzmitteln, die diesen Wirkstoff enthalten, gegebenenfalls erteilt, geändert bzw. widerrufen werden. Pflanzenschutzmittel dürfen nur zugelassen werden, wenn die Bedingungen in Zusammenhang mit der Aufnahme des betreffenden Wirkstoffs in Anhang I sowie die einheitlichen Grundsätze gemäß der Richtlinie auf der Grundlage von Unterlagen, die den Datenanforderungen entsprechen, erfüllt sind.

⁽¹⁾ ABl. L 230 vom 19.8.1991, S. 1.⁽²⁾ ABl. L 313 vom 30.11.2001, S. 37.⁽³⁾ ABl. L 366 vom 15.12.1992, S. 10.⁽⁴⁾ ABl. L 259 vom 13.10.2000, S. 27.⁽⁵⁾ ABl. L 107 vom 28.4.1994, S. 8.⁽⁶⁾ ABl. L 225 vom 22.9.1995, S. 1.

- (7) Der Beurteilungsbericht der Kommission ist für die ordnungsgemäße Umsetzung bestimmter Abschnitte der in der Richtlinie 91/414/EWG festgelegten einheitlichen Grundsätze durch die Mitgliedstaaten erforderlich. Es ist daher vorzuschreiben, dass die Mitgliedstaaten den endgültigen Beurteilungsbericht (mit Ausnahme von vertraulichen Informationen) allen Interessierten zur Einsicht zur Verfügung stellen oder zugänglich machen. Wird dieser Beurteilungsbericht aktualisiert, um den technischen und wissenschaftlichen Entwicklungen Rechnung zu tragen, so müssen die Bedingungen für die Aufnahme des betreffenden Wirkstoffs in Anhang I der Richtlinie 91/414/EWG in Übereinstimmung mit der Richtlinie ebenfalls geändert werden.
- (8) Vor der Aufnahme eines Wirkstoffs in Anhang I ist eine angemessene Frist einzuräumen, um es den Mitgliedstaaten und Interessierten zu ermöglichen, sich auf die sich daraus ergebenden neuen Anforderungen vorzubereiten. Nach der Aufnahme ist den Mitgliedstaaten außerdem eine angemessene Frist einzuräumen, um die Bestimmungen der Richtlinie 91/414/EWG über Pflanzenschutzmittel, die Isoproturon enthalten, umzusetzen. Die Mitgliedstaaten müssen innerhalb dieser Frist gemäß den Bestimmungen der Richtlinie 91/414/EWG insbesondere bestehende Zulassungen überprüfen und gegebenenfalls neue Zulassungen erteilen. Für die Übermittlung und Bewertung der für jedes Pflanzenschutzmittel vollständigen Unterlagen gemäß den in der Richtlinie 91/414/EWG festgelegten einheitlichen Grundsätzen ist ein längerer Zeitraum vorzusehen. Pflanzenschutzmittel, die mehrere Wirkstoffe enthalten, können jedoch auf der Grundlage der einheitlichen Grundsätze erst vollständig bewertet werden, wenn alle enthaltenen Wirkstoffe in Anhang I der Richtlinie 91/414/EWG aufgenommen sind.
- (9) Die in dieser Richtlinie vorgesehenen Maßnahmen entsprechen der Stellungnahme des Ständigen Ausschusses Pflanzenschutz —

HAT FOLGENDE RICHTLINIE ERLASSEN:

Artikel 1

Anhang I der Richtlinie 91/414/EWG wird gemäß dem Anhang der vorliegenden Richtlinie geändert.

Artikel 2

Die Mitgliedstaaten stellen den Beurteilungsbericht für Isoproturon (mit Ausnahme von vertraulichen Informationen im Sinne des Artikels 14 der Richtlinie 91/414/EWG) allen Interessierten zur Einsicht zur Verfügung oder machen ihn gegebenenfalls auf besonderen Antrag zugänglich.

Artikel 3

(1) Die Mitgliedstaaten erlassen die erforderlichen Rechts- und Verwaltungsvorschriften, um dieser Richtlinie bis spätestens 30. Juni 2003 nachzukommen. Sie unterrichten die Kommission unverzüglich davon.

