



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Ioxynil
SANCO/4349/2000 final
13 February 2004

Review report for the active substance **ioxynil**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 13 February 2004
in view of the inclusion of ioxynil 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 ioxynil, 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 2266/2000⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Ioxynil 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, Rhône-Poulenc Agro (then Aventis CropScience and now Bayer CropScience) on 15 July 1993, ACI International on 30 July 1993, CFPI on 28 July 1993, Markhteshim Agran on 20 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 ioxynil in Annex I to the Directive.

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 France as rapporteur Member State to carry out the assessment of ioxynil on the basis of the dossier/s submitted by the notifier/s. 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 **ioxynil** this deadline was 31 October 1995

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 259, 13.10.2000, p.27.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

Only Rhone Poulenc Agro (now Bayer CropScience) and Makhteshim Agan were considered to have submitted in time a dossier to the rapporteur Member State which was not considered containing substantial data gaps, taking into account the supported uses. An incomplete dossier was submitted by CFPI (now Nufarm) but, on a letter dated 16 July 1999, CFPI Nufarm stated its intention not to support bromoxynil further. ACI international (now Sanachem international) did not submit a dossier in time. Luxan on a letter dated on 17 January 1995 stated its intention not to support Ioxynil further and did not submit a dossier.

Therefore Rhone Poulenc Agro (now Bayer CropScience) and Makhteshim Agan were considered to be the main data submitters.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, France submitted on 08 March 2000 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 ioxynil 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 ioxynil from Rhône Poulenc Agro (now Bayer CropScience) and Makhteshim Agan on 10 August 2000.

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 on 27 June 2000 as well as to Rhone Poulenc Agro (now Bayer CropScience) and Makhteshim Agan main data submitters.

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 Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from March to September 2001 and by the Pesticide Safety Directorate (PSD) in York, United Kingdom, from February to September 2003.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitters on 16 November 2001 for comments and further clarification.

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 the Food Chain and Animal 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 December 2001 to November 2003, and was finalised in the meeting of the Standing Committee on 13 February 2004.

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

The present review report contains the conclusions of the 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.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed and finalised in support of the Directive 2004/58/EC⁵ concerning the inclusion of ioxynil in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing ioxynil 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.

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 ioxynil 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

⁵ OJ No L 120, 24.4.2004, p.26.

91/414/EEC, for each ioxynil containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the main data submitter and mentioned in the list of uses supported by available data (attached as Appendix IV to this Review Report).

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 below 5% 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. Estimates of acute dietary exposure of adults and toddlers revealed that the Acute Reference Dose (ARfD) would not be exceeded (< 0.5 and 1.1 % respectively for adults and toddlers).

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.

These conclusions were reached, in particular, for the octanoate ester of ioxynil, for which detailed information was submitted. Further studies, in particular bridging studies, may be necessary in relation to the acceptance of esters of ioxynil other than the octanoate ester evaluated.

4. Identity and Physical/chemical properties

The main identity and the physical/chemical properties of ioxynil are given in Appendix I.

The active substance shall comply with the FAO specification 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 Rhône Poulenc Agro (now Bayer CropScience), 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, France is not satisfied, on the basis of the information currently available, that the substance notified by the other submitter 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 were identified during the re-evaluation process. These endpoints are listed in Appendix II. For esters of Ioxynil other than octanoate ester evaluated, it may be necessary to use other endpoints than those 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 ioxynil

On the basis of the proposed and supported uses (as listed in Appendix IV), 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:

- Member States must pay particular attention to the protection of birds and wild mammals in particular if the substance is applied in winter. Conditions of authorisation should include risk mitigation measures, where appropriate.
- Member States must pay particular attention to the protection of aquatic organisms. Conditions of authorisation must include risk mitigation measures, where appropriate.

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 ioxynil 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. This may particularly be the case for studies to support risk assessments for the terrestrial environment, e.g. for applications in winter under particular conditions on treated crops to support a risk assessment for birds and wild mammals. Additional studies, in particular bridging studies, may also be necessary in relation to the acceptance of esters of ioxynil other than octanoate ester evaluated.

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.

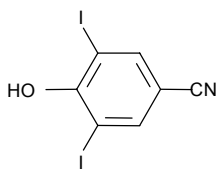
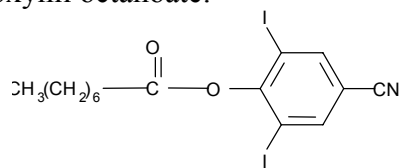
9. Updating of this review report

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 the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for ioxynil in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

IOXYNIL

Common name (ISO)	IOXYNIL
Chemical name (IUPAC)	Ioxynil : 4- hydroxy- 3,5- di-iodobenzonitrile Ioxynil octanoate : 4-cyano -2,6-di-iodophenyl octanoate
Chemical name (CA)	Ioxynil : 4- hydroxy- 3,5- di-iodobenzonitrile Ioxynil octanoate : 4-cyanophenyl -2,6-di-iodophenyl octanoate
CIPAC No	Ioxynil : 86 Ioxynil octanoate : 86.407
CAS No	Ioxynil : 1689-83-4 Ioxynil octanoate : 3861-47-0
EEC No	Ioxynil : 216-881-1 Ioxynil octanoate : 223-375-4
FAO SPECIFICATION	1996
Minimum purity	Ioxynil : ≥ 960 g/kg Ioxynil octanoate : ≥ 920 g/kg
Molecular formula	Ioxynil : $C_7 H_3 I_2 NO$ Ioxynil octanoate : $C_{15} H_{17} I_2 NO_2$
Molecular mass	Ioxynil : 370.9 g/mol Ioxynil octanoate : 497.1 g/mol
Structural formula	
Ioxynil :	
	
Ioxynil octanoate:	
	

Melting point	Ioxynil : 207.8°C Ioxynil octanoate : 56.6 °C
Boiling point	Ioxynil octanoate : no boiling point before decomposition (starts at 240°C)
Appearance	Ioxynil : white cristalline powder Ioxynil octanoate : white fine powder
Relative density	Ioxynil : 2.72 g/ml as density Ioxynil octanoate : 1.81 g/ml as density
Vapour pressure	Ioxynil : 2.04×10^{-6} Pa at 20 °C Ioxynil octanoate : $< 0.9 \times 10^{-7}$ Pa at 45 °C
Henry's law constant	Ioxynil : 1.5×10^{-5} Pa m ³ mol ⁻¹ at 25°C Ioxynil octanoate : cannot be calculated because values of the solubility in water and vapour pressure.
Solubility in water	Ioxynil : 539 mg/l at pH 5 and 5.53 g/l at pH 9 Ioxynil octanoate : < 0.03 mg/l at pH 5.0, 7.2 and 8.7 at 20°C
Solubility in organic solvents	<u>Ioxynil</u> : Acetone = 73.5 g/l Methanol = 22.2 1,2 dichloroethane = 14.2 Ethyl acetate = 34.6 Acetonitrile = 14.2 Xylene = 5.8 Octanol = 15.1 n-heptane = 37.5 <u>Ioxynil octanoate</u> : Acetone = > 1000 g/l ethyl acetate = > 1000 methanol = 111.8 octanol = 100 Acetonitrile = 851.5 Xylene = > 1000 n-heptane = 0.073
Partition co-efficient (log P_{ow})	Ioxynil : log P = 2.2 (pH5), 0.23 (pH8.7) Ioxynil octanoate : log P = 6.0
Hydrolytic stability (DT₅₀)	<u>Ioxynil</u> : No degradation detected at pH2 for 17 h no degradation at pH 5-7 up to 52 days at 22°C <u>Ioxynil octanoate</u> : DT ₅₀ = no degradation at pH5 = 6 days at pH7 = 19 days at pH9
Dissociation constant	Ioxynil : pKa = 4.1 Ioxynil octanoate : not applicable, no ionisable group
Quantum yield of direct photo-transformation in water at $\lambda > 290$ nm	Ioxynil : 5.8×10^{-2} mole x einstein ⁻¹ Ioxynil octanoate : 2.88×10^{-2} mole x einstein ⁻¹
Flammability	Ioxynil and Ioxynil octanoate : not flammable
Explosive properties	Ioxynil and Ioxynil octanoate : no oxidising properties

UV/VIS absorption (max.)	<p><u>Ioxynil</u> :</p> <p>$\lambda_{\text{max}} = 237.2 \text{ nm}$ $\epsilon = 28030 \text{ l x mol}^{-1} \text{ x cm}^{-1}$ $\lambda \text{ at } 287 \text{ nm}$ $\epsilon = 17380 \text{ l x mol}^{-1} \text{ x cm}^{-1}$ shoulder at 295 nm ($= 8300 \text{ l x mol}^{-1} \text{ x cm}^{-1}$)</p> <p><u>Ioxynil octanoate</u> :</p> <p>$\lambda_{\text{max}} = 227 \text{ nm}$ $\epsilon = 29738 \text{ l x mol}^{-1} \text{ x cm}^{-1}$ $\lambda \text{ at } 295 \text{ nm}$ $\epsilon = 1099 \text{ l x mol}^{-1} \text{ x cm}^{-1}$</p>
Photostability in water (DT₅₀)	<p><u>Ioxynil</u> : DT50 : 120 h continuous light. 2 major by-products : 3-iodo-4-hydroxybenzotrile and an isomer of ioxynil</p> <p><u>Ioxynil octanoate</u> : degradation into Ioxynil . DT50 = <4 days</p>

APPENDIX II

END POINTS AND RELATED INFORMATION

IOXYNIL

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	At least 90% based on urine excretion and tissue residues
Distribution:	Widely distributed, highest residue in plasma
Potential for accumulation:	No potential for accumulation for Ioxynil. Dose dependant accumulation of iodine in thyroid
Rate and extent of excretion:	Almost completely in 7 days, mainly via urine
Toxicologically significant compounds:	Parent compound and metabolite
Metabolism in animals:	Moderately metabolised up to 26% of parent compound in urine, deiodination, conjugation

Acute toxicity

Rat LD ₅₀ oral:	Ioxynil : 114 mg/kg Ioxynil octanoate: 165 mg/kg
Rat LD ₅₀ dermal:	Ioxynil : 1050 mg/kg Ioxynil octanoate: > 2000 mg/kg
Rat LC ₅₀ inhalation:	Ioxynil : 0.38 mg/l Ioxynil octanoate: > 4.36 mg/l
Skin irritation:	Ioxynil : not irritant Ioxynil octanoate: not irritant
Eye irritation:	Ioxynil : irritant Ioxynil octanoate: irritant
Skin sensitization (test method used and result):	Ioxynil : not sensitizer Ioxynil octanoate: sensitizer

Short term toxicity

Target / critical effect:	Liver (hypertrophy and enzyme induction). Thyroid (hyperactivity)
Lowest relevant oral NOAEL / NOEL:	1 mg/kg/d (90 d, rat and dog)
Lowest relevant dermal NOAEL / NOEL:	No data required
Lowest relevant inhalation NOAEL / NOEL:	No data required

Genotoxicity

No overall genotoxic potential. Some positive results in vitro, negative in vivo for the ioxynil phenol

Long term toxicity and carcinogenicity

Target / critical effect:	Reduced body weight gain. Liver (hypertrophy and enzyme induction). Thyroid (hyperactivity)
Lowest relevant NOAEL:	10 ppm (0.5 mg/kg/d), 2 year study in rat
Carcinogenicity:	Liver tumours in rat and male mice. Thyroid tumours (rat), uterus tumours (mice)

Reproductive toxicity

Target / critical effect - Reproduction:	Reduced litter size and pups weight at parentally toxic dose levels
Lowest relevant reproductive NOAEL / NOEL:	30 ppm (2.5 mg/kg/d)
Target / critical effect - Developmental toxicity:	Increased of malformations in rat and rabbit at maternal toxic dose levels, variations and retardation below maternal toxic dose levels
Lowest relevant developmental NOAEL / NOEL:	Oral: 4 mg/kg/d (rat) Dermal: 40 mg/kg/d (rat)

Delayed neurotoxicity

No data required

Other toxicological studies

Mechanistic studies suggest that the mechanism of Ioxynil-induced thyroid carcinogenesis in the rat is the result of a species specific perturbation of thyroid hormone homeostasis.
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Medical data

Acute exposure of workers cause clinical symptoms as excessive sweating, dizziness and headaches
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Summary

	Value	Study	Safety factor
ADI:	0.005 mg/kg/d	2 year study in rat	100
AOEL systemic:	0.01 mg/kg/d	90 day study (rat and dog)	100
AOEL inhalation:	-	-	-
AOEL dermal:	-	-	-
ARfD (acute reference dose):	0.04 mg/kg	Teratogenicity studies (rat)	100

Dermal absorption

4% diluted and undiluted (<i>in vivo</i> rat and <i>in vitro</i> rat and human)
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2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

^{14}C -phenyl-ioxynil : 27.5 % (42 d) - 27.3 % (48 d)
[U-ring ^{14}C]-ioxynil octanoate: 50.2 to 54.7 % of AR (120 d) (3 soils)
 ^{14}C -phenyl-di-iodo-4-OH-benzamide : 60.5 % - 66.3 % (128 d)

Non-extractable residues after 100 days:

^{14}C -phenyl-ioxynil : 70.6 % (42 d) - 77 % (48 d)
[U-ring ^{14}C]-ioxynil octanoate: 38.6 to 44.0 % of AR (120 d)(3 soils)
 ^{14}C -phenyl-di-iodo-4-OH-benzamide : 25.2 % - 31.6 % (128 d); max: 31.9 % - 32.1 % (32 d)

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

^{14}C -phenyl-ioxynil
- di-iodo-4-OH-benzamide : max. 10.5 % (3 d)
- di-iodo-4-OH-benzoic acid : max. 12.6 % (1d) - 20.4 % (3 d)
[U-ring ^{14}C]-ioxynil octanoate:
- Ioxynil : max 52.6 % of AR (3 soils)
- 4-OH-3,5-diiodobenzamide: max 15.3 % of AR

Supplemental studies

Anaerobic:

From a water-sediment study with Ioxynil octanoate; in the whole system:
- Ioxynil : max. 12.2 % (14 d) and 0.7 % (91 d)
- 4-OH-benzonitrile: max. 31.5 % (28 d) and 0.2 % (91 d)
- Mineralisation: 37.6 % (91 d)
- Bound residues: max 11.1 % (56 d) and 10.4 % (91 d)
- 40 % volatiles mainly as methane

Soil photolysis:

DT50 44 hours
- Mineralization : 26.5 % (192 hours)
- Bound residues : 37.4 % (192 hours)
Ioxynil : max. 33.7 % (48 hours)

Remarks:

none

Rate of degradation

Laboratory studies

DT₅₀lab (20 °C, aerobic):

