

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Bromoxynil
SANCO/4347/2000 - final
13 February 2004

Review report for the active substance **bromoxynil**

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 bromoxynil 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 bromoxynil, 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. Bromoxynil 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 Agro, now Bayer CropScience) on 15 July 1993, Pen-Taso-Materia Medica Center GmbH on 14 July 1993, ACI International (now Sanachem International) on 30 July 1993, CFPI (now Nufarm) on 28 July 1993, Makhteshim Agan 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 bromoxynil 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 bromoxynil 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 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 submitted a dossier in time. Pen-Taso-Materia Medica Center GmbH did not submitted a dossier. Luxan on a letter dated on 10 January 1995 stated its intention not to support Bromoxynil further and did not submit a dossier. Information has furthermore been submitted by KEMI.

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 bromoxynil 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 bromoxynil from Rhone Poulenc Agro (now Bayer CropScience) and Makhteshim Agan, on 25 February 1998.

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 being the designated representative of the bromoxynil main data submitters, on 25 August 2000.

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 bromoxynil in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing bromoxynil 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 bromoxynil will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each bromoxynil containing plant protection product for which Member States will grant or review the authorisation.

⁵ OJ No L 120, 24.4.2004, p.26.

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 <2% of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994) and taking into account cereals only. 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 (< 7%).

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 heptanoate and octanoate esters of bromoxynil, for which detailed information was submitted. Further studies, in particular bridging studies, may be necessary in relation to the acceptance of esters of bromoxynil other than the heptanoate and octanoate esters evaluated.

4. Identity and Physical/chemical properties

The main identity and the physical/chemical properties of bromoxynil 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 submitters [Rhône Poulenc Agro now Bayer Crop Science and Makhteshim Agan], 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 also satisfied, on the basis of the information currently available, that the substances notified by the other data submitters (Nufarm) and Makhteshim Agan, do not, in the meaning of Article 13(2) and (5) of the Directive, differ significantly in degree of purity and nature of impurities from the composition registered in the dossier submitted by the main data submitter.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in Appendix II. For esters of Bromoxynil other than octanoate and heptanoate esters 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 bromoxynil

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 bromoxynil 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 bromoxynil other than octanoate and heptanoate esters 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

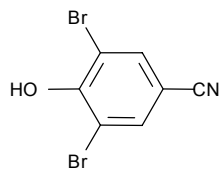
The technical information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. 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 bromoxynil in Annex I of the Directive.

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

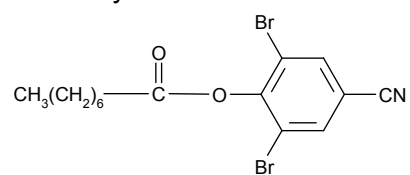
Common name (ISO)	BROMOXYNIL
Chemical name (IUPAC)	Bromoxynil : 3,5 dibromo -4- hydroxybenzonitrile bromoxynil octanoate : 2,6- dibromo -4-cyanophenyl octanoate bromoxynil heptanoate : 2,6-dibromo-4-cyanophenyl heptanoate
Chemical name (CA)	Bromoxynil : benzonitrile, 3,5 – dibromo - 4 – hydroxy bromoxynil octanoate : octanoic acid, 2,6- dibromo -4-cyanophenyl ester bromoxynil heptanoate : heptanoic acid 2,6- dibromo -4-cyanophenyl ester
CIPAC No	Bromoxynil : 87 bromoxynil octanoate : 87.407 bromoxynil heptanoate : 87.406
CAS No	Bromoxynil : 1689-84-5 bromoxynil octanoate : 1689-99-2 bromoxynil heptanoate : 56634-95-8
EEC No	Bromoxynil : 608-006-00-0 (216-882-7) bromoxynil octanoate : 608-017-00-0 (216-885-3) bromoxynil heptanoate : -
FAO SPECIFICATION	970 g/kg (1996)
Minimum purity	Bromoxynil : ≥ 970 g/kg bromoxynil octanoate : ≥ 920 g/kg bromoxynil heptanoate : ≥ 930 g/kg
Molecular formula	Bromoxynil : C ₇ H ₃ Br NO bromoxynil octanoate : C ₁₅ H ₁₇ Br ₂ NO ₂ bromoxynil heptanoate : C ₁₄ H ₁₅ Br ₂ NO ₂
Molecular mass	Bromoxynil : 276.9 g/mol bromoxynil octanoate : 403.0 g/mol bromoxynil heptanoate : 389.1 g/mol

Structural formula

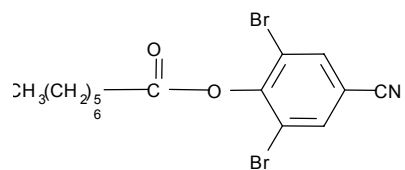
Bromoxynil :



Bromoxynil octanoate:



Bromoxynil heptanoate :



Melting point	Bromoxynil : 188.7°C bromoxynil octanoate : 45.3 °C bromoxynil heptanoate : 44.1 °C
Boiling point	Bromoxynil : 318.7 °C bromoxynil octanoate : no boiling point up to 185°C bromoxynil heptanoate : no boiling point up to 180°C
Appearance	Bromoxynil : white cristalline powder bromoxynil octanoate : white fine powder bromoxynil heptanoate : white fine powder
Relative density	Bromoxynil : 1.632 g/ml bromoxynil octanoate : 1.638 g/ml bromoxynil heptanoate : 1.632 g/ml
Vapour pressure	Bromoxynil : 1.7×10^{-4} Pa at 25 °C Bromoxynil octanoate : $< 10^{-7}$ Pa at 25 °C Bromoxynil heptanoate : $< 10^{-7}$ Pa at 25 °C
Henry's law constant	Bromoxynil : 5.3×10^{-4} Pa.m ³ .mol ⁻¹ Bromoxynil octanoate and heptanoate : not calculated due to the very low level of the vapour pressure. Very low possibility for volatilization from water to air
Solubility in water	Bromoxynil : 90 mg/l in distilled water ; 539 mg/l at pH5 ; > 3100 mg/l at pH9. bromoxynil heptanoate : 0.17 mg/l at pH5 ; 0.08 mg/l at pH7 ; 0.15 mg/l at pH9 bromoxynil octanoate : 0.04 mg/l at pH5 . 0.03 mg/l at pH7 and pH9
Solubility in organic solvents	Bromoxynil : Acetone = 170 g/l Methanol = 90 Tetrahydrofuran = 410 Petroleum oils < 20 bromoxynil heptanoate : Acetone = 1113 g/l dichloromethane = 851 ethyl acetate = 811 methanol = 553 toluene = 838 heptane = 562 octanol = 270 bromoxynil octanoate : Acetone = 1215 g/l ethyl acetate = 847 methanol = 207 octanol = 196 toluene = 813 heptane = 368
Partition co-efficient (log P_{ow})	Bromoxynil : log P = 1.04 (pH7), 1.31 (pH2) bromoxynil octanoate : log P = 5.9 (pH7) bromoxynil heptanoate : log P = 5.4 (pH7)