Gemäß der Richtlinie 91/414/EWG ändern oder widerrufen sie erforderlichenfalls bis zu diesem Zeitpunkt insbesondere bestehende Zulassungen für Pflanzenschutzmittel, die Isoproturon als Wirkstoff enthalten.

Bei Erlass dieser Vorschriften nehmen die Mitgliedstaaten in den Vorschriften selbst oder durch einen Hinweis bei der amtlichen Veröffentlichung auf diese Richtlinie Bezug. Die Mitgliedstaaten regeln die Einzelheiten der Bezugnahme.

(2) Hinsichtlich der Bewertung und Entscheidungsfindung gemäß den einheitlichen Grundsätzen von Anhang VI der Richtlinie 91/414/EWG auf der Grundlage von Unterlagen, die die Anforderungen von Anhang III der genannten Richtlinie erfüllen, läuft die Frist für die Änderung oder den Widerruf von Zulassungen von Pflanzenschutzmitteln, die Isoproturon als einzigen Wirkstoff enthalten, bis zum 1. Januar 2007.

(3) Bei Pflanzenschutzmitteln, die Isoproturon zusammen mit einem anderen in Anhang I der Richtlinie 91/414/EWG aufgeführten Wirkstoff enthalten, läuft die Frist für die Änderung oder den Widerruf von Zulassungen vier Jahre nach dem Inkrafttreten der Richtlinie zur Änderung von Anhang I der Richtlinie 91/414/EWG mit der Aufnahme des letzten dieser Wirkstoffe ab.

Artikel 4

Diese Richtlinie tritt am 1. Januar 2003 in Kraft.

Artikel 5

Diese Richtlinie ist an alle Mitgliedstaaten gerichtet.

Brüssel, den 22. Februar 2002

Für die Kommission
David BYRNE
Mitglied der Kommission

ANHANG

An das Ende der Tabelle in Anhang I der Richtlinie 91/414/EWG anzufügende Einträge:

Nr.	Gebräuchliche Bezeichnung, Kennnummern	IUPAC-Bezeichnung	Reinheit (†)	Inkrafttreten	Aufnahme befristet bis	Besondere Bedingungen
„28	Isoproturon CAS-Nr. 34123-59-6 CIPAC-Nr. 336	3-(4-isopropylphenyl)-1,1-dimethylurea	970 g/kg	1. Januar 2003	31. Dezember 2012	<p>Nur Verwendungen als Herbizid dürfen zugelassen werden.</p> <p>Bei der Anwendung der einheitlichen Grundsätze gemäß Anhang VI sind die Schlussfolgerungen des vom Ständigen Ausschuss Pflanzenschutz am 7. Dezember 2001 abgeschlossenen Beurteilungsberichts über Isoproturon und insbesondere dessen Anlagen I und II zu berücksichtigen. Bei dieser Gesamtbewertung müssen die Mitgliedstaaten</p> <ul style="list-style-type: none"> — dem Grundwasserschutz besondere Aufmerksamkeit widmen, wenn der Wirkstoff in Regionen mit empfindlichen Böden und/oder Klimabedingungen oder höheren Aufwandmengen, als sie im Beurteilungsbericht vorgegeben sind, ausgebracht wird, und ggf. Maßnahmen zur Risikobegrenzung ergreifen; — dem Schutz von Wasserorganismen besondere Aufmerksamkeit widmen und sicherstellen, dass die Zulassungsbedingungen ggf. Maßnahmen zur Risikobegrenzung umfassen.

(†) Für weitere Angaben zur Identität und Spezifikation des Wirkstoffs siehe Beurteilungsbericht.“

COMMISSION DIRECTIVE 2002/18/EC
of 22 February 2002

amending Annex I to Council Directive 91/414/EEC concerning the placing of plant-protection products on the market to include isoproturon as an active substance

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant-protection products on the market ⁽¹⁾, as last amended by Commission Directive 2001/103/EC ⁽²⁾, and in particular Article 6(1) thereof,

Whereas:

- (1) Commission Regulation (EEC) No 3600/92 of 11 December 1992 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 concerning the placing of plant-protection products on the market ⁽³⁾, as last amended by Regulation (EC) No 2266/2000 ⁽⁴⁾, provides for the adoption of a list of active substances of plant-protection products to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list is contained in Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant-protection products and designating the rapporteur Member State for the implementation of Commission Regulation (EEC) No 3600/92 ⁽⁵⁾, as last amended by Regulation (EC) No 2230/95 ⁽⁶⁾, and includes isoproturon.
- (2) For isoproturon the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifiers. Under Regulation (EC) No 933/94, Germany was designated as rapporteur Member State. The rapporteur Member State submitted the relevant assessment reports and recommendations to the Commission on 30 July 1999 in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92.
- (3) This assessment report has been reviewed by the Member States and the Commission within the Standing Committee on Plant Health. The review was finalised on 7 December 2001 in the format of the Commission review report for isoproturon.
- (4) The review did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants.
- (5) It has appeared from the various examinations made that plant-protection products containing the active substance concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include the active substance concerned in Annex I to that Directive, in order to ensure that in all Member States the authorisations of plant-protection products containing the active substances concerned can be granted in accordance with the provisions of Directive 91/414/EEC.
- (6) A period should be specified following the inclusion of isoproturon in Annex I to Directive 91/414/EEC, during which Member States must grant, vary or withdraw, as appropriate, the authorisations of the plant-protection products containing this active substance. In particular, plant-protection products should not be authorised unless account is taken of the conditions associated with the inclusion of the active substance in Annex I and the uniform principles laid down in the Directive on the basis of a dossier satisfying the prescribed data requirements.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 313, 30.11.2001, p. 37.

⁽³⁾ OJ L 366, 15.12.1992, p. 10.

⁽⁴⁾ OJ L 259, 13.10.2000, p. 27.

⁽⁵⁾ OJ L 107, 28.4.1994, p. 8.

⁽⁶⁾ OJ L 225, 22.9.1995, p. 1.

- (7) The Commission review report is required for the proper implementation by the Member States, of several sections of the uniform principles laid down in Directive 91/414/EEC. It is, therefore, appropriate to provide that the finalised review report, except for confidential information, is kept available or made available by the Member States for consultation by any interested parties. If the review report has to be updated to take account of technical and scientific developments, the conditions for the inclusion of the substance concerned in Annex I to Directive 91/414/EEC should also be amended in accordance with that Directive.
- (8) A reasonable period must be provided for before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion. Moreover, after inclusion, a reasonable period is necessary to permit Member States to implement the provisions of Directive 91/414/EEC on plant-protection products containing isoproturon. In particular, Member States must, within that period, review existing authorisations and, where appropriate, grant new authorisations in accordance with the provisions of Directive 91/414/EEC. A longer period should be provided for the submission and assessment of the complete dossier of each plant-protection product in accordance with the uniform principles laid down in Directive 91/414/EEC. For plant-protection products containing several active substances, the complete evaluation on the basis of the uniform principles can only be carried out when all the active substances concerned have been included in Annex I to Directive 91/414/EEC.
- (9) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall keep available the review report for isoproturon, except for confidential information within the meaning of Article 14 of Directive 91/414/EEC, for consultation by any interested parties or shall make it available to them on specific request.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive, by 30 June 2003 at the latest. They shall forthwith inform the Commission thereof.

In particular they shall, in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant-protection products containing isoproturon as active substance by that date.

When Member States adopt this provision, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. With regard to evaluation and decision-making pursuant to the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III thereto, the deadline for amending or withdrawing authorisations for plant-protection products containing isoproturon as the only active substance shall be 1 January 2007.

3. For plant-protection products containing isoproturon together with another active substance which is in Annex I to Directive 91/414/EEC, the period for amending or withdrawing authorisations shall expire four years after the entry into force of the Directive which amended Annex I to Directive 91/414/EEC so as to add the last of those substances to it.

Article 4

This Directive shall enter into force on 1 January 2003.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 22 February 2002.

For the Commission
David BYRNE
Member of the Commission

ANNEX

The following entries shall be added at the end of the table in Annex I to Directive 91/414/EC:

No	Common name, identification numbers	IUPAC name	Purity (%)	Entry into force	Expiration of inclusion	Specific provisions
'28	Isoproturon CAS No 34123-59-6 CIPAC No 336	3-(4-isopropylphenyl)-1,1-dimethylurea	970 g/kg	1 January 2003	31 December 2012	<p>Only uses as herbicide may be authorised</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on isoproturon, and in particular Appendices I and II thereto, as finalised in the Standing Committee on Plant Health on 7 December 2001 shall be taken into account. In this overall assessment Member States:</p> <ul style="list-style-type: none"> — must pay particular attention to the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions or at use rates higher than those described in the review report and must apply risk mitigation measures, where appropriate, — must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures

(¹) Further details on identity and specification of active substance are provided in the review report.