Ioxynil (22° C)
Soil type OC % pH DT50 (d) R²

Sand	1.4	6.7	1.5 (1.8*)	0.99
Loam	1.8	7.0	2.0 (2.3*)	0.99
Clay	3.3	7.3	2.5 (3.0*)	0.98
*recalculated for 20°C				
<u>Ioxynil octanoate (22° C) - Study 1:</u>				
<u>Soil type</u>	<u>OC %</u>	<u>pH</u>	<u>DT50 (d)</u>	
Speyer 2.2	2.3	6.5	10*	
Speyer 2.3	0.95	7.0	3*	
*Indicative values				
<u>[U-ring ¹⁴C]-ioxynil octanoate (20°C; 45% MC) - Study 2</u>				
Simple overall first-order kinetics:				
<u>Soil type</u>	<u>OC %</u>	<u>pH H₂O (KCl)</u>	<u>DT50</u>	<u>(d) R²</u>
loam	2.1	7.1 (6.6)	2.9	0.99
sandy loam	1.2	5.3 (4.3)	6.4	0.99
clay loam	2.0	8.1 (7.5)	1.2	0.94
Multi-compartments with SFO exchange:				
<u>Soil type</u>	<u>DT50 (20°C)</u>	<u>DT50(10°C)</u>	<u>B*</u>	
Loam				
- octanoate	2.9	6.4		
- phenol	1.6	3.4	0.97	
- amide	0.5	1.1		
sandy loam				
- octanoate	6.4	14.1		
- Ioxynil	6.5	14.3	0.73	
- amide	0.6	1.3		
clay loam				
- octanoate	1.2	2.6		
- Ioxynil	0.6	1.3	0.81	
- amide	0.2	0.4		
average				
- octanoate	2.8	6.1		
- Ioxynil	1.8	4.0		
- amide	0.4	0.9		
(* equivalent to R ² for Topfit)				
<u>3,5-di-iodo-4-OH-benzamide (20° C)</u>				
<u>Soil type</u>	<u>OC %</u>	<u>pH</u>	<u>DT50 (d)</u>	<u>R²</u>
Speyer 2.1 standard soil			3.7 (0 - 16 d)	0.98
Speyer 2.2 standard soil			7.7 (0 - 32 d)	-
<u>3,5-di-iodo-4-OH-benzoic acid (22° C)</u>				
DT ₅₀ < 2 d (sand and loam soils), as deduced from degradation of ioxynil .				
DT _{90lab} (20 °C, aerobic):	DT _{90lab} (20°C, aerobic): not calculated			

DT_{50lab} (10 °C, aerobic):DT_{50lab} (10°C, aerobic):Ioxynil

<u>Soil type</u>	<u>OC %</u>	<u>pH</u>	<u>DT50</u> (d)	<u>R²</u>
Sand	1.4	6.7	3.2	-
Loam	1.8	7.0	6.5	0.98
Clay	3.3	7.3	7.5	0.99

Ioxynil octanoate

not determined, calculation required

DT_{50lab} (20 °C, anaerobic):DT_{50lab} (20°C, anaerobic):Ioxynil octanoate

Anaerobic soil : not determined

Anaerobic water-sediment system: DT₅₀ 13.8 d (0–21 d)**Field studies (country or regi**DT_{50f} from soil dissipation studies:DT_{50f}: No data, not requiredDT_{90f} from soil dissipation studies:DT_{90f}: No data, not required

Soil accumulation studies:

Not relevant

Soil residue studies:

Not relevant

Remarks:

e.g. effect of soil pH on degradation rate

Rapid degradation at all pH (DT 50 could be slightly higher in acidic pH)

Adsorption/desorptionK_f / K_{oc}:Ioxynil

Study 1:

K_d:

Soil type	OC %	pH	K _f	1/n	K _{oc}
Sand 1.4	6.7	3.5	0.88	250	
Loam	1.8	7.0	5.1	0.88	276
Clay 3.3	7.3	6.0	0.88	182	

pH dependence:

values overestimated due to possible degradation

Study 2:

adsorption

Soil type	OC %	pH	K _f	1/n	K _{oc}
Loamy Sand 0.5	7.6	1.25	0.96	249	
Loam	2.2	6.7	4.79	0.91	218
Clay loam	4.7	7.3	5.27	0.91	112
Sandy loam	1.2	4.3	7.60	0.90	633

Desorption (1step)

<u>Soil type</u>	<u>OC %</u>	<u>pH</u>	<u>K_f</u>	<u>1/n</u>	<u>K_{oc}</u>
Loamy Sand 0.5	7.6	2.98	1.12	595	
Loam	2.2	6.7	6.79	0.96	309
Clay loam	4.7	7.3	7.61	0.95	162
Sandy loam	1.2	4.3	7.98	0.92	665

Ioxynil octanoate

data submitted ; adsorption coefficient not measurable
ioxynil octanoate is expected to be more adsorbed than ioxynil (Koc values available for Ioxynil can be used for worst case risk assessment of octanoate)

[U-ring ¹⁴C]-3,5-diiodo-4-hydroxybenzamide

adsorption

<u>Soil type</u>	<u>OC %</u>	<u>pH</u>	<u>Kf</u>	1/n	Koc
Loamy Sand0.5	7.6	0.90	1.04	181	
Loam	2.2	6.7	2.94	0.91	134
Clay loam	4.7	7.3	3.01	0.91	64
Sandy loam	1.2	4.3	5.70	0.80	475

Desorption (1step)

<u>Soil type</u>	<u>OC %</u>	<u>pH</u>	<u>Kf</u>	1/n	Koc
Loamy Sand0.5	7.6	9.27	1.49	1854	
Loam	2.2	6.7	4.48	0.89	203
Clay loam	4.7	7.3	4.84	0.90	103
Sandy loam	1.2	4.3	7.83	0.81	653

[U-ring ¹⁴C]-3,5-diiodo-4-hydroxybenzoic acid

adsorption

<u>Soil type</u>	<u>OC %</u>	<u>pH</u>	<u>Kf</u>	1/n	Koc
Loamy Sand0.5	7.6	0.48	0.66	96	
Loam	2.2	6.7	2.45	0.52	111
Clay loam	4.7	7.3	3.40	0.65	72
Sandy loam	1.2	4.3	9.44	0.90	786

Desorption (1step)

<u>Soil type</u>	<u>OC %</u>	<u>pH</u>	<u>Kf</u>	1/n	Koc
Loamy Sand0.5	7.6	2.58	0.53	577	
Loam	2.2	6.7	46.07	0.74	2094
Clay loam	4.7	7.3	492.00	1.21	10467
Sandy loam	1.2	4.3	26.21	0.77	2184

Mobility**Laboratory studies:**

Column leaching:

Fresh residues₂Ioxynil

Leaching with 206 mm water, 4 d. (Poor recovery)

<u>Soil type</u>	<u>OC %</u>	<u>pH</u>	<u>% in leachate</u>
Sand	1.4	6.7	0.45
Loam	1.8	7.0	0.13
Clay	3.3	7.3	0.02

Soil radioactivity (75.9 % – 89.9 %) mainly located in the 4 (sand), 3 (loam and clay) and 1 (peat) top 4 cm soil layers (layers with > 5 %)

Aged residue leaching:

It is a non GLP study, not conducted according to current guidelines

Ioxynil octanoate : no data, expected to be less mobile

Aged residues;

Ioxynil

Incubation for 1, 2 or 3 days before leaching with 206 mm water, 4 d.
(Poor recovery)

After ageing: residues mainly as ioxynil + 3.1 % amide and 21.5 % acid

<u>Soil type</u>	<u>OC %</u>	<u>pH</u>	<u>% in leachate</u>
Sand	1.4	6.7	2.97
Loam	1.8	7.0	1.13
Clay	3.3	7.3	not detected
Peat*	17.4	4.9	not detected

*not representative

Soil radioactivity (61.5 % - 112.2 %) mainly located in the 5 (sand), 3 (loam), 2 (clay) and 1 (peat) top 4 cm soil layers (layers with > 5 %)
Amide and acid derivatives expected to have low potential for groundwater contamination

It is a non GLP study, not conducted according to current guidelines

Field studies:

Lysimeter/Field leaching studie not submitted. Requirement depending on modelling PEC gw

Remarks:

none

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

Ioxynil
Stable at pH 5, 7 and 9 at 22°C, 10 d

Ioxynil octanoate (2 studies)
pH 4-5 (22-25° C) stable
pH 7 (22° C) DT₅₀ 6 d - (25° C) DT₅₀ 52 d
expected metabolite : ioxynil
pH 9 (22° C) DT₅₀ 16 d - (25° C) DT₅₀ 5.3 d
expected metabolites : ioxynil and 3-iodo-4-hydroxybenzoxitrile

Major metabolites:

ioxynil and 3-iodo-4-hydroxybenzoxitrile

Photolytic degradation:

Ioxynil
Continuous artificial light 216 h
DT₅₀ 120 h or 0.8 - 11.2 h at 52° N
Quantum yield 0.058 mole einstein⁻¹

Ioxynil octanoate
(study 1):
pH 5, continuous artificial light 48 h, 20° C _ DT₅₀ 6.9 h

(study 2)
pH 4.5, 20 ± 2 °C within 24 h continuous artificial light - DT50 4.4 h.
3 major metabolites detected : ioxynil , 4-hydroxy-benzoxitrile and 4-cyano-2-iodophenyl octanoate.
4-hydroxy-3-iodobenzoxitrile and 4-hydroxy-3,5-diiodobenzamide also detected as minor metabolites.

Quantum yield 2.88 10⁻² mole einstein⁻¹

Major metabolites:

ioxynil , 4-hydroxy-benzoxitrile and 4-cyano-2-iodophenyl octanoate

Biological degradation

Readily biodegradable:	Ioxynil octanoate: no Ioxynil : no
Water/sediment study:	<u>Ioxynil (first-order)</u> DT ₅₀ water: 3.5 d (R ² 0.99)- 3.8 d (R ² 0.98) ; DT ₉₀ water: 11.7 d - 12.6 d DT ₅₀ whole system: 4.6 d (R ² 0.99) - 4.9 d (R ² 0.95) ; DT ₉₀ whole system: 15.3 d - 16.3 d
DT ₅₀ water:	
DT ₉₀ water:	
DT ₅₀ whole system:	
DT ₉₀ whole system:	
	<u>Ioxynil octanoate</u> Octanoate: first-order (0 - 14 d), Ioxynil derivative: KIM model, apparent half life, all data) DT ₅₀ water. octanoate: 0.42 d (R ² 0.84) - 0.91 d (R ² 0.98), Ioxynil : 1.6 d (R ² 0.97) - 8.6 d (R ² 0.98) ; DT ₉₀ water. octanoate: 1.39 d - 3.03 d, Ioxynil : 6.6 - 23.0 d DT ₅₀ whole system. octanoate: 2.87 d (R ² 0.95)- 3.76 d (R ² 0.83), Ioxynil : 3.5 d (R ² 0.99) - 4.9 d (R ² 0.98) ; DT ₉₀ whole system. octanoate: 9.5 d - 12.5 d, Ioxynil : 9.3 d - 20.2 d)
Distribution in water / sediment systems (active substance)	<u>Ioxynil :</u> max. 15.1 % (7 d) - 20.6 % (7 d) in sediment vs 27.8 % (7 d) - 37.8 % (7 d) in water - No residues after 14 d <u>Ioxynil octanoate:</u> max. 34.5 % (1 d) - 44.2 % (<1 d) in sediment vs 20.7 % (1 d) - 28.8 % (<1 d) in water 1.5 % - 1.3 % (60 d, sediment)
Distribution in water / sediment systems (metabolites)	<u>Ioxynil</u> - di-iodo-4-OH-benzamide : max. 11.3 % in water, 3.6 % in sediment (7 d). No residues after 14 d <u>Ioxynil octanoate</u> - ioxynil : max. 41.2 % (2 d) - 52.2 % (2 d) in water vs 11.8 % (7 d) - 10.7 % (1 d) in sediment. - 0 % - 0.3 % in sediment at 60 d
Accumulation in water and/or sediment:	none
Degradation in the saturated zone	Not required

Remarks:

none

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

Ioxynil : 2.04×10^{-6} Pa at 20 °C
Ioxynil octanoate : $< 0.9 \times 10^{-7}$ Pa at 45 °C

Henry's law constant:

Ioxynil: 1.5×10^{-5} Pa m³ mol⁻¹ at 25°C
Ioxynil octanoate : cannot be calculated because values of the solubility in water and vapour pressure.

Photolytic degradation

Direct photolysis in air:

No data

Photochemical oxidative degradation in air

DT₅₀:DT₅₀ : 7.2 h for Ioxynil octanoate and 8 h for Ioxynil (Atkinson)

Volatilisation:

Ioxynil octanoate
from plant surfaces: 0.2 % (107.3 % associated with plant material, 90.4 % extractable mainly as Ioxynil octanoate)Ioxynil octanoate
from soil surface: 0.47 % (98.7 % recovered from soil)

Remarks:

none

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	DL ₅₀ (ioxynil , rat) = 130 mg/kg b.w. DL ₅₀ (ioxynil octanoate, rat) = 165 mg/kg b.w. NOEL (Ioxynil and ioxynil octanoate , rat, rabbit) = 1 – 15 mg/kg b.w./d (mean 5 mg/kg b.w.) NOEL (ioxynil , reproduction, rat) = 30 mg/kg diet ¹ , corresponding to 10 mg/kg bw/d
Acute toxicity to birds:	LD ₅₀ (ioxynil , quail) = 62 mg/kg b.w. LD ₅₀ (ioxynil octanoate, quail) = 677 mg/kg b.w. LD ₅₀ (MEXTROL H, quail) > 2 000 mg/kg b.w.
Dietary toxicity to birds:	LC ₅₀ (ioxynil , quail) = 1 346 mg/kg diet LC ₅₀ (ioxynil octanoate, quail) = 2 563 mg/kg diet
Reproductive toxicity to birds:	NOEC (ioxynil , quail) = 100 mg/kg diet ¹ (parent), 300 mg/kg diet (reproduction), corresponding to 37.6 mg/kg bw/d NOEC (ioxynil octanoate, quail) = 250 mg/kg diet (parent), 500 mg/kg diet (reproduction)
Long term toxicity to mammals:	NOEL (ioxynil , reproduction, rat) = 30 mg/kg diet ¹ , corresponding to 10 mg/kg bw/d NOEL (ioxynil octanoate and , rat, rabbit) = 1 – 15 mg/kg b.w./d (mean 5 mg/kg b.w.)