Hydrolytic stability (DT₅₀)	<p>Bromoxynil : No degradation detected at pH5, 7, 9.</p> <p>bromoxynil octanoate : DT₅₀ = 34 days at pH5 11 days at pH7 1.7 days at pH9</p> <p>bromoxynil heptanoate : DT₅₀ = 11.7 days at pH5 5,3 days at pH7 4.1 days at pH9</p>
Dissociation constant	<p>Bromoxynil : pKa = 3.86</p> <p>bromoxynil octanoate : not applicable, no ionisable group</p> <p>bromoxynil heptanoate : not applicable, no ionisable group</p>
Quantum yield of direct photo-transformation in water at λ >290 nm	<p>Bromoxynil : 4.8 x 10⁻² mole x einstein⁻¹</p> <p>bromoxynil octanoate : 1.2 x 10⁻⁴ mole x einstein⁻¹</p> <p>bromoxynil heptanoate : 4.07 x 10⁻⁵ mole x einstein⁻¹</p>
Flammability	Bromoxynil , octanoate, bromoxynil heptanoate : not flammable
Explosive properties	Bromoxynil , octanoate, heptanoate : no oxidising properties.
UV/VIS absorption (max.)	<p>Bromoxynil : λ max = 221.2 ε = 30343 l x mol⁻¹ x cm⁻¹ 287 ε = 18302 l x mol⁻¹ x cm⁻¹</p> <p>bromoxynil octanoate : λ max = 214 nm ε = 61353 l x mol⁻¹ x cm⁻¹ and at λ = 295 nm ε = 1494 l x mol⁻¹ x cm⁻¹</p> <p>bromoxynil heptanoate : λ max = 214 nm ε = 44688 l x mol⁻¹ x cm⁻¹ and at λ = 295 nm ε = 669 l x mol⁻¹ x cm⁻¹ no absorption after 300 nm</p>
Photostability in water (DT₅₀)	<p>Bromoxynil : DT 50 <10 h (2 major by-products)</p> <p>bromoxynil octanoate : DT50 = 4-5 hours (degradation into phenol. Other by-products < 10%).</p> <p>bromoxynil heptanoate : DT50 = 18 hours (degradation into phenol).</p>

APPENDIX II

END POINTS AND RELATED INFORMATION

BROMOXYNIL

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	At least 80 %, based on urine excretion
Distribution:	Widely distributed in the tissues
Potential for accumulation:	No potential for accumulation
Rate and extent of excretion:	Almost completely eliminated within 7 days mainly by urine
Toxicologically significant compounds:	Bromoxynil
Metabolism in animals:	Hydrolysis of the esters, mainly excreted as bromoxynil

Acute toxicity

Rat LD ₅₀ oral:	Bromoxynil : 81 mg/kg bw Bromoxynil octanoate: 238 mg/kg bw Bromoxynil heptanoate: 291 mg/kg bw
Rat LD ₅₀ dermal:	Bromoxynil : > 2000 mg/kg bw Bromoxynil octanoate: > 2000 mg/kg bw Bromoxynil heptanoate: > 2000 mg/kg bw
Rat LC ₅₀ inhalation:	Bromoxynil : 0.15 mg/l Bromoxynil octanoate: 0.72 mg/l Bromoxynil heptanoate: 1.48 mg/l
Skin irritation:	Bromoxynil : Not irritant Bromoxynil octanoate and heptanoate : Not irritant
Eye irritation:	Bromoxynil : Not irritant Bromoxynil octanoate and heptanoate: Not irritant
Skin sensitization (test method used and result):	Bromoxynil : Sensitizer (M & K) Bromoxynil octanoate : Sensitizer (M & K) Bromoxynil heptanoate: Sensitizer (M & K)

Short term toxicity

Target / critical effect:	Reduced body weight gain. Liver (hypertrophy, enzyme induction and indication of liver toxicity)
Lowest relevant oral NOAEL / NOEL:	NOEL = 1 mg/kg bw/day (90 d and 1 year, dog)
Lowest relevant dermal NOAEL / NOEL:	NOEL >1000 mg/kg bw /day (28 d dermal, rabbit)
Lowest relevant inhalation NOAEL / NOEL:	No data required

Genotoxicity

Some positive results in vitro in mammalian cells, negative in vivo

Long term toxicity and carcinogenicity

Target / critical effect:	Liver (histopathological changes), reduced body weight
Lowest relevant NOAEL:	NOEL = 10 ppm = 1.3 mg/kg bw/day, (18 months, mice)
Carcinogenicity:	Liver tumours in male mice, classification not considered necessary.