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
12 March 2002

**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 isotoproturon 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 isotoproturon this deadline was 31 Oktober 1995.

Rhone-Poulenc Agro on behalf of the isotoproturon 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 isotoproturon 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 isotoproturon 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 isotoproturon from the isotoproturon 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.

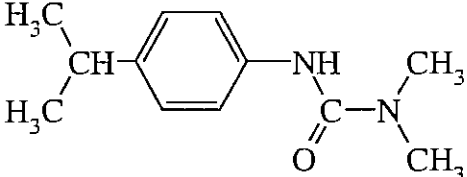
9. Updating of this review report

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 × 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 l mol ⁻¹ 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

GenotoxicityNegative in standard *in vitro* and *in vivo* assays**Long term toxicity and carcinogenicity**

Target / critical effect:

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

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

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

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

Other toxicological studiesMechanistic 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 (*S. typhimurium*, *E. coli*).**Medical data**

No toxic effects reported in manufacturing plant personnel

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) K_d

no pH dependence

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 $\mu\text{g/l}$
average annual concentration of M 1 + M 3 (combined): 0.051 and 0.022 $\mu\text{g/l}$ 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 $\mu\text{g/l}$.
average annual concentration of M 1 + M 3 (combined): 0.000 and 0.016 $\mu\text{g/l}$ **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

Remarks:

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

Henry's law constant:

Photolytic degradation

Direct photolysis in air:

Photochemical oxidative degradation in air
DT₅₀:

Volatilisation:

Remarks:

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 isotroturon 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 isotroturon-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	Reports ² 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	Reports ² 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	Reports ² 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	Urtizbera, 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	(¹⁴ C)-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	[¹⁴ C]-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	[¹⁴ C]-Isoproturon: Photodegradation on soil. RPA Document 201894 Owner: ROP GLP, unpublished BOD 1999-784	1999-11-25
AIIA- 7.1.1.2.1	Ellβel, 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/Weinstraβe, 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 (<i>Oncorhynchus mykiss</i>); 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 (<i>Cyprinus carpio</i> 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 <i>Daphnia magna</i> 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 <i>Daphnia magna</i> 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 bibrarianus</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

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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 rhopalosiphi</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

**SUMMARY REPORT
OF THE MEETING OF THE STANDING COMMITTEE ON PLANT HEALTH
HELD ON 7 DECEMBER 2001 IN BRUXELLES**

President : G. Del Bino

All Member States were present.

1 Examination and possible vote on a draft Commission Directive concerning the inclusion of isoproturon in Annex 1 to Council Directive 91/414/EEC (SANCO/3253/2001 rev 2; Review Report SANCO/3045/99-rev. 2).

The Commission presented the Review Report on isoproturon in document SANCO/3045/99-rev. 2. The Committee took note of the Review Report.

The following declarations were made:

Denmark: Denmark declares disagreement with the ADI and AOEL values defined in the list of endpoints provided in the review report.

Commission: At the adoption of the Uniform Principles by Council in 1997, the Council and Commission agreed to the following declaration:

“The Council and the Commission note that application of this Directive is without prejudice to the legislation in force concerning the protection of workers. The Council and the Commission state that this principle will be unequivocally clarified in Directive 91/414/EEC on the occasion of the first amendment of that Directive. The Commission intends to submit a proposal for such amendment within one year from the date of notification of this Directive.”

The Commission can for its part confirm its agreement with this declaration (subject to adequate adaptation of the deadline in the declaration).

The Commission presented the draft Directive.

Vote : favourable opinion by qualified majority (3 votes against)

The substance is an existing active substance used as herbicide.

The measures on which the Committee has given its opinion are subject to the appropriate procedures for formal adoption by the Commission.

A CHECCHI LANG
Director

Berichte aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft erscheinen seit 1995 in zwangloser Folge.

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