¹ EC containing 253.9 g/l ioxynil octanoate (180 g/l Ioxynilequivalent) + 468.7 g mecoprop-P butoxyethanol ester (i.e. 290 g/l mecoprop-P)

Aquatic Organisms

Group	Endpoint	Toxicity (mg/l) ¹
Ioxynil		
Acute toxicity fish:	LC ₅₀ – 96 h	8.5
	LC ₅₀ – 96 h	0.64 ² (M. agan, 1985)
	LC ₅₀ – 96 h	3.5
Long term toxicity fish:	NOEC – 21 d	3.2 ²
Bioaccumulation fish:	Ioxynil : logPow = 0.23 at pH 8.7, BCF = 6 (edible), 65 (inedible), 29 (whole fish)	
Acute toxicity invertebrate (daphnids):	EC ₅₀ – 48 h	3.9
	EC ₅₀ – 48 h	7.7 (M. agan, 1985)
	EC ₅₀ – 48 h	3.14 ²
Chronic toxicity invertebrate (daphnids):	NOEC – 21 d	0.013
Acute toxicity algae:	EC ₅₀ – 96 h	24
	EC ₅₀ – 72 h	0.15 ²

Chronic toxicity sediment dwelling organism:	No data, not required	
Toxicity aquatic plants: (for herbicides only)	EC ₅₀ – 14 d	0.027 ²
Toxicity to <i>Xenopus laevis</i>	NOEC – 42 d	0.844
Ioxynil octanoate		
Acute toxicity fish:	LC ₅₀ – 96 h	0.043
	LC ₅₀ – 96 h	0.024 ²
with sediment:	EC ₅₀	0.285 ²
	NOEC	0.213
Long term toxicity fish:	NOEC – 21 d	0.021
	NOEC – 36 d	0.0022 ²
Bioaccumulation fish:	Ioxynil octanoate : Log Pow > 3, BCF <i>ca</i> 100- 135 Ioxynil octanoate : BCF (steady state of total residues) = 83-71 (edible), 399-298 (inedible), 212-163 (whole fish)	
Acute toxicity invertebrate (daphnids):	EC ₅₀ – 48 h	0.011 ²
	EC ₅₀ – 48 h	8.9
with sediment	EC ₅₀	> 0.068 ²
	NOEC	0.068
Acute toxicity invertebrate (daphnids):	EC ₅₀ – 48 h	0.011 ²
	EC ₅₀ – 48 h	8.9
	EC ₅₀	> 0.068 ²
	NOEC	0.068
Chronic toxicity invertebrate (daphnids):	NOEC – 21 d	0.010
	NOEC - 21 d	0.0026 ²
Acute toxicity algae:	EC ₅₀ – 96 h	> 4.6
	EC ₅₀ – 72 h	0.24 ²
Chronic toxicity sediment dwelling organism:	NOEC – 21 d	0.1 ²
	EC ₅₀ – 14 d	0.017 ²
Ioxynil sodium salt		
Acute toxicity fish:	LC ₅₀ – 96 h	0.37
Long term toxicity fish:	NOEC – 21 d	0.0909
Bioaccumulation fish:	No data, not required, refer to ioxynil	
Acute toxicity invertebrate (daphnids):	EC ₅₀ – 48 h	5.2
	NOEC – 21 d	0.05 ^{3,4}
Chronic toxicity invertebrate (daphnids):	EC ₅₀ – 72 h	31
	No data, not required, refer to ioxynil	
Acute toxicity algae:	No data, not required, refer to ioxynil	
	No data, not required, refer to ioxynil	
MEXTROL H		
Acute toxicity fish:	LC ₅₀ – 96 h	0.25

Long term toxicity fish:
 Bioaccumulation fish:
 Acute toxicity invertebrate
 (daphnids):
 Chronic toxicity invertebrate
 (daphnids):
 Acute toxicity algae:
 Chronic toxicity sediment
 dwelling organism:
 Acute toxicity aquatic plants: (for
 herbicides only)

No data, not required	
No data, not required	
EC ₅₀ – 48 h	0.0849
No data, not required	
EC ₅₀ – 72 h	1.68
No data, not required	
No data, not required	

¹ mg a.s. or preparation/l

² value relevant for risk assessment

³ correction to take account of the purity of the test substance (50 g sa/l, expressed as Ioxynil equivalent)

⁴ value relevant for risk assessment agreed at ECCO 110 to replace the less reliable value 0.013 mg/l

⁵ EC containing 253.9 g/l ioxynil octanoate (180 g/l Ioxynil equivalent) + 468.7 g mecoprop-P butoxyethanol ester (i.e. 290 g/l mecoprop-P)

Honeybees

Acute oral toxicity:

LD₅₀ = 10.1 microg ioxynil /bee
 LD₅₀ > 3.27 microg ioxynil octanoate/bee

Acute contact toxicity:

LD₅₀ > 100 microg ioxynil /bee
 LD₅₀ > 200 microg ioxynil octanoate/bee

Other arthropod species

Test species	Stage	Test substance	Dose (kg as/ha)	End point	% Effect
Laboratory tests					
<i>A. rhopalosiphi</i>	adults	TOTRIL	0.625 ²	mortality	E = 55.6
			0.025 ²	fecundity	E = 19
				mortality	E = - 5.6
				fecundity	E = - 6
			2.7 l/ha ¹ 15 d-aged residues in extended lab test	mortality	E = 5
				fecundity	E = - 13.4
<i>T. pyri</i>	proto-nymphs	TOTRIL	0.625 ²	mortality	E = 98.7
			0.025 ²	fecundity	E = ND
			(glass)	mortality	E = 17.7
				fecundity	E = 57
			0.025 ² (leave)	mortality	E = 18.7
				fecundity	E = 4.4
			0.0045 ² (glass)	mortality	E = 0
				fecundity	E = 4.4
<i>P. cupreus</i> <i>P. cupreus</i>	adults	TOTRIL	0.625 ²	mortality	E = 0
				food consumption	E = 8.5
		MEXTROL H	2.2 kg/ha ¹	mortality	E = 0
				food consumption	E = 0
<i>A. bilineata</i>	adults	MEXTROL H	1.81 kg/ha ¹	parasitisation	E = 0
				hatching rate	E = 21.8
<i>C. carnea</i>	larvae	TOTRIL	0.625 ²	mortality	E = 8.4
				fecundity	E = 48.8

¹ preparation² dose expressed as ioxynil Ioxynil equivalent³ EC containing 324.2 g/l ioxynil octanoate (225 g/l Ioxynil equivalent)⁴ EC containing 253.9 g/l ioxynil octanoate (180 g/l Ioxynil equivalent) + 468.7 g mecoprop-P butoxyethanol ester (i.e. 290 g/l mecoprop-P)**Earthworms**

Acute toxicity:

LC ₅₀ > 60 mg ioxynil /kg soil
LC ₅₀ > 60 mg ioxynil octanoate / kg soil
LD ₅₀ = 663 mg EXP03334 ¹ /kg soil
LD ₅₀ = 863 mg MEXTROL H ² /kg soil

Reproductive toxicity:

NOEC = 20 mg ioxynil /kg soil soil

¹ OXYTRIL CM: EC preparation containing 294.2 g/l bromoxynil octanoate (200 g/l Ioxynil equivalent) + 281.7 g/l ioxynil octanoate (200 g/l Ioxynil equivalent)² EC containing 253.9 g/l ioxynil octanoate (180 g/l Ioxynil equivalent) + 468.7 g mecoprop-P butoxyethanol ester (i.e. 290 g/l mecoprop-P)

Soil micro-organisms

Nitrogen mineralization:

effects < 25% at 2.94 mg ioxynil octanoate/kg soil ¹

Carbon mineralization:

effects < 25% at 2.94 mg ioxynil octanoate/kg soil ¹

¹ concentration equal to 3.7-fold PECs for the maximum use in cereals (0.603 kg ioxynil octanoate/ha)

APPENDIX IIIA**IOXYNIL**

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 inclusion.

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	Reports⁶ on previous use in granting national authorizations
IIA, 1.11	Gomez, F., Duverney-Prêt, P., Just, D., Rosati, D.	1995	Ioxynil technical grade active ingredient Analysis and certification of product ingredients Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-27 Date: September 29, 1995 Bayer CropScience Doc n°439087 GLP Not published	
IIA, 2.1.1/01	Certon, A., Cousin, J.	1995	Ioxynil active ingredient : physical characteristics Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-41 part A Date: May 15, 1995 Bayer CropScience Doc n°438346 GLP Not published	

⁶ Entries are based on information received from the Notifier(s) and in certain cases Member States. Neither the Commission nor the Member States are responsible for the completeness or validity of this information received.

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 ⁶ on previous use in granting national authorizations
IIA, 2.1.1/02	Duverney-Prêt P., Bascou J.Ph.	1999	Ioxynil octanoate: physical characteristics Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-206 part A, DOC 445442 Date: March 10, 1999 Bayer CropScience Doc n°445442 GLP Not published	
IIA, 2.1.1/03	Cousin J.A.	1995	Ioxynil active ingredient : physical characteristics Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-41 part A Date: may 16, 1995 Bayer CropScience GLP Not published	
IIA, 2.1.1/04	Bascou J.P.	1999	Ioxynil octanoate : physical characteristics Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-206 part A Date: april 22, 1999 Bayer CropScience GLP Not published	

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	Reports⁶ on previous use in granting national authorizations
IIA, 2.1.2./01	Bascou J.P.	1999	Ioxynil octanoate : physical characteristics Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-206 part A Date: april 22, 1999 Bayer CropScience GLP Not published	
IIA, 2.2/01	Cousin J.A.		2.1.1./03	
IIA, 2.2/02	Fillon J	1996	Determination of the flash point, the auto-flammability ant the explosion properties of EXP03273B* Generated by: Rhône-Poulenc Agrochimie Submitted by: Rhône-Poulenc Agrochimie Report n°: 96-67 Date: 20 august 1996 Bayer CropScience GLP Not published	
IIA, 2.3.2/01	Bascou JP	1999	Ioxynil : Henry's Law Constant Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: R&D/CRLD/AN/9916115 Date: 06 july 1999 Bayer CropScience document 446101 GLP Not published	

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	Reports⁶ on previous use in granting national authorizations
IIA, 2.3.2/02	Bascou JP	1999	Ioxynil octanoate : Henry's Law Constant Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: R&D/CRLD/AN/9916116 Date: 06 July 1999 Bayer CropScience Doc n°446104 GLP Not published	
IIA, 2.4.1			See 2.1.1	
IIA, 2.4.2			See 2.1.1	
IIA, 2.5.1/01	Just, D., Vidal, J., Guesnet, J.L.	1998	Ioxynil NMR, IR and MS Spectra Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-156 Date: August 24, 1998 Bayer CropScience Doc n°444236 GLP Not published	
IIA, 2.5.1/02	Jendrejczak, N. Turier, G. and Adrian P.	1991	Ioxynil UV visible spectrum Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 9116861 11/24/1991	

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	Reports⁶ on previous use in granting national authorizations
IIA, 2.5.1/03	Just, D., Vidal, J., Guesnet, J.L.	1998	Ioxynil Octanoate NMR, IR and MS Spectra Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-157 Date: August 25, 1998 Bayer CropScience Doc n°444237 GLP Not published	
IIA, 2.5.1/04	Jendrejczak, N. Turier, G. and Adrian P.	1991	Ioxynil octanoate UV visible spectrum Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 9116888 12/03/1991	
IIA, 2.6/01	Certon, A., Cousin, J.	1994	Ioxynil - water and solvent solubility Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-41 part C Date: June 13, 1994 Bayer CropScience Doc n°438262 GLP Not published	
IIA, 2.6.1./02	Cousin J.A.	1995	Ioxynil active ingredient : physical characteristics Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-41 part B Date: may 16, 1995 Bayer CropScience GLP Not published	

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	Reports⁶ on previous use in granting national authorizations
IIA, 2.6.1/03	Cousin J.A.	1995	Ioxynil : water and solvent solubility Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-41 part C Date 26 april 1995 Bayer CropScience GLP Not published	
IIA, 2.6.1/04	Duverney-Prêt P., Bascou J.P.	1999	Ioxynil octanoate - water and solvent solubility Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-206, part C Date: July 05, 1999 Bayer CropScience Doc n°445886 GLP Not published	
IIA, 2.6.1/05	Bascou JP	1999	Ioxynil octanoate : water and solvent solubility Generated by : Rhône-Poulenc Agrochimie, France Submitted by : Rhône-Poulenc Agrochimie Report n° : R&D/CRLD/AN/9915972 Date : 05 july 1999 Bayer CropScience GLP Not published	
IIA, 2.7./01	Cousin J.A.		2.6.1.	
IIA, 2.7./02	Carpenter		2.1.1	
IIA, 2.7./03	Bascou J.P.		2.6.1.	

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	Reports⁶ on previous use in granting national authorizations
IIA, 2.8.1/01	Bascou JP	1995	Ioxynil active ingredient : n-octanol/water partition coefficient Generated by : Rhône-Poulenc Agrochimie, France Submitted by : Rhône-Poulenc Agrochimie Report n° : R&D/CRLD/AN/9515752 Date may 18, 1995 Bayer CropScience GLP Not published	
IIA, 2.8.1/02	Certon, A., Cousin, J.	1995	Ioxynil active ingredient - n-Octanol/water partition coefficient. Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-41 part D Date: May 5, 1995 Bayer CropScience Doc n°438323 GLP Not published	
IIA, 2.8.1/03	Duverney-Prêt P., Bascou J.P.	1999	Ioxynil octanoate - n-Octanol/water partition coefficient. Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-206 part D Date: June 06, 1999 Bayer CropScience Doc n°445720 GLP Not published	

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	Reports⁶ on previous use in granting national authorizations
IIA, 2.8.1/04	Bascou JP	1999	Ioxynil octanoate : n-octanol/water partition coefficient Generated by : Rhône-Poulenc Agrochimie, France Submitted by : Rhône-Poulenc Agrochimie Report n° : R&D/CRLD/AN/9915676 Date : 18 June 1999 Bayer CropScience GLP Not published	
IIA, 2.9.1./01	England, D.A. et al	1987	Ioxynil octanoate, hydrolysis in water containing acetonitrile (1%) as co solvent at 22°C, 50°C, 70° Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: Ag 305 Date 17 february 1987	
IIA, 2.9.2./01	Cicotti, M	1992	Determination of phototransformation of ioxynil in water Generated by : Battelle-Europe, Switzerland Submitted by : Rhône-Poulenc Agrochimie Report n° : BE-P-1-91-PHO-01-BG Date : 1 May 1992	
IIA, 2.9.3/02	Offizorz, P.	1993	Determination of the direct phototransformation of bromoxynil heptanoate in water Generated by : RCC Umweltchemie, Germany Submitted by : Rhône-Poulenc Agrochimie Report n° : 327306 Date : 3 February 1993 Bayer CropScience GLP Not published	
IIA, 2.9.4/01	Carpentier, K		see 2.1.1.	