Reproductive toxicity

Target / critical effect - Reproduction:	Retardation of development (body weight gain and eye opening) at parental toxic dose level
Lowest relevant reproductive NOAEL / NOEL:	NOEL = 50 ppm approx. 2 mg/kg bw
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 bw /day (rat) Dermal: 10 mg/kg bw /day (rat)

Delayed neurotoxicity

No data required

Other toxicological studies

Studies on transient soil metabolite : 3,5 Dibromo-4-HydroxyBenzoic Acid (DBHA) Cause liver and development effects at higher dose levels than the parent compound
--

Medical data

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

Summary

(bromoxynil, octanoate and heptanoate bromoxynil)

ADI:

Value Study Safety factor

0.01 mg/kg/day	18 months mice study and overall short term NOEL = 1 mg/kg/day	100
0.01 mg/kg/day	90 days and 1 year dog study (overall short term NOEL) NOEL = 1 mg/kg/day	100
0.04 mg/kg/day	Teratogenicity, NOAEL= 4 mg/kg bw /day	100

AOEL systemic:

ARfD (acute reference dose):

Dermal absorptionBromoxynil octanoate: 3.5%
(*in vivo* rat and *in vitro* rat and human)

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	¹⁴ C-cyano Bromoxynil octanoate : 64.3 % (90 d) ¹⁴ C-phenyl Bromoxynil : 27.3 - 33.6 % (28 d) ¹⁴ C-phenyl 3,5-diBr-4-OH-benzamide : Study 1: 45.2 - 67.7 % (128 d) Study 2: 46 - 55.9 % (55 d) ¹⁴ C-phenyl 3,5-diBr-4-OH-benzoic acid : 23.5 -34.4 % (86 d)
Non-extractable residues after 100 days:	¹⁴ C-cyano Bromoxynil octanoate : 13.6 % (90 d) max:14.1 % (60 d) ¹⁴ C-phenyl Bromoxynil : 72.9 - 74.2 % (28 d); max: 95.2 % (7 d) - 74.2 % (28d) ¹⁴ C-phenyl 3,5-diBr-4-OH-benzamide : Study 1: 11.6 - 17.9 % (128 d); max: 18.9 % (16 d) - 16.8 % (8 d) Study 2: 34.6 - 47.4 % (55 d); max: 50.8 % (28 d) - 61 % (7 d) ¹⁴ C-phenyl 3,5-diBr-4-OH-benzoic acid : 59.9 - 66.9 % (86 d); max: 70.8 % (1 d) - 82.7 % (4 d)
Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	<u>Bromoxynil octanoate (and heptanoate)</u> - Bromoxynil : max. 44.6 % (4 d) - 3,5-diBr-4-OH-benzamide : max. 20 % (28 h) <u>Bromoxynil :</u> - 3,5-diBr-4-OH-benzamide : max. 20.9 - 21.6 % (1 d); <1.4 % (4 d) - 3,5-diBr-4-OH-benzoic acid : max. 16.1 - 34.8 % (1 d); <2 % (14 d) <u>3,5-diBr-4-OH-benzamide :</u> - 3,5-diBr-4-OH-benzoic acid: max 18.2 % (4 d) - polar compounds: 16.6 - 35.7 %; max: 40.4 %

Supplemental studies**Anaerobic:**

Soil study: No significant role expected under real conditions due to rapid degradation under aerobic conditions.

Water-Sediment study; in the sediment:

- Bromoxynil (max. 48.6 % after 7 d)
- 4-OH-benzonitrile (max. 45.5 % after 14 d)

Soil photolysis:

No significant role for both Bromoxynil and Bromoxynil octanoate

Remarks:

none

Rate of degradation**Laboratory studies**

DT₅₀lab (20 °C, aerobic):

Bromoxynil octanoate :

4 soils (OC 2.8 - 5.9 % , pH 6.6 - 7.4) ; 22° C

DT₅₀ < 1 d (7.1 - 18.7 h; mean: 12.9 h; first-order, R²>0.92)

Bromoxynil heptanoate :

no data; expected to behave as the octanoate ester

Bromoxynil :

4 soils (OC 0.7 - 5.2 % , pH 5.3 - 7.4) ; 22° C

DT₅₀ < 1 d (15 - 18 h; mean: 16.5 h; first-order, R²>0.81)

3,5-diBr-4-OH-benzamide :

Study 1: 2 soils (OC: 0.4-1.9 % , pH: 5.3 - 7.1), 22°C

DT₅₀: 1.5 - 5.2 d (first-order, R²> 0.90)

Study 2: 3 soils (OC 1.9 - 2.5 % , pHw 6.4 - 7.8) ; 20° C

DT₅₀ < 1.4 d (0.47 - 1.43 d, Timme &Frehse, R²>0.95)

3,5-diBr-4-OH-benzoic acid :

3 soils as study 2 above

DT₅₀ < 0.5 d (0.16 - 0.48 d, Timme & Frehse, R²>0.84

DT₉₀lab (20 °C, aerobic):

Not calculated for Bromoxynil octanoate and Bromoxynil.

3,5-diBr-4-OH-benzamide : DT₉₀ < 6.7 d (1.8 - 6.7 d, KIM, R² 0.99)

3,5-diBr-4-OH-benzoic acid : DT₉₀ < 5.3 d (1.8 - 5.3, Timme & Frehse, R²>

	0.84)
DT ₅₀ lab (10 °C, aerobic):	<u>Bromoxynil octanoate</u> 4 soils (OC 2.8 - 5.9 % , pH 6.6 - 7.4) DT ₅₀ < 1.5 d (18.8 - 34.1 h; mean: 25.5 h, first-order, R ² >0.92)
	<u>Bromoxynil</u> 4 soils (OC 0.7 - 5.2 % , pH 5.3 - 7.4) DT ₅₀ < 2.5 d (1.8 - 2.4 d; mean: 2.1 d, first-order, R ² > 0.81)
DT ₅₀ lab (20 °C, anaerobic):	Soil study: not determined Water - Sediment study: 3.7 d for Bromoxynil octanoate and < 7 d for Bromoxynil phenol

Field studies (country region)

DT _{50f} from soil dissipation studies	<u>Bromoxynil octanoate</u> , 0.56 kg/ha, spring appl., 2 US sites, LOD 0.01 mg/kg (4 %) <ul style="list-style-type: none"> - California (sandy loam, pH 7.7) : DT₅₀: 7.7 d (first-order, R²= 0.99), (Bromoxynil ester + phenol) - North Carolina (loamy sand, pH 5.9) DT₅₀: 1 d (first-order, R²= 0.98), (Bromoxynil ester +) - UK (clay loam, pH 6.5) DT₅₀ : 8 d (1st order, R² 0.71), (Bromoxynil ester + bromoxynil)
DT _{90f} from soil dissipation studies	not determined, not required
Soil accumulation studies:	Not relevant
Soil residue studies:	Not relevant

Remarks:

e.g. effect of soil pH on degradation rate

no

Adsorption/desorption

K_f / K_{oc} :