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	Reports⁶ on previous use in granting national authorizations
IIA, 2.9.4/02	Cousin J.A.		see 2.6.1.	
IIA, 2.9.4/03	Certon A., Kochian C., Cousin J.A.	1995	Ioxynil active ingredient : pH and dissociation constant Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-41 part B Date: june 9, 1995 Bayer CropScience document 438404 GLP Not published	
IIA, 2.9.4/04	Duverney-Prêt P., Bascou J.P.	1999	Ioxynil octanoate : pH and dissociation constant Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-206 part B Date: april 22, 1999 Bayer CropScience document 445460 GLP Not published	
IIA, 2.9.5/01	Bascou J.P.		see 2.9.4.	
IIA, 2.9.5/02	Bosselin B.	1995	Confirmation of identity and determination of the physical, chemical and technical properties of Mextrol H – document J * Generated by : CFPI Submitted by : CFPI Study CROT 06/C/516/RI Date : 3 march 1995 Bayer CropScience Nufarm GLP Not published	

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	Reports⁶ on previous use in granting national authorizations
IIA, 2.10/01	Corgier M. and Plewa A.	1998	Active substance Ioxynil estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions (Atkinson equation) – Study 98-154 Bayer CropScience, Document R014991 GLP not published	
IIA, 2.10/02	Corgier M. and Plewa A.	1998	Ioxynil octanoate estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions (Atkinson equation) – Study 98-155 Bayer CropScience, Document R014993 GLP Not published	
IIA, 2.11.1			See 2.13	
IIA, 2.11.2			See 2.13	
IIA, 2.13/01	Treand G.	1996	Determination of the explosion properties, flammability, and the relative self-ignition temperature of ioxynil. Generated by : CRIT/D, France Submitted by : Rhône-Poulenc Agro Report n° : 96-18 Bayer CropScience Doc n°440826 GLP Not published	
IIA, 2.13/02	Treand G.	1996	Determination of the explosion properties, flammability, and the relative self-ignition temperature of ioxynil octanoate. Generated by : CRIT/D, France Submitted by : Rhône-Poulenc Agro Report n° : 96-19 Date : November 15, 1996 Bayer CropScience Doc n°440827 GLP Not published	

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 ⁶ on previous use in granting national authorizations
IIA, 2.14/01	Kochian C., Cousin JA	1995	Ioxynil active ingredient : surface tension Generated by: Rhône-Poulence Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-41 part E Date : April 6, 1995 Bayer CropScience Doc n°438264 GLP Not published	
IIA, 2.14/02	Bascou J.P.		2.1.2.	
IIA, 2.15/01	Francois JM	1998	Determination of the oxidizing properties of the technical ioxynil Generated by : CRIT/D, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-191 Date: 27 october 1998 Bayer CropScience Doc n°444602 GLP Not published	
IIA, 2.15/02	Francois JM	1998	Determination of the oxidizing properties of the technical ioxynil octanoate Generated by : CRIT/D, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-192 Date: 27 october 1998 Bayer CropScience Doc n°444603 GLP Not published	

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 ⁶ on previous use in granting national authorizations
IIA, 4.1./01	Uceda L., Yslan F.	1996	Ioxynil octanoate, determination by GLC analysis in formulation EXP 03273B.* Date : 1996 Generated by : Rhône-Poulenc Agrochimie Submitted by : Rhône-Poulenc Agrochimie Study 9615725 Bayer CropScience GLP Not published	
IIA, 4.1./02	Gomez F.	1996	Ioxynil – Technical grade active ingredient. Analysis and certification of product ingredient Generated by : Rhône-Poulenc Agrochimie Submitted by : Rhône-Poulenc Agrochimie Study 95-27 doc no : R&D/CRLD/AN/9516368 Bayer CropScience GLP Not published	
IIA, 4.1./03	Duverney-Prêt P.	1995	Ioxynil – Technical grade active ingredient HPLC determination of active ingredient content method I-807-04-95 – 3/05/95 Generated by : Rhône poulenc agrochimie Submitted by : Aventis CropScience GLP Not published	
IIA, 4.1./04	Bowen T.	2001	Analytical method – Ioxynil octanoate (AE F065322) – Determination of ioxynil octanoate in ioxynil octanoate technical material by HPLC. method AL 090/ 00-0) – Generated by : Aventis CropScience Submitted by: : Aventis CropScience Bayer CropScience document C012076 Not published	

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	Reports⁶ on previous use in granting national authorizations
IIA, 4.1/05	Bowen T.	2001	Validation of the Analytical method AL 090/00-0 for the determination of ioxynil octanoate in the ioxynil octanoate technical material Report PA00/040 – Generated by : Aventis CropScience Submitted by : Aventis CropScience :Bayer CropScience document C012077 GLP Not published	
IIA, 4.1/06	Gabay P.	1993	Assay procedure for Ioxynil octanoate and mecoprop-p 2-butoxyethyl ester reference method : C-organic-444-TA Generated by : CFPI Qualité Submitted by : CFPI Qualité Date : 01/01/93 CFPI Nufarm GLP Not published	
IIA, 4.1/07	Duverney-Prêt P.	1995	Ioxynil – Technical grade active ingredient HPLC determination of organic impurities method I-813-06-95 – Generated by : Rhône poulenc agrochimie Submitted by : Aventis CropScience Bayer CropScience GLP	
IIA, 4.1/08	Bowen T.	2001	Analytical method – Determination of organic impurities in ioxynil octanoate technical material by HPLC. Report AL003/01-2 Generated by : Aventis CropScience Submitted by : : Aventis CropScience Bayer CropScience document C013166 Not published	

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	Reports⁶ on previous use in granting national authorizations
IIA, 4.1/09	Bowen T.	2001	Validation of the Analytical method AL 003/01-2 for the determination of organic impurities in ioxynil octanoate technical material Report PA01/004 Generated by : Aventis CropScience Submitted by : : Aventis CropScience Bayer CropScience document C013167 GLP Not published	
IIA, 4.1/10	Bowen T.	2001	Analytical method – Determination of organic impurities in ioxynil octanoate technical material by GC Report AL004/01-2 Generated by : Aventis CropScience Submitted by : : Aventis CropScience Bayer CropScience document C013486 Not published	
IIA, 4.1/11	Adam C	2001	Determination of Ioxynil octanoate impurity contents in technical by GC – Updated version of method C-organique-00485-C-TA – Generated by : CFPI Submitted by : CFPI Nufarm GLP Not published	
IIA, 4.1/12	Bowen T.	2001	Validation of the Analytical method LM 004/01-1 for the determination of organic impurities in ioxynil octanoate technical material Report PA01/005 Generated by : Aventis CropScience Submitted by : : Aventis CropScience Bayer CropScience document C013487 GLP Not published	

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 ⁶ on previous use in granting national authorizations
IIA, 4.1/13	Adam C	2001	Ioxynil octanoate: Determination of active ingredient contents in technical by GC – Updated version of method C-organique-00484-C-TA – Generated by : CFPI Submitted by : CFPI Nufarm GLP Not published	
IIA, 4.1/14	Adam C	2001	Determination of Ioxynil octanoate impurity contents in technical by HPLC –Updated version of method C-organique-00483-C-TA – Generated CFPI Submitted by : CFPI Nufarm GLP Not published	
IIA, 4.1/15	Guzikevich-Guerstein, M.Sc		Analysis of 5 lots of ioxynil technical Date : 1995 Generated by : Makhteshim Agan Manufacturer Submitted by : Makhteshim Agan Manufacturer Study 94-01 Not published	
IIA, 4.1/16	Guzikevich-Guerstein, M.Sc		Analysis of 5 lots of iotril technical Date : 1995 Generated by : Makhteshim Agan Manufacturer Submitted by : Makhteshim Agan Manufacturer Study 94-02 Not published	
IIA, 4.1/17	Weiss, A		Ioxynil technical – determination of the active ingredient and five impurities in five production batches Date : april 25, 1995 Generated by : Huntingdon Research Centre Ltd Submitted by : Makhteshim Agan Manufacturer Study AGM 29/950422 Not published	

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 ⁶ on previous use in granting national authorizations
IIA, 4.1/18	Weiss, A		Iotril technical – determination of the active ingredient and ten impurities in five production batches Date : July 11, 1995 Generated by : Huntingdon Research Centre Ltd Submitted by : Makhteshim Agan Manufacturer Study AGM 32/950904 Not published	
IIA, 4.2.1/01	Anding, C.	1997	Method for the analysis of residues of Bromoxynil, Ioxynil and their metabolites in rape. Generated by : Rhône-Poulenc Agro, France Submitted by : Rhône-Poulenc Agro Report n° : 95-502 ; 95-501 ; 95-503 ; 96-510 ; 96-509 ; 96-511 Date : July 18, 1997 Bayer CropScience document 445237 GLP Not published	
IIA, 4.2.1/02	Le Brun G	2000	Development and validation of a method of analysis for the determination of Ioxynil (phenol, heptanoate, octanoate) in cereals and cotton seeds - RPA/BROM/99001 (RPA study 99-70, method AR 202-99) - Generated by : GIRPA, Beaucouzet , France Submitted by : Aventis CropScience Bayer CropScience document R015033 GLP Not published	

IIA, 4.2.1/03	Fuchsbichler G.	1999	Validation of the multi-residue method (DFGS19) for the determination of Ioxynil Octanoate in Cereals : grain and straw. Study 99-60 (Method AR197-99), HVA 11/99 generated by : Bayerische Hauptversuchsanstalt für Landwirtschaft Bayer CropScience document R015009 GLP Not published
IIA, 4.2.1/04	Fuchsbichler G.	2000	Independent laboratory validation of analytical method AR 202-99 for the determination of Ioxynil (phenol, octanoate) in cereals (grain) and cotton seed - Aventis CropScience study 00-03 (HVA 10/00) – generated by : Bayerische Hauptversuchsanstalt für Landwirtschaft Bayer CropScience document R015037 GLP Not published
IIA, 4.2.2/01	Geraupt F., Le Brun G.	1999	Development and validation of a method of analysis for the determination of ioxynil (phenol, octanoate) in soils Generated by : GIRPA Submitted by Rhône Poulenc Agrochimie Report n° : 99-72 (method AR 204-99) date : october 05, 1999 Bayer CropScience document 446443 GLP Not published
IIA, 4.2.2/02	Le Brun G.	1999	Development and validation of a method of analysis for the determination of Ioxynil (phenol, octanoate) in soils -RPA/IOXY/99002 (RPA study 99-72, method AR 204-99) Generated by : GIRPA, Beaucouze, France Submitted by Rhône Poulenc Agrochimie Bayer CropScience document R015025 GLP Not published

IIA, 4.2.3/01	Le Brun G.	1999	Development and validation of a method of analysis for the determination of Ioxynil (phenol, octanoate) in waters - RPA/IOXY/99003 (RPA study 99-74, method AR 206-99) - Generated by : GIRPA, Beaucouze, France Submitted by Rhône Poulenc Agrochimie Bayer CropScience document R015027 GLP Not published	
IIA, 4.2.3/02	Gerault F., Le Brun G.	1999	Development and validation of a method of analysis for the determination of ioxynil (phenol, octanoate) in water Generated by : GIRPA, France Submitted by Rhône Poulenc Agrochimie Report n° : 99-74 (method AR 206-99) date : october 05, 1999 Bayer CropScience Doc n°446444 GLP Not published	
IIA, 4.2.4/01	Jendrzejjczak, N and Maestracci, M.	1994	Analytical method for the determination of Ioxynil in air Generated by: RP Agrochimie. Submitted by: Rhône-Poulenc Agrochimie Report n°: R&D/CRLD :AN :9415412 Date: 14 april 1994 Bayer CropScience , document 436447 GLP Not published	
IIA, 4.2.4/02	Maestracci M.M. and Turier G.P..	1994	Analytical method for the determination of ioxynil octanoate in air Generated by: RP Agrochimie. Submitted by: Rhône-Poulenc Agrochimie Report n°: R&D/CRLD :AN :9415538 Date: 24 may 1994 Bayer CropScience , document 436517 GLP Not published	

IIA, 4.2.5/01	Bourgade, C., Faure, C., Guillet, M., Simonin, B.	1997	Ioxynil : analytical method for the determination of residues in foodstuffs of animal origin Generated by Rhône-Poulenc Agro, France Submitted by : Rhône-Poulenc Agro Report n° : AR 137-96 Date : March 7 , 1997 Bayer CropScience Doc n°441391 GLP Not published	
IIA, 4.2.5/02	Guillet, M., Simonin, B.	1997	Ioxynil : analytical method for the determination of residues in foodstuffs of animal origin. Generated by : Rhône-Poulenc Agro, France Submitted by : Rhône-Poulenc Agro Report n° : 9715297 Date : March 13, 1997 Bayer CropScience GLP Not published	
IIA, 4.2.5/03	Yslan, F.	1999	Ioxynil : analytical method for the determination of residues in foodstuffs of animal origin - Amendment N°1. Generated by : Rhône-Poulenc Agro, France Submitted by : Rhône-Poulenc Agro Report n° : 9715297 Date : February 12, 1999 Bayer CropScience GLP Not published	
IIA, 4.2.5/04	Yslan, F.	1999	Ioxynil : analytical method for the determination of residues in foodstuffs of animal origin. Amendment N°1 Generated by : Rhône-Poulenc Agro, France Submitted by : Rhône-Poulenc Agro Report n° : AR 137-96 Date : February 8, 1999 Bayer CropScience Doc n°441391 GLP Not published	

IIA, 4.2.5./05.	Le Brun G.	2000	Development and validation of a method of analysis for the determination of Ioxynil (phenol, octanoate) in foodstuffs of animal origin -RPA/ IOXY/99004 (RPA study 99-76, method AR 208-99) Generated by : GIRPA, Beaucouze, France Submitted by Aventis CropScience Bayer CropScience document R015031 GLP Not published	
IIA, 4.2.5./06	Bacher R., Class Th.	2000	Independant laboratory validation of Aventis CropScience analytical method AR 208-99 for the determination of Ioxynil in products of animal origin Aventis CropScience study 00-05 (PTRL Europe study n° P 397 G, Report n° B 379G) Generated by : PTRL europe Submitted by Aventis CropScience Bayer CropScience document R015039 GLP Not published	
IIA, 4.2.5./07	Goller G.	2000	Development and validation of an analytical method for the determination of Bromoxynil (phenol, heptanoate, octanoate) and Ioxynil (phenol and octanoate) in blood – Study ACS 00-61 (Method AR 247-00) - generated by : ADME bioanalyses submitted by : Aventis Crop Science, document R011964 GLP Not published	

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
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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
IIA, 5.2.1	Ruat C	2000	loxynil phenol: single dose toxicity by oral route in the rat Generated by : Phoenix International 198/100 Submitted by Aventis CropScience Bayer CropScience document C012173 GLP Not published	
IIA, 5.2.6	Ruat C	2000	loxynil octanoate: sensitising potential in the guinea-pig. M & K test Phoenix International 198/094 Submitted by Aventis CropScience Bayer CropScience document C012716 GLP Not published	
IIA, 5.4/01	Whitwell J	2000	loxynil phenol: Induction of micronuclei in the bone marrow of treated mice Covariance Lab Ltd 198/161-D5140 Submitted by Aventis CropScience Bayer CropScience document R015077 GLP Not published	
IIA, 5.4/02	Ballantyne M	2002	loxynil octanoate: reverse mutation in five histidine-requiring strains of Salmonella typhimurium. Covance Laboratories, Harrogate, North Yorkshire, GBR 2014/36-D6171 Submitted by Aventis CropScience Bayer CropScience document C021982 GLP Not published	

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
IIA, 5.4/03	Lloyd M	2002	loxynil octanoate: Mutation of the Thymidine Kinase (tk) Locus of the mouse lymphoma L5178y cells (MLA) Covance Laboratories, Harrogate, North Yorkshire, GBR 2014/38-D6173 Submitted by Aventis CropScience Bayer CropScience document C021427 GLP Not published	
IIA, 5.4/04	Howe J, Semino G	2002	loxynil octanoate: Induction of micronuclei in the bone marrow of treated mice Covance Laboratories, Harrogate, North Yorkshire, GBR 2014/37-D6172 Submitted by Aventis CropScience Bayer CropScience document C021980 GLP Not published	
IIA, 5.8/01	Denton SM	2001	AE 0540061: acute oral toxicity study in the rat Covance Laboratories, Harrogate, North Yorkshire, GBR 2014/17-D6144 Submitted by Aventis CropScience Bayer CropScience document C021605 GLP Not published	
IIA, 5.8/02	Ballantyne M	2001	AE 0540061: reverse mutation in five histidine-requiring strains of Salmonella typhimurium. Covance Laboratories, Harrogate, North Yorkshire, GBR 2014/16-D6171 Submitted by Aventis CropScience Bayer CropScience document C021615 GLP Not published	

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
IIA, 5.8./03	Chasseaud LF Taylor T Forrest TJ McTigue JJ Hood AJ	1993	The effects of loxynil on the binding of 125I-Thyroxine (T4) to rat plasma proteins in vitro HRC/ITT 1/930764 Submitted by Rhône Poulenc Agro Bayer CropScience GLP Not published	
IIA, 5.9/01	Johnston RD	1989	Medical surveillance in HBN production plant in the years 1983/1984 and 1989 Code: AE F025943, AE F051835. Rhone Poulenc Ltd, UK Occupational health. Submitted by Rhône Poulenc Agro Bayer CropScience document C022770 Non GLP, Not published	
IIA, 5.9/02	Johnston RD	1991	Medical surveillance in HBN production plant in the years 1983/1984 and 1989, update 1991; Code: AE F025943, AE F051835. Rhone Poulenc Ltd, UK Occupational health. Submitted by Rhône Poulenc Agro Bayer CropScience document C022772 Non GLP, Not published	
IIA, 5.9/03	Rivett J	1998	Abnormal thyroid function tests amongst chemical process operators. Code: AE F051835. Rhone Poulenc Agriculture Ltd., UK Submitted by Rhône Poulenc Agro Bayer CropScience document C022776 Non GLP, Not published	