K_d :

pH dependence:

Bromoxynil octanoate

Loamy sand, OC 1.1 %, pH 7.2

K_f 7.0 ; $1/n$ 0.96 ; K_{oc} 639

*other data submitted ; adsorption coefficient not measurable (low stability)
bromoxynil octanoate is expected to be more adsorbed than bromoxynil
 K_{oc} 4847 (model calculation)*

Bromoxynil heptanoate

no data; might be slightly less adsorbed than the octanoate ester

Bromoxynil

4 soils, OC 0.7 - 5.25 % , pH 5.3 - 7.4

K_f 1.6 - 12.5 ; $1/n$ 0.7 - 0.9 ; K_{oc} 108 – 239

3,5-diBr-4-OH-benzamide

4 soils, OC 0.9 - 2.8 % , pH_w 5.0 - 8.0

K_f 0.5 - 9.2 ; $1/n$ 0.67 - 0.87 ; K_{oc} 32 - 330

3,5-diBr-4-OH-benzoic acid

3 soils, OC 0.9 - 2.8 % , pH_w 5.0 - 7.5

K_f 3.1 - 10.5 ; $1/n$ 0.72 - 0.76 ; K_{oc} 284 - 639

General comment

Values probably overestimated due to rapid degradation

No data available on desorption

Mobility

Laboratory studies:

Column leaching:

<u>Bromoxynil octanoate</u> (500 mm, duration not mentioned, 20°C)				
Soil type	OM %	pH	leachates %	nature
Sandy loam	1.21	7.1	4.4	CO ₂
Sand	0.17	6.2	55.7	CO ₂ *
Loam	5.28	6.8	10.0	CO ₂
Sandy loam	1.86	7.0	14.2	CO ₂

* mainly CO₂ expected, Bromoxynil, 3-Br-4-OH benzonitrile detected (sand soil only), amounts not determined

Soil radioactivity mainly located in the 12 cm top soil layer.

Bromoxynil heptanoate

no data, expected to behave as the octanoate ester

Bromoxynil (206 mm, 4 d)

Soil type	OC %	pH	leachates %	nature
Clay loam	0.7	7.3	2.1	CO ₂
Loamy sand	1.3	7.4	5.7	CO ₂
Loam	1.5	5.3	0.5	CO ₂
Sandy loam	5.25	6.2	0.1	CO ₂

Soil radioactivity (%) : 74.6 - 72.3 - 70.1 - 74.3

Aged residue leaching:

<u>Bromoxynil octanoate</u>				
Study 1: Incubation 51 h, 22° C (extr. 93.2 %, B. oct. 51.5 % after 48 h)				
Leaching: 500 mm, duration not reported, 20°C.				
Soil type	OM %	pH	leachates %	nature
Sandy loam	1.21	7.1	17.4	CO ₂
Sand	0.17	6.2	57.3	CO ₂ *
Loam	5.28	6.8	3.7	CO ₂
Sandy loam	1.86	7.0	13.1	CO ₂
* mainly CO ₂ expected, Bromoxynil detected (sand soil only), amount not determined				
Soil radioactivity mainly located in the 12 cm top soil layer				
Study 2: Incubation 28 - 100 h, 20° C, final metabolites: bromoxynil, max. 22.7 %; 3,5-diBr-4-OH-benzamide, max. 20 %, CO ₂ : 1.9 - 11.1 %				
Leaching 508 mm, 9 – 15 d (depending on soil):				
Soil type	OC %	pH	leachates %	nature

Sand	0.3	7.3	3.5	CO2
Clay loam	1.4	5.9	0.2	CO2
Sediment	4.7	5.5	0.2	CO2
Loam	1.7	5.0	0.2	CO2
Sandy loam	2.6	5.9	0.2	CO2
Mineralisation (%): 38.4 - 49.6				
Soil radioactivity mainly located in the first 5 cm top soil layer				
<u>Bromoxynil</u>				
Incubation one half life at 18-22° C				
(3,5-diBr-4-OH-benzamide and -benzoic acid significant)				
Leaching with 206 mm, 4 d				
Soil type	OC %	pH	leachates %	nature
Clay loam	0.7	7.3	4.5	CO2
Loamy sand	1.3	7.4	9.8	CO2
Loam	1.5	5.3	0.2	CO2
Sandy loam	5.25	6.2	0.2	CO2
Soil radioactivity (%): 73.7 - 69.0 - 75.8 - 78.4				

Field studies:Lysimeter/Field leaching studies Requirement depending on modelling PECgw.**Remarks:**none

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

pH 5

Bromoxynil heptanoate DT₅₀ 11.7 d

Bromoxynil octanoate DT₅₀ 34.1 d

metabolites: Bromoxynil (stable): 35 % (30 d)

3,5-diBr-diOH-cyclohexadienylnitrile: 10.4 % (21 d)

pH 7

Bromoxynil heptanoate DT₅₀ 5.3 d

Bromoxynil octanoate DT₅₀ 11.5 d

metabolite: Bromoxynil (stable): 77.2 % (30 d)

3,5-diBr-diOH-cyclohexadienylnitrile: 10.7 % (21 d)

pH 9

Bromoxynil heptanoate DT₅₀ 4.1 d

Bromoxynil octanoate DT₅₀ 1.7 d

metabolite: Bromoxynil (stable): 76 % (120 h)

: 7.9 % (30 h)

Major metabolites:

bromoxynil and 3,5-diBr-diOH-cyclohexadienylnitrile

Photolytic degradation:

Bromoxynil, pH 7

DT₅₀ < 10 h continuous artificial light, not estimated under real conditions

metabolites : 3-Br-4-OH-benzonitrile, 4-OH-benzonitrile

Bromoxynil octanoate and heptanoate, pH 5

DT₅₀ 18 h continuous artificial light but not significant under real conditions

Bromoxynil octanoate, pH 7.5

DT₅₀ 4-5 h continuous artificial light

metabolites: 2-Br-4-cyanophenyl octanoate, polar compounds

Major metabolites:

Bromoxynil : 3-Br-4-OH-benzonitrile ; 4-OH-benzonitrile

Biological degradation

Readily biodegradable:

Bromoxynil octanoate: no

Bromoxynil : no

Water/sediment study:

¹⁴C-phenyl Bromoxynil

Incubation in two water-sediment systems. 20 °C, 60 d

DT₅₀ water:

DT₅₀ water: 9.6 - 16 d

DT₉₀ water:

DT₉₀ water: 31.9 - 53.1 d

DT₅₀ whole system:

DT₅₀ whole system: 9.6 - 15.9 d

DT₉₀ whole system:

DT₉₀ whole system: 31.9 - 52.9 d

¹⁴C-cyano bromoxynil octanoate

Incubation under N₂ for 26 w, 18.5 to 21.4 °C

DT₅₀ 3.7 d (whole system)

¹⁴C-phenyl Bromoxynil octanoate (and heptanoate).

Study 1: one water-soil system, 25°C, 30 d:

DT₅₀ (soil or whole system) 14 h

DT₅₀ (water and whole system) bromoxynil phenol 5 d

Study 2: 2 water-sediment systems, 20 °C, 100 d

DT₅₀ water < 1 h

DT₉₀ water < 6 h

DT₅₀ whole system < 4 h

DT₉₀ whole system < 3 d

For the above 4 studies:

using a simple first-order (SFO) multicompartment model DT₅₀ (range (mean) in days)

Bromoxynil octanoate (Water): 0.03 – 0.07 (0.05)

Bromoxynil (Water): 1.8 – 13.8 (5.9)

Bromoxynil octanoate (Total syst): 0.07 – 0.5 (0.3)

Bromoxynil (Total syst): 1.8 – 13.8 (5.9)

3,5-dibromo-4-OH-benzamide (Total syst): 3.0 – 30.8 (10.4)

3,5-dibromo-4-OH-benzoic acid (Total syst): 0.6 – 25.8 (9.3)

3-bromo-4-OH-benzamide (Total syst): 4.2 – 46.2 (25.2)

3-bromo-4-OH-benzonitrile (Total syst): 0.7 – 32.4 (11.1)

4-OH-benzonitrile (Total syst): 1.1 – 7.5 (4.1)

Distribution in water / sediment systems (active substance)	<p><u>¹⁴C-phenyl bromoxynil</u> : 4.3 - 10.3 % (water) vs 25.9 - 19.8 % (sed) (60 d)</p> <p><u>bromoxynil octanoate</u></p> <p><u>¹⁴C-cyano bromoxynil octanoate</u>: 48.9 % (water) - 40.2 % (sed) after 6 h</p> <p><u>¹⁴C-phenyl bromoxynil octanoate</u>:</p> <p>Water-soil system: 0 % (water) - 87.6 % (sed) (0 d)</p> <p>Water-sediment systems: 2.6 % - 18.1 % (water) vs 34.8 % - 30.8 % (sed) (0 d)</p>
Distribution in water / sediment systems (metabolites)	<p><u>¹⁴C-phenyl bromoxynil</u> :</p> <p>3,5-diBr-4-OH-benzamide: max water: 23.3 % (14 d) - 10.7 % (30 d) vs max sed: 3.2 % (14 d) - 0.93 % (30 d)</p> <p><u>¹⁴C-cyano bromoxynil octanoate</u></p> <p>Bromoxynil : max 40.1 % (water) - 8.5 % (sed) after 7 d</p> <p>4-OH benzonitrile: max 36.1 % (water) - 9.4 % (sed) after 14 d</p> <p><u>¹⁴C-phenyl bromoxynil octanoate</u>:</p> <p><u>Water-soil system</u>:</p> <ul style="list-style-type: none"> - Bromoxynil phenol: max 66.1 % (water, 2 d) and 41.5 % (sed, 0.5 d) - 3,5-diBr-4-OH-hydroxybenzoic acid: max 11.3 % (water, 21 d) and 5 % (soil, 30 d) - 3-Br-4-OH-benzonitrile: max 12.1 % (water, 7d) - 4-OH-benzonitrile: max 16.3 % (water, 14 d) and 9.3 % (sed, 14 d) <p><u>Water-sediment systems</u>:</p> <ul style="list-style-type: none"> - Bromoxynil : max. 56.9 % (1 d) - 63.1 % (2 d) in water with less than 2.1 % in sediment ; DT₅₀ water = 3 - 15 d and DT₉₀ water = 9 - 46 d ; DT₅₀ whole system = 4 - 17 d and DT₉₀ whole system = 10 - 50 d - 3-Br-4-OH-benzonitrile (transient): max. 11.5 % in water (7 d) with 1 % in sediment - 4-OH-benzonitrile (transient): max. 25.4 % in water (30 d) with less than 7.5 % in sediment
Accumulation in water and/or sediment:	no accumulation expected, rapid degradation

Degradation in the saturated zone

No data, not required

Remarks:

none

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

Bromoxynil : 1.7×10^{-4} Pa at 25 °C
Bromoxynil Octanoate : $< 10^{-7}$ Pa at 25 °C
Bromoxynil Heptanoate : $< 10^{-7}$ Pa at 25 °C

Henry's law constant:

Bromoxynil : 5.3×10^{-4} Pa.m³.mol⁻¹
Bromoxynil Octanoate and Heptanoate : not calculated due to the very low level of the vapour pressure. Very low possibility for volatilization from water to air

Photolytic degradation

Direct photolysis in air:

not required due to the low vapour pressure

Photochemical oxidative degradation in air

Bromoxynil : 12 - 51 d

DT₅₀:

Bromoxynil octanoate : 3.5 d

Bromoxynil heptanoate : 4 d

Volatilisation:

from plant surfaces:

- Bromoxynil : 16.4 % of AR after 24 h under ventilation.
- Bromoxynil octanoate : < 7 % after 1 d with 80 – 86 % extractable and 10 % unextractable in plants
- Bromoxynil (octanoate + heptanoate) : < 5 % after 1 d with 85.7 % extractable and 9.1 % unextractable in plants

from soil:

- Bromoxynil : 7.7 % of AR after 24 h under ventilation
- Bromoxynil octanoate < 9 % after 1 d with 95.8 % remaining in soil
- Bromoxynil (octanoate + heptanoate) : < 17 % after 1 d with 90.7 % remaining in soil