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
IIA, 6.1/01	McGhee I.	2000	(14C)-ioxynil octanoate: metabolism in spring wheat Aventis CropScience, Ongar, UK Study 10470 Submitted by Aventis CropScience Bayer CropScience document C036305 GLP, Not published	
IIA, 6.1/02	McGhee I.	2001	(14C)-ioxynil octanoate: Metabolism in onions Aventis CropScience, Ongar, UK Study 10470 Submitted by Aventis CropScience Bayer CropScience document C015021 GLP, Not published	
IIA, 6.1/03	Quintelas G	2001	Stability study of ioxynil in winter rape (grain) and soft winter wheat (grain) after storage in a congelator at a temperature near minus 18°C Defitraces, Brindas, France, Study 98-178 Submitted by Aventis CropScience Bayer CropScience document C014005 GLP, Not published	
IIA, 6.2/01	Philipps, M.	1997	The distribution and metabolism of [¹⁴ C]-Ioxynil octanoate in the lactating goat. Generated by : Inveresk Research Institute – UK Report n° : IRI 158602, Study 158602 Submitted by : Rhône-Poulenc Agro Date : September 1, 1997 Bayer CropScience Doc n°201495 GLP Not published	

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
IIA, 6.2/02	McCorquodale G.Y., Philipps M.	1997	The distribution and metabolism of [¹⁴ C]-Ioxynil octanoate in the laying hen. Generated by : Inveresk Research Institute – UK Submitted by : Rhône-Poulenc Agro Report n° : IRI 14758 Date : September, 1997 Bayer CropScience Doc n°201496 GLP Not published	
IIA, 6.3/01	Crouch R.V.	1994	HERBICIDES : Ioxynil : Residue Studies in Cereals, W. Germany, 1972 Study RG 1872 Generated by MAY & BAKER Ltd Submitted by Rhône-Poulenc Agro Date : 03 janvier 1994 Bayer CropScience GLP Not published	
IIA, 6.3/02	Muller M.A.	1993	Ioxynil - Isoproturon - Formulation EXP04649A(SC) - Essais France 1991 – Résidus dans les Céréales (Blé et Orge) Etude 91-208 Generated and submitted by: Rhône-Poulenc Agro Date: 12 mai 1993 Bayer CropScience GLP Not published	
IIA, 6.3/03	Richard M., Muller M.A.	1993	Bifenox - Ioxynil - Mecoprop-P- Formulation EXP30007B(SC) - Essais France 1991-1992 - Résidus dans le Ray-Grass Study 92-120 Generated by Rhône-Poulenc Agro Submitted by Rhône-Poulenc Agro Date: 08 déc 93 Bayer CropScience GLP Not published	

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
IIA, 6.3/04	Richard M., Muller M.A.	1993	DIFLUFENICAN - BROMOXYNIL - IOXYNIL Formulation EXP04399B (EC) - Essais France 1992 - Résidus dans le Ray-Grass Etude 91-285 Generated by Rhône-Poulenc Agro Submitted by Rhône-Poulenc Agro Date: 30 août 93 Bayer CropScience GLP Not published	
IIA, 6.3/05	Richard M., Muller M.A.	1993	DIFLUFENICAN - BROMOXYNIL - IOXYNIL Formulation EXP04399B (EC) - Essais France 1992 - Résidus dans le Ray-Grass Etude 91-284 Generated by Rhône-Poulenc Agro Submitted by Rhône-Poulenc Agro Date: 01 sept 93 Bayer CropScience GLP Not published	
IIA, 6.3/06	Richard M., Muller M.A.	1994	Bromoxynil - Ioxynil - MECOPROP-P - Formulation EXP30521A (EC) - Essais France 1993 - Résidus dans le Ray-Grass Etude 93-513 Generated by Rhône-Poulenc Agro Submitted by Rhône-Poulenc Agro Date: 03 mars 1994 Bayer CropScience GLP Not published	
IIA, 6.4/01	Ross VA	2003	Ioxynil Octanoate: Residues in the Milk and Tissues of Dairy Cows Generated by Huntingdon Life Sciences, UK, study AES 096/023322 Submitted by Bayer CropScience Bayer CropScience document C029703 GLP, Not published	

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
IIA, 6.4/02	Laporte F	2003	Ioxynil and ioxynil octanoate : Dietary risk assessment for chronic and acute exposure Generated by :Bayer CropScience Frankfurt, study 03F005 Study 03F005 Submitted by : Bayer CropScience Bayer CropScience document C031435 GLP, Not published	

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
IIA, 7.1.1/01.	Goodyear A.	2002	(14C)-ioxynil octanoate: Aerobic route and rate of soil degradation Generated by :Covance Laboratories Ltd. Harrogate, UK study ref 1849/32 Submitted by : Bayer CropScience Bayer CropScience , Document C022859 GLP Not published	
IIA, 7.1.1/02.	Reinken G	2002	Kinetic evaluation of the degradation of ioxynil octanoate, ioxynil phenol and the metabolite 3,5-diiodo-4-hydroxybenzamide in aerobic soils using the TopFit 2.0 model generated by : Aventis CropScience GmbH, DEU Environmental Chemistry, Frankfurt, 33 pages Submitted by Bayer CropScience Bayer CropScience document C022481 GMP Not published	
IIA, 7.1.1/03.	Reinken G.,	2002	Degradation of ioxynil octanoate ioxynil phenol and the metabolite 3,5-diiodo-4-hydroxybenzamide in aerobic soils 10 degrees C generated by : Aventis CropScience GmbH, DEU Environmental Chemistry, Frankfurt, 21 pages Submitted by Bayer CropScience Bayer CropScience document C022481 GLP Not published	

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
IIA, 7.1.1/04.	Greener N.A.	2001	(14C)-ioxynil octanoate: Photodegradation on a soil surface generated by : Covance Laboratories Ltd. Harrogate, UK study ref 1849/026 submitted by Aventis CropScience Bayer CropScience , Document C014981 GLP Not published	
IIA, 7.1.1/05	Greenslade D. , Ward J., Hopkins, R.	1983	A study of the aerobic metabolism of [¹⁴ C]-3,5-di-iodo4-hydroxybenzamide. Generated by : Hazleton EuropeLtd, UK Submitted by : Rhône-Poulenc Agrochimie Report n° 3254-18/7	
IIA, 7.1.1/06	Jackson, R., Hall, B.E., Cameron, B.D.	1991	[¹⁴ C]-Ioxynil Octanoate : Anaerobic Aquatic Metabolism. Generated by : Inveresk Research International., UK. Submitted by : Rhône-Poulenc Agrochimie Report n° 7625	
IIA, 7.1.1/07	Marshall, I.R, Hardy, I.A.J. and Savage E.A.	1991	Ioxynil Octanoate : Investigation into the structure of the Metabolites detected during an Anaerobic Aquatic Soil Study. Generated by : Rhône-Poulenc Agrochimie, UK Submitted by : Rhône-Poulenc Agrochimie. Report n° : D.Ag. 1618	
IIA, 7.1.2/01	Rosenwald J.	2002	(14C)-IOxynil octanoate: Adsorption/desorption in soil (interim report) Generated by : Covance Laboratories GmbH, Muenster, DEU, study 1849-036 submitted by Aventis CropScience Bayer CropScience document C022856 GLP Not published	

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
IIA, 7.1.2/02	Rosenwald J.	2002	(14C)-Ioxynil phenol: Adsorption/desorption in soil generated by : Covance Laboratories GmbH, Muenster, DEU, study 1849-033 submitted by Aventis CropScience Bayer CropScience document C022852 GLP Not published	
IIA, 7.1.2/03	Rosenwald J	2002	3,5-diiodo-4-hydroxybenzamide adsorption/Desorption in Soil. Covance Laboratories GmbH, Münster, Germany, report No 1849-038 submitted by Aventis CropScience Bayer CropScience document C023717 GLP, Not published	
IIA, 7.1.2/04	Rosenwald J	2002	(14C)-Ioxynil octanoate: Adsorption/desorption in Soil Covance Laboratories GmbH, Münster, Germany, report No 1849-036 submitted by Aventis CropScience Bayer CropScience document C028179 GLP, Not published	
IIA, 7.1.2/05	Rosenwald J	2002	(14C)- 3,5 diiodo-4-benzoicacid adsorption/Desorption in Soil. Covance Laboratories GmbH, Münster, Germany, report No 1849-037 submitted by Aventis CropScience Bayer CropScience document C028010 GLP, Not published	
IIA, 7.1.2/06	Rosenwald J.	2002	(14C)-3,5-diiodo-4-hydroxybenzamide: Adsorption/desorption in soil (interim report) Covance Laboratories GmbH, Muenster, DEU, study 1849-038 submitted by Aventis CropScience Bayer CropScience document C022854 GLP Not published	

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IIA, 7.1.2/07	Rosenwald J.	2002	(14C)-3,5-diiodo-4-hydroxybenzoic acid: Adsorption/desorption in soil (interim report) Covance Laboratories GmbH, Muenster, DEU, study 1849-037 submitted by Aventis CropScience Bayer CropScience document C022855 GLP Not published	
IIA, 7.1.3/01 IIA, 9.2.1	Reinken G.	2002	Predicted environmental concentrations in groundwater (PEC _{gw}) for) for ioxynil octanoate, ioxynil phenol and the metabolite 3,5-diiodo-4-hydroxybenzamide using the European FOCUS groundwater scenarios Aventis CropScience GmbH, DEU Environmental Chemistry, Frankfurt, 32 pages submitted by Aventis CropScience Bayer CropScience document C022483 GMP, Not published	
IIA, 7.1.3/02	Reinken G., Meyer H	2003	Predicted environmental concentrations in groundwater (PEC _{gw}) for) for ioxynil metabolite 3,5-diiodo-4-hydroxybenzoic acid using the European FOCUS groundwater scenarios. Bayer CropScience AG, DEU, study MEF 205/03 submitted by Aventis CropScience Bayer CropScience document C034133 GMP, Not published	
IIA, 7.2.1/01	England D.A., Reeves G.L., Savage, E.A.	1987	Ioxynil Octanoate : Hydrolysis in water containing Acetonitrile (1 % v/v) as co-solvent at 22°C, 50°C and 70 %. Generated by : May and Baker Ltd, UK. Submitted by : Rhône-Poulenc Agrochimie. Report n° : D.Ag. 305	

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
IIA, 7.2.1/02	Cicotti, M.	1992	Determination of Phototransformation of Ioxynil in Water according to UBA test Guideline, direct Phototransformation. Generated by : Battelle-Europe, Switzerland. Submitted by : Rhône-Poulenc Agrochimie Report n° : R&D / CRLD / AN/bd	
IIA, 7.2.1/03	Baumann J.	2002	Aqueous photolysis of (14C)-ioxynil octanoate Battelle - Geneva Research Centres, CHE Agrochemical Product Development, Carouge/Geneva, study E-01-02-06 submitted by Aventis CropScience Bayer CropScience document C022861 GLP Not published	
IIA, 7.2.1/04/	Cooper J.L.D., McGhee I., Jones M.K.,	1998	[¹⁴ C]-Ioxynil : Identification of an unknown metabolite generated in water/sediment studies. Generated by : Rhône-Poulenc Agro, Ltd, UK Submitted by : Rhône-Poulenc Agro Report n° : 14005 Bayer CropScience document 201677 GLP Not published	
IIA, 7.2.1./05	Cooper J.L.D., Unsworth R.H.	1997	[¹⁴ C]-Ioxynil : degradation in two water/sediment systems. Generated by : Rhône-Poulenc Agro, Ltd, UK Submitted by : Rhône-Poulenc Agro Report n° 11714 Bayer CropScience document 201415 GLP Not published	

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
IIA, 7.2.1/06	McMillan-Staff, S.L., Jones, M.K.	1997	[¹⁴ C]-Ioxynil Octanoate : degradation in two water/sediment systems. Generated by : Rhône-Poulenc Agro, Ltd, UK Submitted by : Rhône-Poulenc Agro Report n°: 11715 Bayer CropScience, document 201374 GLP Not published	
IIA, 7.2.1/07	Reinken G	2002	Estimation of the Ioxynil Octanoate K _{oc} Soil Adsorption Coefficient using the PCKOCWIN Model Bayer CropScience, Monheim Bayer CropScience document C028577 GMP, Not published	
IIA, 7.2.1/08	Baumann J	2003	Aqueous Photolysis of [¹⁴ C]-Ioxynil Octanoate. Identification of Unknowns Batelle, Geneva Switzerland, Study E-14-02-04 submitted by Bayer CropScience Bayer CropScience document C028822 GLP Not published	
IIA, 7.2.1/09	Maestracci, M.	1992	Calculation of Photolytic half-life of Ioxynil in water. Generated by : Rhône-Poulenc Secteur Agro. Submitted by : Rhône-Poulenc Agrochimie Report n° : AG / CRLD / AN/9216222	
IIA, 7.2.1/10	McMillan-Staff, S.L., Jones, M.K.	1997	[¹⁴ C]-Ioxynil Octanoate : degradation in two water/sediment systems. Generated by : Rhône-Poulenc Agro, Ltd, UK Submitted by : Rhône-Poulenc Agro Report n°: 11715	

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
IIA, 7.2.1/11	Offizorz, P.	1992	Determination of the Direct Phototransformation of Ioxynil Octanoate in water. Generated by : RCC Umweltchemie GmbH. Submitted by : Rhône-Poulenc Agrochimie. Report n° : AG / CRLD / AN/9216082	
IIA, 7.2.2/01	Jendrzejjczak, N., Maestracci, M., Turier, G	1994	Soil surface volatility study of Ioxynil octanoate formulated as totiril – emulsion concentrate (EC) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: R&D/CRLD/AN/9415316 Study 94-002 Date: March, 15 1994 Bayer CropScience Doc n°435898 GLP Not published	
IIA, 7.2.2/02	Maestracci, M.P.	1995	Ioxynil. Estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions. Generated by: Rhône-Poulenc Secteur Agro Submitted by: Rhône-Poulenc Agrochimie Report n°: R&D/CRLD/AN/9416907 Date: January 1995. Bayer CropScience Doc n°437407 GLP Not published	

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
IIA, 7.2.2/03	Corgier, M.M., Plewa, A.P.	1998	Ioxynil octanoate : estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions. Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-155 ; Docmap 444198 Date: July 22, 1998 Bayer CropScience Doc n°444198 GLP Not published	
IIA, 7.2.2/04	Corgier, M.M., Plewa, A.P.	1998 a	Ioxynil octanoate : estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions. Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: R&D/CRLD/AN/9816269 Bayer CropScience GLP Not published	
IIA, 7.2.2/05	Corgier, M.M., Plewa, A.P.	1998	Ioxynil : estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions. Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-154 ; Docmap 444197 Date: July 22, 1998 Bayer CropScience Doc n°444197 GLP Not published	