Remarks:

none

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:

Bromoxynil :
DL50 (rat, acute oral) = 81 mg /kg bw
Bromoxynil octanoate:
DL50 (rat, acute oral) = 238 mg /kg b
Bromoxynil heptanoate:
DL50 (rat, acute oral) = 291 mg /kg bw

Acute toxicity to birds:

Bromoxynil :
DL50 (bobwhite quail) = 217 mg /kg bw
Bromoxynil octanoate:
DL50 (bobwhite quail) = 170 mg /kg bw
Bromoxynil heptanoate:
DL50 (bobwhite quail) = 379 mg /kg bw
EMBLEM¹:
DL50 (Japanese quail) = 486.5 mg /kg bw

Dietary toxicity to birds:

Bromoxynil :
CL50 (mallard duck) = 1 380 mg/kg diet
Bromoxynil octanoate:
CL50 (bobwhite quail) = 1 315 mg/kg diet
Bromoxynil heptanoate:
CL50 (bobwhite quail) = 4 525 mg/kg diet

Reproductive toxicity to birds:

Bromoxynil :
No data, estimation from NOEC of bromoxynil octanoate 110 mg/kg diet:
NOEC = 75.6 mg/kg diet, corresponding to 10.8 mg /kg bw
Bromoxynil octanoate:
NOEL (mallard duck) = 110 mg/kg diet
Bromoxynil heptanoate:
No data, not required (refer to bromoxynil octanoate)

Long term toxicity to mammals:

Bromoxynil :
NOEL (reproduction, rat) = 250 mg/kg diet, corresponding to 21.4 mg/kg bw
Bromoxynil octanoate:
NOEL (rat, 90 d oral) = 150 mg/kg diet
Bromoxynil heptanoate:
NOEL no data, refer to bromoxynil octanoate

¹ WP preparation containing 30.7 % w/w bromoxynil octanoate

Aquatic Organisms

S: static, SS: semi-static, D: dynamic

	Test species	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Acute toxicity fish:	<i>Lepomis macrochirus</i>	Bromoxynil	Acute 96 h, SS	LC50	29.2
		Bromoxynil heptanoate	Acute 96 h, D	LC50	0.029
	<i>Oncorhynchus mykiss</i>	Bromoxynil octanoate	Acute 96 h, D	LC50	0.041
		Bromoxynil octanoate	Acute 96 h, S, with sediment	LC50 NOEC	0.18 0.093
		4-hydroxy-benzonitrile	Acute 96 h, SS	LC50	8.8
		EMBLEM ¹	Acute 96 h, SS	LC50	0.033
		CDG 97040 H ²	Acute 96 h, S	LC50	0.71
OXYTRIL CM ³	Acute 96 h, D	LC50	0.11		
Long term toxicity fish:	<i>Oncorhynchus mykiss</i>	Bromoxynil	Chronic 21 d, SS	NOEC	2
	<i>Pimephales promelas</i>	Bromoxynil octanoate	Chronic 35 d, D	NOEC	0.0034
	<i>Oncorhynchus mykiss</i>	CDG 97040 H ²	Chronic 21 d, D	NOEC	0.2
Bioaccumulation fish:		Bromoxynil	No data, not required (log Pow = 1.04 @ pH 7)		
		Bromoxynil heptanoate	No data, not required, refer to bromoxynil octanoate		
	<i>Lepomis macrochirus</i>	Bromoxynil octanoate		BCF	230
Acute toxicity invertebrate:	<i>Daphnia magna</i>	Bromoxynil	Acute 48 h, S	EC50	12.5
		Bromoxynil heptanoate	Acute 48 h, D	EC50	0.031
		Bromoxynil octanoate	Acute 48 h, S	EC50	0.046
		Bromoxynil octanoate	Acute 48 h, S with sediment	EC50 NOEC	> 0.13 0.09
		4-hydroxy-benzonitrile	Acute 48 h, SS	EC50	33
		EMBLEM ¹	Acute 48 h, SS	EC50	0.091
		CDG 97040 H ²	Acute 48 h, S	EC50	0.73
		OXYTRIL CM ³	Acute 48 h, SS	EC50	0.01
Chronic toxicity invertebrate:	<i>Daphnia magna</i>	Bromoxynil	Chronic 21 d, SS	NOEC	3.1
		Bromoxynil octanoate	Chronic 21 d, D	NOEC	0.0025
		CDG 97040 H ²	Chronic 21 d, SS	NOEC	0.05

	Test species	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Acute toxicity algae:	<i>Navicula pelliculosa</i>	Bromoxynil	72 h, S	EC50	0.12
	<i>Selenastrum capricornutum</i>	Bromoxynil heptanoate	120 h, S	EC50	0.083
	<i>Navicula pelliculosa</i>	Bromoxynil octanoate	120 h, S	EC50	0.043
	<i>Scenedesmus subspicatus</i>	EMBLEM ¹	72 h, S	EC50	2.31
	<i>Scenedesmus subspicatus</i>	CDG 97040 H ²	72 h, S	EC50	0.0487
Chronic toxicity sediment dwelling organism:	<i>Chironomus riparius</i>	Bromoxynil octanoate	22 d, S	NOEC	0.1
Toxicity aquatic plants: (for herbicides only)	<i>Lemna gibba</i>	Bromoxynil	14 d, S	EC50	0.033
		Bromoxynil heptanoate	14 d, S	EC50	0.21
		Bromoxynil octanoate	14 d, S	EC50	> 0.073

¹ WP preparation containing 30.7 % w/w bromoxynil octanoate

² SC preparation containing 150 g/l bromoxynil equivalent (118 g/l bromoxynil octanoate + 113 g/l bromoxynil heptanoate) + 333 g/l terbuthylazine

³ EC preparation containing 294.2 g/l bromoxynil octanoate (200 g/l equivalent.) + 281.7 g/l ioxynil octanoate (200 g/l equivalent.)