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
IIA, 7.2.2/06	Corgier, M.M., Plewa, A.P.	1998 b	Ioxynil : estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions. Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: R&D/CRLD/AN/9816268 Bayer CropScience GLP Not published	
IIA, 7.2.2/07	Jendrzeczak, N., Turier, G., Maestracci, M.	1994	Soil surface volatility study of Ioxynil octanoate formulated as totril - emulsion concentrate (EC) Generated by : Rhône-Poulenc Agro, France Submitted by : Rhône-Poulenc Agro Report n°: 94002 ; Docmap 435898 Date : March 2, 1994 Bayer CropScience Doc n°435898 GLP Not published	
IIA, 7.2.2/08	Jendrzeczak, N., Maestracci, M., Turier, G.,	1994	Soil surface volatility study of Ioxynil octanoate formulated as totril - emulsion concentrate (EC). Generated by : Rhône-Poulenc Agro, France Submitted by : Rhône-Poulenc Agro Report n°: R&D/CRLD/AN/9415316 Bayer CropScience GLP Not published	

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
IIA, 7.2.2/09	Kubiak, R.	1994	Investigation of the volatilisation of [¹⁴ C]-Ioxynil octanoate formulated according TOTRIL (EC) with a total amount of 229 g/l Ioxynil octanoate from plant surfaces under laboratory conditions. Generated by : FB Phytomedizin in SLFA, Germany. Submitted by : Rhône-Poulenc Agrochimie Report n° : R&D / CRLD / AN/bd/9415308 Bayer CropScience GLP Not published	
IIA, 9.2.1	Gatzweiler, E.W.	1995	Ioxynil and Ioxynil octanoate : Computer Simulation of the Behaviour in Soil Using the PELMO Model Generated by : Rhône-Poulenc Agriculture Ltd., UK Submitted by : Rhône-Poulenc Agrochimie Report n°: 200920 Bayer CropScience GLP Not published	

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
IIA, 8.1.1/01	Hakin B., Norman A.J.	1989	The acute oral toxicity (LD ₅₀) of Ioxynil Octanoate to the Japanese quail Generated by: HRC - UK Submitted by : Rhône-Poulenc Agrochimie Report RNP 294/89254 Unpublished report	

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
IIA, 8.1.1/02	Rodgers M.	1996	Ioxynil octanoate: Acute Toxicity (LD50) to Bobwhite Quail Generated by: HLS - UK Report RNP 487/961732, DOC 601755 Unpublished report Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience document 601755 GLP	
IIA, 8.1.2/01	Rodgers M.	1996a	Ioxynil phenol: Subacute Dietary Toxicity (LC50) to the Bobwhite Quail. Generated by: HLS - UK Report RNP 489/961729, DOC 601760 Unpublished report Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience document 601760 GLP	
IIA, 8.1.2/02	Rodgers M.	1996b	Ioxynil octanoate: Subacute Dietary Toxicity (LC50) to the Bobwhite Quail. Generated by: HLS - UK Report RNP 488/961731, DOC 601757 Unpublished report Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience document 601757 GLP	
IIA, 8.1.3/01	Gillham A.	1999	Ioxynil Phenol - Avian reproduction test with the Japanese quail Generated by: HLS - UK Report RNP 593/984051, Unpublished report Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience DOC 603895 GLP	

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
IIA, 8.1.3/02	Johnson A.J.	1998	loxynil octanoate: Effects on reproduction in Japanese Quail after dietary administration Generated by: HLS - UK Report RNP 508/971369, DOC 603109 Unpublished report Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience document 603109 GLP	
IIA, 8.1	Ebeling M	2002	Refined Long Term Risk Assessment in Birds and Mammals loxynil Code: AE F051835, AE F065322. Bayer CropScience, Frankfurt Bayer CropScience document C022402 Not published	
IIA, 8.1	Semino G.	2002	loxynil - NOAEL proposal for long-term risk assessment on wild mammals Code: AE F051835, AE F065322 Aventis CropScience S.A., FRA Regulatory Toxicology, 14 pages Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience document C022713 Not published	
IIA, 8.1	Sonder K	2002	Decline of residues in winter wheat: Special degradation curve to determine decline of residues in animal feed, European Union (northern zone) 2002, Bromoxynil-octanoate + loxynil octanoate Bayer CropScience Frankfurt - 76 p Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience document C028055 GLP, Not published	

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IIA, 8.2.1/01	Jonas W.	1993	Acute toxicity test (Flow-Through) on the Rainbow trout (<i>Oncorhynchus mykiss</i>) Generated by: NATEC, Germany Submitted by : Rhône-Poulenc Agrochimie Report M & B 150A/82324 Unpublished report Bayer CropScience doc 432173 GLP	
IIA, 8.2.1/02	Grinell AJ, Croudace CP, Caunter JE & Cornish SK	1996	Ioxynil phenol: Acute toxicity to bluegill sunfish (<i>Lepomis macrochirus</i>) Generated by: Brixham Environmental Laboratory ZENECA Ltd - UK Report n°: BL5741, Doc 601636 Unpublished report Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience Doc 601636 GLP	
IIA, 8.2.1/03	McElligott, A., Suteau, P.	1998	Acute toxicity (96-hours) to bluegill sunfish (<i>Lepomis macrochirus</i>) under flow-through conditions. Generated by: Rhône-Poulenc Agro, France Report n°: SA 98357 Submitted by : Rhône-Poulenc Agrochimie Unpublished report Bayer CropScience Doc n°603435 GLP	
IIA, 8.2.1./04	McElligott A	2001	Ioxynil Octanoate: Acute Toxicity To Rainbow Trout (<i>Oncorhynchus Mykiss</i>) Static Exposure And Recovery Phase Bayer CropScience - Sophia Antipolis, SA 01117 Bayer CropScience document C015458 GLP, Not published	

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IIA, 8.2.1./05	Dorgerloh M.	2003	Ioxynil Octanoate: Acute Toxicity To Fish (<i>Oncorhynchus Mykiss</i>) in a Water Sediment System Under Static Conditions Bayer CropScience – Monheim, DOM 22080 Bayer CropScience document C031956 GLP, Not published	
IIA, 8.2.1./06	Mc Elligot A.	2003	Ioxynil octanoate-Acute toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) static exposure and recovery phase. Bayer CropScience AG report C015458.	
IIA, 8.2.1./07	Putt A.E.	2000	4-hydroxybenzoxitrile – Acute toxicity to Rainbow Trout (<i>Oncorhynchus mykiss</i>) under static-renewal conditions. Springborn Laboratories Inc, report ref 10566.6570 Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience GLP Not published	
IIA, 8.2.2.1/01	Douglas M Sewell I.G. MacDonald I.A.	1989a	The prolonged toxicity of Ioxynil Technical to rainbow trout (<i>Salmo gairdneri</i>) Generated by: HRC, UK Submitted by : Rhône-Poulenc Agrochimie Report RNP 295/89190 Unpublished report	
IIA, 8.2.2.1/02	Douglas M Sewell I.G. MacDonald I.A.	1989b	The prolonged toxicity of Ioxynil Octanoate to rainbow trout (<i>Salmo gairdneri</i>) Generated by: HRC - UK Submitted by : Rhône-Poulenc Agrochimie Report RNP 306/89568 Unpublished report	

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IIA, 8.2.2.1/03	Memmert U. Offizorf P.	1991	Toxicity test of Ioxynil Sodium salt to Rainbow trout (<i>Oncorhynchus mykiss</i>) in a prolonged semi-static test (21 days) at pH 6.5 Generated by: RCC Umweltchemie, Germany Submitted by : Rhône-Poulenc Agrochimie Report 216314 Unpublished report	
IIA, 8.2.2.2/01	Sankey S.A., Maddock B.G., Caunter J.E., Stanley R.D.	1992	Ioxynil Octanoate: Chronic toxicity to fathead minnow (<i>Pimephales promelas</i>) embryos and larvae Generated by: ICI, UK Submitted by : Rhône-Poulenc Agrochimie Report BL 4408/B Unpublished report	
IIA, 8.2.3/01	Chapleo S., Hope J.	2000	Bioaccumulation and metabolism of (14C)-ioxynil octanoate in rainbow trout Inveresk Research, project 393347, report 18014 Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience document R016547 GLP Not published	
IIA, 8.2.3/02	Voigt A.	1989	Bioakkumulation Ioxynil octanoat für Regenbogenforellen (<i>Salmo gairdneri</i>) Generated by: Ökolimna Gesellschaft für Ökologie und Gewässerkunde mbH - Germany Submitted by : Rhône-Poulenc Agrochimie Report n°: 06/89/ Unpublished report	

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
IIA, 8.2.3/03	Odin-Feurtet M	2000	Chronic effects of ioxynil to Amphibian (<i>Xenopus laevis</i>) under semi-static conditions. Aventis CropScience Sophia Antipolis study ref SA99591 Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience, document C010798 GLP Not published	
IIA, 8.2.4/01	Croudace, C.P.	1996	Ioxynil octanoate : acute toxicity to daphnia magna (48 hours). Generated by: Brixham env. Laboratory, UK Report n°: BL 5740/B Unpublished report Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience Doc n°601586 GLP	
IIA, 8.2.4/02	McElligott, A., Ebeling, M.	1998	Ioxynil octanoate : acute toxicity (48 hours) to daphnids (<i>Daphnia magna</i>) in a sediment water system under static conditions. Generated by: Rhône-Poulenc Agro, France Submitted by : Rhône-Poulenc Agrochimie Report n°: SA 98493 Unpublished report Bayer CropScience Doc n°603576 GLP	
IIA, 8.2.4/03	Knacker T., Hilt J.	1989a	A study of the acute immobilisation to <i>Daphnia</i> of Ioxynil octanoate Generated by: Battelle Europe, Germany Submitted by : Rhône-Poulenc Agrochimie Report BE-ET-01-89-02-DAK-8 Unpublished report	

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IIA, 8.2.4/04	Knacker T., Hilt J.	1989b	Acute immobilisation test for <i>Daphnia</i> sp. of the test substance Ioxynil Generated by: Battelle Europe, Germany Submitted by : Rhône-Poulenc Agrochimie Report ETA1DAK1 Unpublished report	
IIA, 8.2.4/05	Putt A.E.	2000	4-hydroxybenzoxonitrile – Acute toxicity to Daphnids (<i>Daphnia magna</i>) under static-renewal conditions. Springborn Laboratories Inc, report ref 10566.6569 Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience GLP Not published	
IIA, 8.2.5/01	Croudace, C.P.	1996	Ioxynil octanoate : chronic toxicity to <i>Daphnia magna</i> . Generated by: Brixham Env. Laboratory, UK Submitted by : Rhône-Poulenc Agrochimie Report n°: BL 5739/B Unpublished report Bayer CropScience Doc n°601587 GLP	
IIA, 8.2.5/02	Jonas W.	1994	Reproduction test on <i>Daphnia magna</i> Generated by: Natec, Germany Submitted by : Rhône-Poulenc Agrochimie Report NA 94 9407 Unpublished report Bayer CropScience document 600312 GLP	

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IIA, 8.2.5/03	Knacker T. Reifenberg P., Schallnass H.	1989	Reproduction test for <i>Daphnia sp.</i> of the test substance Ioxynil Generated by: Battelle Europe, Germany Submitted by : Rhône-Poulenc Agrochimie Report ETA1DCH1 Unpublished report	
IIA, 8.2.5/04	Knacker T. Zeitz E. Reifenberg P., Schallnass H.	1990	A study of the chronic toxicity to <i>Daphnia</i> of Ioxynil octanoate Generated by: Battelle Europe, Germany Submitted by : Rhône-Poulenc Agrochimie Report BE-ET-01-89-02-DCH-8 Unpublished report	
IIA, 8.2.6/03	Hoberg, J.R.	1998a	Ioxynil phenol : toxicity to the freshwater diatom, <i>Navicula pelliculosa</i> . Generated by: Springborn Laboratories AG Submitted by : Rhône-Poulenc Agrochimie Report n°: SLI 98-10-7507 Unpublished report Bayer CropScience Doc n°603446 GLP	
IIA, 8.2.6/04	Hoberg, J.R.	1998	Ioxynil octanoate : toxicity to the freshwater diatom, <i>Navicula pelliculosa</i> . Generated by: Springborn Laboratories AG Submitted by : Rhône-Poulenc Agrochimie Report n°: SLI 98-9-7483 Unpublished report Bayer CropScience Doc n°603442 GLP	

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IIA, 8.2.6/05	Oldersma H. Hansveit A.O.	1990	Effect of Ioxynil Octanoate on the growth of the green alga <i>Scenedesmus subspicatus</i> Generated by: TNO, The Netherlands Submitted by : Rhône-Poulenc Agrochimie Report n°: R89/458 Unpublished report	
IIA, 8.2.7	Suteau, P., McElligott, A.	1998	Ioxynil octanoate : toxicity to the sediment dwelling chironomid larvae (<i>Chironomus riparius</i>) - 28 days - Generated by: Rhône-Poulenc Agro Ltd, UK Submitted by : Rhône-Poulenc Agrochimie Report n°: SA 98004 Unpublished report Bayer CropScience Doc n°603008 GLP	
IIA, 8.2.8/01	Hoberg, J.R.	1998	Ioxynil phenol : toxicity to the duckweed (<i>Lemna gibba</i>). Generated by: Springborn Laboratories, AG Submitted by : Rhône-Poulenc Agrochimie Report n°: SLI 98-10-7512 Unpublished report Bayer CropScience Doc n°603458 GLP	
IIA, 8.2.8/02	Hoberg, J.R.	1998	Ioxynil octanoate : toxicity to the duckweed (<i>Lemna gibba</i>). Generated by: Springborn Laboratories, AG Submitted by : Rhône-Poulenc Agrochimie Report n°: SLI 98-10-7519 Unpublished report Bayer CropScience Doc n°603441 GLP	

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
IIA, 8.3.1.1/01	Candolfi	1997	Ioxynil octanoate: Laboratory oral and acute contact test with the honey bee, <i>Apis mellifera</i> , based on the EPPO guideline 170 (1992). Generated by: Springborn Laboratories, Switzerland Submitted by : Rhône-Poulenc Agrochimie Report n°: 96-049-1013 Unpublished report Bayer CropScience Doc n°602093 GLP	
IIA, 8.3.1.1/02	Schmitzer, S.	1998	Laboratory testing for toxicity (acute contact and oral LD ₅₀) of Ioxynil to honey bees (<i>Apis mellifera</i> L.) (Hymenoptera, Apidae). Generated by: Ibacon Institut Submitted by : Rhône-Poulenc Agrochimie Report n°: 4590036 Unpublished report Bayer CropScience Doc n°603589 GLP	
IIA, 8.3.2/01 and IIIA, 10.5.1/01	Gossmann, A.	1998	Effects of EXP 03273B on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) in the laboratory. Generated by: Ibacon GmbH, Germany Submitted by : Rhône-Poulenc Agrochimie Report n°: 4371063, DOC603617 Unpublished report Bayer CropScience document 603617 GLP	

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
IIA, 8.3.2/02	Gossmann, A.	1998	Effects of EXP 03165A on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) in the laboratory. Generated by: Ibacon GmbH, Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: 4381063 Unpublished report Bayer CropScience Doc n°603615 GLP	
IIA, 8.3.2/03 and IIIA, 10.5.1/01	Künher C.	1993	Determination of the side effects of SPI 87030 H on the ground beetle, <i>Poecilus cupreus L.</i> , in lab Report N°: 171/01-Pc; Ref 068 Generated by: CFPI Submitted by : Rhône-Poulenc Agrochimie Unpublished report Bayer CropScience GLP	
IIA, 8.3.2/04 IIIA, 10.5.1.	Lührs U.	1999	Effects of EXP 03273B on the predatory mite <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) - extended laboratory study. Generated by: Ibacon GmbH, Germany Submitted by : Rhône-Poulenc Agrochimie Report n°: 5613062, Doc 604308 Unpublished report Bayer CropScience Doc 604308 GLP	