Honeybees

Acute oral toxicity:

Bromoxynil :	5 microg/bee
Bromoxynil heptanoate:	no data, not required, refer to bromoxynil octanoate
Bromoxynil octanoate:	> 119.8 microg/bee
CGD 97040 H ² :	> 100 microg/bee ¹

Acute contact toxicity:

Bromoxynil :	150 microg/bee
Bromoxynil heptanoate:	no data, not required, refer to bromoxynil octanoate
Bromoxynil octanoate:	> 100 microg/bee

² SC preparation containing 150 g/l bromoxynil equivalent (118 g/l bromoxynil octanoate + 113 g/l bromoxynil heptanoate) + 333 g/l terbuthylazine

Other arthropod species

<i>Test species</i>	Stage	Test substance	Dose (kg as/ha)	Endpoint	Effect
Laboratory tests					
<i>Aphidius rhopalosiphi</i>	adult	EMBLEM ¹	0.45	survival parasitism	82.1% -23.6%
<i>Trichogramma cacaoecia</i>	female	BUCTRIL EC ⁴	0.4	parasitism	78.1%
<i>Typhlodromus pyri</i>	nymph	EMBLEM ¹	0.45	survival	100%
			0.018 (4% drift rate)	survival reproduction	84.5% 100%
			0.0045 (1% drift rate)	survival reproduction	14.3% 38%
<i>Aleochara bilineata</i>	adult	BUCTRIL EC ⁴	0.45	parasitism development	< 0% 18%
		EMBLEM ¹	0.45	reproduction	-20.1%
		CDG 97040 H ²	0.3	survival feeding reproduction	0% 4% 60.6%
<i>Poecilus cupreus</i>	adult	BUCTRIL EC ⁴	0.45	survival feeding	0% 7%
		CDG 97040 H ²	0.3	survival feeding	0% < 0%
		EMBLEM ¹	0.45	survival feeding	0% 13.3%
<i>Pardosa sp.</i>	adult	EMBLEM ¹	0.45	survival feeding	0% 5%
Extended laboratory tests					
<i>Aphidius rhopalosiphi</i> <i>Typhlodromus pyri</i>	female	EMBLEM ¹	0.45	survival parasitism	0% 26.4%
	nymph	EMBLEM ¹	0.45	survival	100%
EXP31112C ⁵			0.018	survival reproduction	78.82% 13%
			Dose response test	mortality reproduction	LR50: 32.2 g/ha No effect at 31.8 g/ha

¹ WP preparation containing 30.7 % w/w bromoxynil octanoate² SC preparation containing 150 g/l bromoxynil equivalent (118 g/l bromoxynil octanoate + 113 g/l bromoxynil heptanoate) + 333 g/l terbutylazine; dose in bromoxynil equivalent⁴ EC preparation containing 33.4% bromoxynil octanoate⁵ WP preparation containing bromoxynil octanoate at 189 g equivalent /kg bromoxynil octanoate, results in bromoxynil equivalent

Earthworms

Acute toxicity:

Bromoxynil :	LD50 = 45 mg/kg soil
Bromoxynil heptanoate:	LD50 = 29 mg/kg soil
Bromoxynil octanoate:	LD50 = 96.7 mg/kg soil
EMBLEM ¹ :	LD50 = 331 mg/kg soil
CGD 97040 H ² :	LD50 = 625 mg/kg soil
OXYTRIL CM ³ :	LD50 = 663 mg/kg soil
no data, not required	

Reproductive toxicity:

¹ WP preparation containing 30.7 % w/w bromoxynil octanoate

² SC preparation containing 150 g/l bromoxynil t (118 g/l bromoxynil octanoate + 113 g/l bromoxynil heptanoate) + 333 g/l terbuthylazine

³ EC preparation containing 294.2 g/l bromoxynil octanoate (200 g/l bromoxynil equivalent) + 281.7 g/l ioxynil octanoate (200 g/l bromoxynil equivalent.)

Soil micro-organisms

Nitrogen mineralization:

Bromoxynil : Unclear data, however low and transient effect
CGD 97040 H ² : < ±25% (2.6 and 13.35 mg preparation/kg soil)
OXYTRIL CM ³ : < ±25% (2.3 and 11.52 mg preparation/kg soil)

Carbon mineralization:

Bromoxynil : Unclear data, however low and transient effect
CGD 97040 H ² : < ±25% (2.6 and 13.35 mg preparation/kg soil)
OXYTRIL CM ³ : < ±25% (2.3 and 11.52 mg preparation/kg soil)

² SC preparation containing 150 g/l bromoxynil equivalent (118 g/l bromoxynil octanoate + 113 g/l bromoxynil heptanoate) + 333 g/l terbuthylazine; test concentrations were 0.31 and 1.58 mg bromoxynil octanoate /kg soil and 0.3 and 1.51 mg bromoxynil heptanoate /kg soil, or 0.39 and 2 mg bromoxynil equivalent / kg soil.

³ EC preparation containing 294.2 g/l bromoxynil octanoate (200 g/l phenol equ.) + 281.7 g/l ioxynil octanoate (200 g/l bromoxynil equivalent), test concentrations were 0.68 and 3.39 mg bromoxynil octanoate /kg soil, or 0.46 and 2.3 mg bromoxynil equivalent / kg soil.

APPENDIX III A**BROMOXYNIL**

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, 1.11/01	Gomez, F.,	1995	Bromoxynil technical grade active ingredient Analysis and certification of product ingredients Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-23 Doc n°438854 GLP – Yes Published - No	
IIA, 1.11/02	Emeric G.T	2001	Composition statement of bromoxynil octanoate Code: AE F065321 Aventis CropScience GmbH, DEU Produktanalytik, Frankfurt, 2 pages Generated by: Aventis, France Submitted by: Aventis, France Report n°: C014931 GLP – Yes Published - No	
IIA, 1.11/03	Feucht G., Emeric G	2002	Bromoxynil heptanoate - Evaluation of validity of 5-batch analyses study (addendum) Code: AE 0503060 Generated by: Aventis CropScience GmbH, DEU - Product Analysis, Frankfurt, 5 pages Report n°: C022907 GLP – Yes Published - No	