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
IIA, 8.3.2/05 IIA, 10.5.1.	Lührs U.	1999	Effects of EXP 03273B on the predatory mite <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) - in the laboratory. Generated by: Ibacon GmbH, Germany Submitted by : Rhône-Poulenc Agrochimie Report n°: 5611063, Doc 603950 Unpublished report Bayer CropScience GLP	
IIA, 8.3.2/06	Moll, M.	1999	Effects of EXP 03273B and EXP 03165A on the parasitoid <i>Aphidius rhopalosiphii</i> (Hymenoptera, aphidiidae) - Extended Laboratory study. Generated by: Ibacon GmbH, Germany Submitted by : Rhône-Poulenc Agrochimie Report n°: 5020002 Unpublished report Bayer CropScience Doc n°603829 GLP	
IIA, 8.3.2/07	Moll, M, Groer, M.	1998	Effects of EXP 03165A on the parasitoid <i>Aphidius rhopalosiphii</i> (Hymenoptera, aphidiidae) in the laboratory. Generated by: Ibacon GmbH, Germany Submitted by : Rhône-Poulenc Agrochimie Report n°: 4382001 Unpublished report Bayer CropScience Doc n°603614 GLP	

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
IIA, 8.3.2/08	Moll, M., Groer, M.	1998	Effects of EXP 03273B on the parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera, aphidiidae) in the laboratory. Generated by: Ibacon GmbH, Germany Submitted by : Rhône-Poulenc Agrochimie Report n°: 4372001 Unpublished report Bayer CropScience Doc n°603616 GLP	
IIA, 8.3.2/09	Moll, M., Groer, M.	1999	Effects of EXP 03165A on the lacewing <i>Chrysoperla carnea</i> Steph. (neuroptera, Chrysopidae) in the laboratory. Generated by: Ibacon GmbH, Germany Submitted by : Rhône-Poulenc Agrochimie Report n°: 4384046 Unpublished report Bayer CropScience Doc n°603694 GLP	
IIA, 8.3.2/10	Moll, M., Groer, M.	1999	Effects of EXP 03273B on the lacewing <i>Chrysoperla carnea</i> Steph. (neuroptera, Chrysopidae) in the laboratory. Generated by: Ibacon GmbH, Germany Submitted by : Rhône-Poulenc Agrochimie Report n°: 4374046 Unpublished report Bayer CropScience Doc n°603693 GLP	

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
IIA, 8.3.2/11 10.5.1.	Schmitzer, S.	1998	Effects of EXP 03273B on the carabid beetle (<i>poecilus cupreus</i> L.) (Coleoptera, carabidae) in the laboratory. Generated by: Ibacon GmbH, Germany Submitted by : Rhône-Poulenc Agrochimie Report n°: 4373006 Unpublished report Bayer CropScience Doc n°603592 GLP	
IIA, 8.3.2/12	Schmitzer, S.	1998	Effects of EXP 03165A on the carabid beetle (<i>poecilus cupreus</i> L.) (Coleoptera, carabidae) in the laboratory. Generated by: Ibacon GmbH, Germany Submitted by : Rhône-Poulenc Agrochimie Report n°: 4383006 Unpublished report Bayer CropScience Doc n°603590 GLP	
IIA, 8.3.2/13	Pietrzik J.	1992	Determination of the side effects of SPI 87030 H on the short-winged beetle, <i>Aleochara bilineata</i> Gyll. in lab Generated by: CFPI Submitted by : Rhône-Poulenc Agrochimie Report N°: 171/01-Ab; Ref 069 Unpublished report	
IIA, 8.3.2/14	Pietrzik J.	1992	Determination of the side effects of SPI 87030 H on the short-winged beetle, <i>Aleochara bilineata</i> Gyll. in lab Generated by: CFPI Submitted by : Rhône-Poulenc Agrochimie Report N°: 171/01-Ab; Ref 069 Unpublished report	

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
IIA, 8.4.1/01	Lührs U	2000	Acute Toxicity (14 days) of Ioxynil phenol to the earthworm <i>Eisenia fetida</i> (Savigny 1826) in Artificial Soil. IBACON study ref 7391021 Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience GLP Not published	
IIA, 8.4.1/02	Lührs U	2000	Acute Toxicity (14 days) of Ioxynil octanoate to the earthworm <i>Eisenia fetida</i> (Savigny 1826) in Artificial Soil. IBACON study ref 7411021 Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience GLP Not published	
IIA, 8.4.1/03	Suteau P	1995	EXP 03334 acute toxicity to earthworms (<i>Eisenia foetida</i>) artificial soil method. Generated by: Rhône-Poulenc Agrochimie Centre de Recherche, Sophia Antipolis - France Submitted by : Rhône-Poulenc Agrochimie Report n°: SA95045 Unpublished report Bayer CropScience Doc n°600729 GLP	
IIA, 8.4.2	Lührs U	2000	Effects of Ioxynil phenol on the Reproduction and growth of <i>Eisenia fetida</i> (Savigny 1826) in Artificial Soil. IBACON study ref 7461022 Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience GLP Not published	

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
IIA, 8.5.1/01	Forster J.	1996	A laboratory assessment of the effects of EXP 03334C on soil microflora respiration and nitrogen transformations according to BBA guidelines VI 1-1 (1990) Generated by: Euro Laboratories Ltd - UK Submitted by: Rhône-Poulenc Agrochimie Report n°: ELL/1036 Unpublished report Bayer CropScience Doc n°201197 GLP	
IIA, 8.5.1/02	Goebel G.	1992	Report on the verification of the effect of SPI 87030 H (Mextrol H) on the activity of soil microflora according to the BBA guidelines, part VI, 1-1 of March 1990 Submitted by : Rhône-Poulenc Agrochimie Report N°: U91 BMH 01 Generated by: CFPI Unpublished report	
IIA, 8.7/01	Hertl, J.	1998	Toxicity of Ioxynil Octanoate to activated sludge in a respiration inhibition test. Generated by: Ibacon GmbH, Germany Submitted by : Rhône-Poulenc Agrochimie Report n°: 4490170 Unpublished report Bayer CropScience Doc n°603591 GLP	

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
IIA, 8.7/02	Mead C.	1999	Ioxynil phenol: Assessment of the inhibitory effect on the respiration of activated sewage sludge. Generated by: Safepharm Laboratories Ltd Submitted by : Rhône-Poulenc Agrochimie Report n°: 282-567, Doc 603984 Unpublished report Bayer CropScience Doc n°603984 GLP	
IIA, 8.8/01	Gaus I.	1999	Biotest zur Bewertung der Auswirkungen des Herbizides Totril (Wirkstoff Ioxynil) auf terrestrische Pflanzen (Bioassay for evaluation of the effects of the herbicide Totril (active ingredient ioxynil) on terrestrial plants) BBA Berlin study ref OC9903 Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience document C017725 GLP Not published	
IIA, 10.5.1/01	Gossmann A.	1998	Effects of exp 03273b on the predatory mite Typhlodromus pyri Scheuten (Acari phytoseiidae) in the laboratory Generated by: IBACON, Germany Submitted by : Rhône-Poulenc Agrochimie Report n°: 4371063, DOC603617	

APPENDIX IIIB**IOXYNIL**

List of studies which were submitted during the evaluation process and were not cited in the draft assessment report:

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
IIA, 4.1.1.1.	Duverney-Prêt P.	1995	Ioxynil – Technical grade active ingredient HPLC determination of active ingredient content method I-807-04-95 – 3/05/95 Generated by : Rhône poulenc agrochimie Submitted by : Aventis CropScience GLP Not published
IIA, 4.1.1.1.	Bowen T.	2001	Analytical method – Ioxynil octanoate (AE F065322) – Determination of ioxynil octanoate in ioxynil octanoate technical material by HPLC. method AL 090/ 00-0) – Generated by : Aventis CropScience Submitted by : Aventis CropScience Bayer CropScience document C012076 Not published
IIA, 4.1.1.1.	Bowen T.	2001	Validation of the Analytical method AL 090/00-0 for the determination of ioxynil octanoate in the ioxynil octanoate technical material Report PA00/040 – Generated by : Aventis CropScience Submitted by : Aventis CropScience Bayer CropScience document C012077 GLP Not published
IIA, 4.1.1.2.	Duverney-Prêt P.	1995	Ioxynil – Technical grade active ingredient HPLC determination of organic impurities method I-813-06-95 – Generated by : Rhône poulenc agrochimie Submitted by : Aventis CropScience Bayer CropScience GLP

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
IIA, 4.1.1.2	Bowen T.	2001	Analytical method – Determination of organic impurities in ioxynil octanoate technical material by HPLC. Report AL003/01-2 Generated by : Aventis CropScience Submitted by : Aventis CropScience Bayer CropScience document C013166 Not published
IIA, 4.1.1.2	Bowen T.	2001	Validation of the Analytical method AL 003/01-2 for the determination of of organic impurities in ioxynil octanoate technical material Report PA01/004 Generated by : Aventis CropScience Submitted by : Aventis CropScience Bayer CropScience document C013167 GLP Not published
IIA, 4.1.1.2	Bowen T.	2001	Analytical method – Determination of organic impurities in ioxynil octanoate technical material by GC Report AL004/01-2 Generated by : Aventis CropScience Submitted by : Aventis CropScience Bayer CropScience document C013486 Not published
IIA, 4.1.1.2	Bowen T.	2001	Validation of the Analytical method LM 004/01-1 for the determination of of organic impurities in ioxynil octanoate technical material Report PA01/005 Generated by : Aventis CropScience Submitted by : Aventis CropScience Bayer CropScience document C013487 GLP Not published
IIA, 4.2.1.2	Corgier M. and Plewa A.	1998	Active substance Ioxynil estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions (Atkinson equation) – Study 98-154 Submitted by : Aventis CropScience Bayer CropScience, Document R014991 GLP not published

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
IIA, 4.2.1.2	Corgier M. and Plewa A.	1998	Ioxynil octanoate estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions (Atkinson equation) – Study 98-155 Submitted by : Aventis CropScience Bayer CropScience, Document R014993 GLP Not published
IIA, 4.2.2	Fillion J.	1996	Plant protection product Totril – Determination of the flash point, the auto-flammability and the explosion properties of EXP 03273B – Study 96-67 – Submitted by : Aventis CropScience Bayer CropScience, Document R014981 GLP Not published
IIA, 4.2.2	Uceda L. and Le Gren I.	1993	Totril – EXP03273B : Determination of kinematic viscosity at 40°C and surface tension at 25°C – Study 99-241 – Submitted by : Aventis CropScience Bayer CropScience, document R015029 GLP Not published
IIA, 4.5.1.1	Adam C	2001	Ioxynil octanoate: Determination of active ingredient contents in technical by GC – Updated version of method C-organique-00484-C-TA – CFPI Submitted by : CFPI Nufarm GLP Not published
IIA, 4.5.1.1	Adam C	2001	Determination of Ioxynil octanoate impurity contents in technical by GC – Updated version of method C-organique-00485-C-TA – CFPI Submitted by CFPI Nufarm GLP Not published
IIA, 4.5.1.1	Adam C	2001	Determination of Ioxynil octanoate impurity contents in technical by HPLC – Updated version of method C-organique-00483-C-TA – CFPI Submitted by : CFPI Nufarm GLP Not published

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
IIA, 4.5.2.1	Le Brun G	2000	Development and validation of a method of analysis for the determination of Ioxynil (phenol, heptanoate, octanoate) in cereals and cotton seeds - RPA/BROM/99001 (RPA study 99-70, method AR 202-99) - Generated by : GIRPA, Beaucouzet , France Submitted by : Aventis CropScience Bayer CropScience document R015033 GLP Not published
IIA, 4.5.2.3	Fuchsbichler G.	1999	Validation of the multi-residue method (DFGS19) for the determination of Ioxynil Octanoate in Cereals : grain and straw. Study 99-60 (Method AR197-99), HVA 11/99 generated by : Bayerische Hauptversuchsanstalt für Landwirtschaft Submitted by : Aventis CropScience Bayer CropScience document R015009 GLP Not published
IIA, 4.5.2.4	Fuchsbichler G.	2000	Independent laboratory validation of analytical method AR 202-99 for the determination of Ioxynil (phenol, octanoate) in cereals (grain) and cotton seed - Aventis CropScience study 00-03 (HVA 10/00) – generated by : Bayerische Hauptversuchsanstalt für Landwirtschaft Submitted by : Aventis CropScience Bayer CropScience document R015037 GLP Not published
IIA, 4.5.3	Le Brun G.	1999	Development and validation of a method of analysis for the determination of Ioxynil (phenol, octanoate) in waters -RPA/ IOXY/99003 (RPA study 99-74, method AR 206-99) - Generated by : GIRPA, Beaucouze, France Submitted by : Aventis CropScience Bayer CropScience document R015027 GLP Not published

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
IIA, 4.5.3.	Le Brun G.	1999	Development and validation of a method of analysis for the determination of Ioxynil (phenol, octanoate) in soils -RPA/ IOXY/99002 (RPA study 99-72, method AR 204-99) Generated by : GIRPA, Beaucouze, France Submitted by : Aventis CropScience Bayer CropScience document R015025 GLP Not published
IIA, 4.5.3.	Le Brun G.	2000	Development and validation of a method of analysis for the determination of Ioxynil (phenol, octanoate) in foodstuffs of animal origin - RPA/ IOXY/99004 (RPA study 99-76, method AR 208-99) Generated by : GIRPA, Beaucouze, France Submitted by : Aventis CropScience Bayer CropScience document R015031 GLP Not published
IIA, 4.5.3.	Bacher R., Class Th.	2000	Independant laboratory validation of Aventis CropScience analytical method AR 208-99 for the determination of Ioxynil in products of animal origin Aventis CropScience study 00-05 (PTRL Europe study n° P 397 G, Report n° B 379G) Generated by : PTRL europe Submitted by : Aventis CropScience Bayer CropScience document R015039 GLP Not published
IIA, 4.5.4	Goller G.	2000	Development and validation of an analytical method for the determination of Bromoxynil (phenol, heptanoate, octanoate) and Ioxynil (phenol and octanoate) in blood – Study ACS 00-61 (Method AR 247-00) - generated by : ADME bioanalyses submitted by : Aventis Crop Science, document R011964 GLP Not published

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
IIA, 5.2.1	Ruat C	2000	loxynil phenol: single dose toxicity by oral route in the rat Phoenix International 198/100 Submitted by : Aventis CropScience Bayer CropScience document C012173 GLP Not published
IIA, 5.2.6	Ruat C	2000	loxynil octanoate: sensitising potential in the guinea-pig. M & K test Phoenix International 198/094 Submitted by : Aventis CropScience Bayer CropScience document C012716 GLP Not published
IIA, 5.4.2	Whitwell J	2000	loxynil phenol: Induction of micronuclei in the bone marrow of treated mice Covariance Lab Ltd Submitted by : Aventis CropScience 198/161-D5140 Bayer CropScience document R015077 GLP Not published
IIA, 5.4	Ballantyne M	2002	loxynil octanoate: reverse mutation in five histidine-requiring strains of Salmonella typhimurium. Covance Laboratories, Harrogate, North Yorkshire, GBR Submitted by : Aventis CropScience 2014/36-D6171 Bayer CropScience document C021982 GLP Not published
IIA, 5.4	Lloyd M	2002	loxynil octanoate: Mutation of the Thymidine Kinase (tk) Locus of the mouse lymphoma L5178y cells (MLA) Covance Laboratories, Harrogate, North Yorkshire, GBR Submitted by : Aventis CropScience 2014/38-D6173 Bayer CropScience document C021427 GLP Not published

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
IIA, 5.4	Howe J, Semino G	2002	Ioxynil octanoate: Induction of micronuclei in the bone marrow of treated mice Covance Laboratories, Harrogate, North Yorkshire, GBR Submitted by : Aventis CropScience 2014/37-D6172 Bayer CropScience document C021980 GLP Not published
IIA, 5.8	Denton SM	2001	AE 0540061: acute oral toxicity study in the rat Covance Laboratories, Harrogate, North Yorkshire, GBR Submitted by : Aventis CropScience 2014/17-D6144 Bayer CropScience document C021605 GLP Not published
IIA, 5.8	Ballantyne M	2001	AE 0540061: reverse mutation in five histidine-requiring strains of Salmonella typhimurium. Covance Laboratories, Harrogate, North Yorkshire, GBR Submitted by : Aventis CropScience 2014/16-D6171 Bayer CropScience document C021615 GLP Not published
IIA, 5.9	Johnston RD	1989	Medical surveillance in HBN production plant in the years 1983/1984 and 1989 Code: AE F025943, AE F051835. Rhone Poulenc Ltd, UK Occupational health. Submitted by : Aventis CropScience Bayer CropScience document C022770 Non GLP, Not published
IIA, 5.9	Johnston RD	1991	Medical surveillance in HBN production plant in the years 1983/1984 and 1989, update 1991; Code: AE F025943, AE F051835. Rhone Poulenc Ltd, UK Occupational health. Submitted by : Aventis CropScience Bayer CropScience document C022772 Non GLP, Not published

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
IIA, 5.9	Rivett J	1998	Abnormal thyroid function tests amongst chemical process operators. Code: AE F051835. Rhone Poulenc Agriculture Ltd., UK Submitted by : Aventis CropScience Submitted by : Aventis CropScience Bayer CropScience document C022776 Non GLP, Not published

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
IIA, 6.1	McGhee I.	2000	(14C)-ioxynil octanoate: metabolism in spring wheat Aventis CropScience, Ongar, UK Study 10470 Submitted by : Aventis CropScience Bayer CropScience document C036305 GLP, Not published
IIA, 6.1	McGhee I.	2001	(14C)-ioxynil octanoate: Metabolism in onions Aventis CropScience, Ongar, UK Study 10470 Submitted by : Aventis CropScience Bayer CropScience document C015021 GLP, Not published
IIA, 6.1	Quintelas G	2001	Stability study of ioxynil in winter rape (grain) and soft winter wheat (grain) after storage in a congelator at a temperature near minus 18°C Defitraces, Brindas, France, Study 98-178 Submitted by : Aventis CropScience Bayer CropScience document C014005 GLP, Not published
IIA, 6.4	Ross VA	2003	Ioxynil Octanoate: Residues in the Milk and Tissues of Dairy Cows Huntingdon Life Sciences, UK, study AES 096/023322 Submitted by : Bayer CropScience Bayer CropScience document C029703 GLP, Not published

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
IIA, 6.4	Laporte F	2003	Ioxynil and ioxynil octanoate : Dietary risk assessment for chronic and acute exposure Bayer CropScience Frankfurt, study 03F005 Study 03F005 Submitted by : Bayer CropScience Bayer CropScience document C031435 GLP, Not published

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
IIA, 7.1.1.1.1 IIA, 7.1.1.2	Goodyear A.	2002	(14C)-ioxynil octanoate: Aerobic route and rate of soil degradation Covance Laboratories Ltd. Harrogate, UK study ref 1849/32 Submitted by : Bayer CropScience Bayer CropScience , Document C022859 GLP Not published
IIA, 7.1.1.1.2	Greener N.A.	2001	(14C)-ioxynil octanoate: Photodegradation on a soil surface Covance Laboratories Ltd. Harrogate, UK study ref 1849/026 Submitted by : Bayer CropScience Bayer CropScience , Document C014981 GLP Not published
IIA, 7.1.1.1.1 IIA, 7.1.1.2	Reinken G	2002	Kinetic evaluation of the degradation of ioxynil octanoate, ioxynil phenol and the metabolite 3,5-diiodo-4-hydroxybenzamide in aerobic soils using the TopFit 2.0 model Aventis CropScience GmbH, DEU Submitted by : Bayer CropScience Environmental Chemistry, Frankfurt, 33 pages Bayer CropScience document C022481 GMP Not published

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
IIA, 7.1.1.1.1 IIA, 7.1.1.2	Reinken G.,	2002	Degradation of ioxynil octanoate ioxynil phenol and the metabolite 3,5-diiodo-4-hydroxybenzamide in aerobic soils 10 degrees C Aventis CropScience GmbH, DEU Submitted by : Bayer CropScience Environmental Chemistry, Frankfurt, 21 pages Bayer CropScience document C022481 GLP Not published
IIA, 7.1.2	Rosenwald J.	2002	(14C)-3,5-diiodo-4-hydroxybenzamide: Adsorption/desorption in soil (interim report) Covance Laboratories GmbH, Muenster, DEU, study 1849-038 Submitted by : Bayer CropScience Bayer CropScience document C022854 GLP Not published
IIA, 7.1.2	Rosenwald J.	2002	(14C)-3,5-diiodo-4-hydroxybenzoic acid: Adsorption/desorption in soil (interim report) Covance Laboratories GmbH, Muenster, DEU, study 1849-037 Submitted by : Bayer CropScience Bayer CropScience document C022855 GLP Not published
IIA, 7.1.2	Rosenwald J.	2002	(14C)-IOxynil octanoate: Adsorption/ desorption in soil (interim report) Covance Laboratories GmbH, Muenster, DEU, study 1849-036 Submitted by : Bayer CropScience Bayer CropScience document C022856 GLP Not published
IIA, 7.1.2	Rosenwald J.	2002	(14C)-Ioxynil phenol: Adsorption/desorption in soil Covance Laboratories GmbH, Muenster, DEU, study 1849-033 Submitted by : Bayer CropScience Bayer CropScience document C022852 GLP Not published

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
IIA, 7.1.2	Rosenwald J	2002	3,5-diiodo-4-hydroxybenzamide adsorption/Desorption in Soil. Covance Laboratories GmbH, Münster, Germany, report No 1849-038 Submitted by : Bayer CropScience Bayer CropScience document C023717 GLP, Not published
IIA, 7.1.2	Rosenwald J	2002	(14C)-ioxynil octanoate: Adsorption/desorption in Soil Covance Laboratories GmbH, Münster, Germany, report No 1849-036 Submitted by : Bayer CropScience Bayer CropScience document C028179 GLP, Not published
IIA, 7.1.2	Rosenwald J	2002	(14C)- 3,5 diiodo-4-benzoic acid adsorption/Desorption in Soil. Covance Laboratories GmbH, Münster, Germany, report No 1849-037 Submitted by : Bayer CropScience Bayer CropScience document C028010 GLP, Not published
IIA, 7.1.3 9.2.1	Reinken G.	2002	Predicted environmental concentrations in groundwater (PEC _{gw}) for) for ioxynil octanoate, ioxynil phenol and the metabolite 3,5-diiodo-4-hydroxybenzamide using the European FOCUS groundwater scenarios Aventis CropScience GmbH, DEU Environmental Chemistry, Frankfurt, 32 pages Submitted by : Bayer CropScience Bayer CropScience document C022483 GMP, Not published
IIA, 7.1.3	Reinken G., Meyer H	2003	Predicted environmental concentrations in groundwater (PEC _{gw}) for) for ioxynil metabolite 3,5-diiodo-4-hydroxybenzoic acid using the European FOCUS groundwater scenarios. Bayer CropScience AG, DEU, study MEF 205/03 Submitted by : Bayer CropScience Bayer CropScience document C034133 GMP, Not published

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
IIA, 7.2.1	Baumann J.	2002	Aqueous photolysis of (14C)-ioxynil octanoate Battelle - Geneva Research Centres, CHE Agrochemical Product Development, Carouge/Geneva, study E-01-02-06 Submitted by : Bayer CropScience Bayer CropScience document C022861 GLP Not published
IIA, 7.2.1	Reinken G	2002	Estimation of the Ioxynil Octanoate K _{oc} Soil Adsorption Coefficient using the PCKOCWIN Model Bayer CropScience, Monheim Submitted by : Bayer CropScience Bayer CropScience document C028577 GMP, Not published
IIA, 7.2.1	Baumann J	2003	Aqueous Photolysis of [¹⁴ C]-Ioxynil Octanoate. Identification of Unknowns Batelle, Geneva Switzerland, Study E-14-02-04 Submitted by : Bayer CropScience Bayer CropScience document C028822 GLP Not published

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
IIA, 8.1	Ebeling M	2002	Refined Long Term Risk Assessment in Birds and Mammals Ioxynil Code: AE F051835, AE F065322. Bayer CropScience, Frankfurt Submitted by : Bayer CropScience Bayer CropScience document C022402 Not published
IIA, 8.1	Semino G.	2002	Ioxynil - NOAEL proposal for long-term risk assessment on wild mammals Code: AE F051835, AE F065322 Aventis CropScience S.A., FRA Regulatory Toxicology, 14 pages Submitted by : Bayer CropScience Bayer CropScience document C022713 Not published

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
IIA, 8.1	Sonder K	2002	Decline of residues in winter wheat: Special degradation curve to determine decline of residues in animal feed, European Union (northern zone) 2002, Bromoxynil-octanoate + Ioxynil octanoate Submitted by : Bayer CropScience Bayer CropScience Frankfurt 76 Pages Bayer CropScience document C028055 GLP, Not published
IIA, 8.1	Ebeling M.	2003	Ioxynil: Refined Long Term Risk Assessment in Birds and Mammals Confirmed by New Residue Data in Cereals. Bayer CropScience, Frankfurt Submitted by : Bayer CropScience Bayer CropScience document C030312 Not published
IIA, 8.2.1..	McElligott A	2001	Ioxynil Octanoate: Acute Toxicity To Rainbow Trout (<i>Oncorhynchus Mykiss</i>) Static Exposure And Recovery Phase Bayer CropScience - Sophia Antipolis, SA 01117 Submitted by : Bayer CropScience Bayer CropScience document C015458 GLP, Not published
IIA, 8.2.1.	Dorgerloh M.	2003	Ioxynil Octanoate: Acute Toxicity To Fish (<i>Oncorhynchus Mykiss</i>) in a Water Sediment System Under Static Conditions Bayer CropScience – Monheim, DOM 22080 Submitted by : Bayer CropScience Bayer CropScience document C031956 GLP, Not published
IIA, 8.2.1..	Putt A.E.	2000	4-hydroxybenzotrile – Acute toxicity to Rainbow Trout (<i>Oncorhynchus mykiss</i>) under static-renewal conditions. Springborn Laboratories Inc, report ref 10566.6570 Submitted by : Aventis CropScience Bayer CropScience GLP Not published

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
IIA, 8.2.3.	Odin-Feurtet M	2000	Chronic effects of ioxynil to Amphibian (<i>Xenopus laevis</i>) under semi-static conditions. Aventis CropScience Sophia Antipolis study ref SA99591 Submitted by : Rhône-Poulenc Agrochimie Bayer CropScience, document C010798 GLP Not published
IIA, 8.2.3.	Chapleo S., Hope J.	2000	Bioaccumulation and metabolism of (14C)-ioxynil octanoate in rainbow trout Inveresk Research, project 393347, report 18014 Submitted by : Bayer CropScience Bayer CropScience document R016547 GLP Not published
IIA, 8.2.4.	Putt A.E.	2000	4-hydroxybenzoxitrile – Acute toxicity to Daphnids (<i>Daphnia magna</i>) under static-renewal conditions. Springborn Laboratories Inc, report ref 10566.6569 Submitted by : Aventis CropScience Bayer CropScience GLP Not published

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
IIA, 8.2.6. C hapleo S., Hope J. 20 00 Bi oaccumul ation and metabolis m of (14C)- ioxynil octanoate in rainbow trout Inveresk Research, project 393347, report 18014 Submitted by : Bayer CropScie nce Bayer CropScie nce document R016547 GLP Not publishe d	Hoberg JR	1999	4-hydroxybenzotrile – Toxicity to the freshwater diatom, Navicula pelliculosa. Springborn Laboratories Inc, report 10566.6568 + amendment Submitted by : Aventis CropScience Bayer CropScience document R011988 GLP Not published

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
IIA, 8.4.1.. C hapleo S., Hope J. 20 00 Bi oaccumul ation and metabolis m of (14C)- ioxynil octanoate in rainbow trout Inveresk Research, project 393347, report 18014 Submitted by : Bayer CropScie nce Bayer CropScie nce document R016547 GLP Not publishe d	Lührs U	2000	Acute Toxicity (14 days) of Ioxynil phenol to the earthworm Eisenia fetida (Savigny 1826) in Artificial Soil. IBACON study ref 7391021 Submitted by : Aventisr CropScience Bayer CropScience GLP Not published

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
IIA, 8.4.1..	Lührs U	2000	Acute Toxicity (14 days) of Ioxynil octanoate to the earthworm Eisenia fetida (Savigny 1826) in Artificial Soil. IBACON study ref 7411021 Submitted by : Aventisr CropScience Bayer CropScience GLP Not published
IIA, 8.4.2..	Lührs U	2000	Effects of Ioxynil phenol on the Reproduction and growth of Eisenia fetida (Savigny 1826) in Artificial Soil. IBACON study ref 7461022 Submitted by : Aventisr CropScience Bayer CropScience GLP Not published

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
IIA, 8.8. C hapleo S., Hope J. 20 00 Bi oaccumul ation and metabolis m of (14C)- ioxynil octanoate in rainbow trout Inveresk Research, project 393347, report 18014 Submitted by : Bayer CropScie nce Bayer CropScie nce document R016547 GLP Not publishe d	Gaus I.	1999	Biotest zur Bewertung der Auswirkungen des Herbizides Totril (Wirkstoff Ioxynil) auf terrestrische Planzen (Bioassay for evaluation of the effects of the herbicide Totril (active ingredient ioxynil) on terrestrial plants) BBA Berlin study ref OC9903 Submitted by : Aventis CropScience Bayer CropScience document C017725 GLP Not published

APPENDIX IV

List of uses supported by available data

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Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/ha min max	water l/ha min max	kg as/ha min max		
Winter cereals wheat (incl. durum), barley, oats	EU	Totril	F	broad leaved weeds	EC	IO 225	spraying	2-3 leaves stage of crop till shooting (2 nodes)	1	-	-	200-400	0.4-0.45*	60	*: expressed as phenol equivalent (on young weeds up to 6 leaf stage, autumn or spring)
Spring cereals wheat (incl. durum), barley, oats, rye, triticale	EU	Totril	F	broad leaved weeds	EC	IO 225	spraying	2-3 leaves stage of crop till shooting (2 nodes)	1	-	-	200-400	0.3 *	60	*: expressed as phenol equivalent (on young weeds up to 6 leaf stage)

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds

(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

(i) g/kg or g/l

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) The minimum and maximum number of application possible under practical conditions of use must be provided

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

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23 September 2003