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, 2.1.1.1/01	Argent, A.J. Buddle, G.C.	1990	Bromoxynil technical: Measurement of melting point Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: D.Ag. 1494 Doc n°423532 Date: August 1990 GLP – Yes Published - No	
IIA, 2.1.1.1/02	Patel, P.T. Buddle, G.C.	1991	Hydroxybenzonnitriles: Bromoxynil octanoate physical properties: Product Chemistry Series 63-2 to 63-7 Generated by: Rhône-Poulenc Agriculture, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: D.Ag. 1627 Doc n°425530 Date: March 1991 GLP – Yes Published - No	
IIA, 2.1.1.1/03	Certon A., Kochian C., Cousin J.	1995	Bromoxynil Active substance - Appearance and melting point Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Study 95-40, part A ; DOC n°438345 GLP – Yes Published - No	
IIA, 2.1.1.1/04	Duverney-Prêt P., Bascou J.Ph	1999	Bromoxynil octanoate - Physical characteristics Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Study 99-04, part A ; DOC n°445441 GLP – Yes Published - No	

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, 2.1.1.1/05	Duverney-Prêt P., Bascou J.Ph	1999	Bromoxynil heptanoate - Physical characteristics Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Study 99-03, part A ; DOC n°445440 GLP – Yes Published - No	
IIA, 2.1.1.2			See point 2.1.1.1/03/04/05	
IIA, 2.1.2/01	Buddle, G.C. Patel, P.T.	1991	Bromoxynil phenol technical - Density, pH, octanol/water partition coefficient and storage stability Generated by: Rhône-Poulenc Agriculture, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: P-90-165, D.Ag. 1665 Doc n°426369 Date: July 1991 GLP – Yes Published - No	
IIA, 2.1.2			See also points 2.1.1.1/04 /05	
IIA, 2.1.3.1/01	Cicotti, M.	1991	Determination of vapour pressure of bromoxynil in accordance with EPA 63-9 and OECD 104/EEC A.4 Guidelines Generated by: Battelle Europe, Switzerland Submitted by: Rhône-Poulenc Agrochimie Report n°: BE-P-1-91-A.4-01-BG Doc n°436438 Date: June 1991 GLP – Yes Published - No	

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, 2.1.3.1/02	Campbell, C.	1993	Bromoxynil octanoate: Analytical method validation and physico-chemical testing with bromoxynil octanoate Generated by: IRI, Scotland Submitted by: Rhône-Poulenc Agrochimie Report n°: 9466 Doc n°433183 and 435032 Date: 15 June 1993 GLP – Yes Published - No	
IIA, 2.1.3.1/03	François B.	2001	Bromoxynil vapour pressure. Batetelle study No P-01-00-21 January 11, 2001 Generated by : Battelle Submitted by : Aventis Crop Science GLP – No Published - No	
IIA, 2.1.3.1/04	Emeric, G.T.	2001	Bromoxynil heptanoate – active ingredient vapour pressure determination – Discussion on the influence of the purity of the test sample – OE 01/010 – January 18, 2001 Generated by : Aventis CropScience Submitted by : Aventis Crop Science GLP – No Published - No	
IIA, 2.1.3.1/05	Emeric, G.T.	2001	Bromoxynil octanoate – active ingredient vapour pressure determination – Discussion on the influence of the purity of the test sample – OE 01/009 – January 18, 2001 Generated by : Aventis CropScience Submitted by : Aventis Crop Science GLP – No Published - No	

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, 2.1.3.2/01	Cicotti, M.	1994	Determination of the Henry's Law Constant of bromoxynil Generated by: Battelle Europe, Switzerland Submitted by: Rhône-Poulenc Agrochimie Report n°: BE-P-1-91-HC-01-BG Doc n°435905 Date: 25 February 1994 GLP – Yes Published - No	
IIA, 2.1.3.2/02	Gomez, F.	1993	Bromoxynil heptanoate and bromoxynil octanoate, Henry's Law Constants Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 9315701 Doc n°431907 Date: 29 March 1993 GLP – Yes Published - No	
IIA, 2.1.3..2/03	Bascou J.P.	2001	Bromoxynil : Henry's law constant Doc 448625 February 01,2001 Generated by : Aventis CropScience Submitted by : Aventis Crop Science GLP – No Published - No	
IIA, 2.1.4.1			See point 2.1.1.1/02/0304/05	
IIA, 2.1.5.1/01	Just, D., Vidal, J., Guesnet, J.L.	1998	Bromoxynil NMR, IR and MS Spectra Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-158 Doc n°444238 Date: August 11, 1998 GLP – Yes Published - No	

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, 2.1.5.1/02	Jendzejczak, N Turier, G.P. Adrian, P.P.	1992	Bromoxynil - UV-Visible Spectrum Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 9116869 Doc n°427455 Date: 30 January 1992 GLP – Yes Published - No	
IIA, 2.1.5.1/03	Just, D., Vidal, J., Guesnet, J.L.	1998	Bromoxynil Octanoate NMR, IR and MS Spectra Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-159 Doc n°444239 Date: August 11, 1998 GLP – Yes Published - No	
IIA, 2.1.5.1/04	Ott, M. Guesnet, J-L.J.	1992	Bromoxynil heptanoate - NMR, IR and MS spectra Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 9218252 Doc n°430725 Date: 14 December 1992 GLP – Yes Published - No	
IIA, 2.1.5.1/05	Meastracci, M.P. Jendzejczak, N.	1993	Bromoxynil heptanoate: UV-Visible characteristics Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 9218358 Doc n°430763 Date: 5 January 1993 GLP – Yes Published - No	

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, 2.1.5.1/06	Adrian, P.P. Jendzejczak, N. Turier, G.P.	1992	Bromoxynil octanoate - UV-Visible spectrum Generated by: Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 9116881 Doc n°427459 Date: 30 January 1992 GLP – Yes Published - No	
IIA, 2.1.5.1/07			See also point 2.1.5.1/03	
IIA, 2.1.6/01	Cicotti, M.	1991	Determination of water solubility of bromoxynil in accordance with EPA 63-8 and OECD 105/EEC A.6 guidelines Generated by: Battelle Europe, Switzerland Submitted by: Rhône-Poulenc Agrochimie Report n°: BE-P-1-91-A.6-01-BG Doc n°436437 Date: December 1991 GLP – Yes Published - No	
IIA, 2.1.6./02	Campbell, C. MacLean, K.	1993	Bromoxynil heptanoate: Analytical method validation and physico-chemical testing with bromoxynil heptanoate Generated by: IRI, Scotland Submitted by: Rhône-Poulenc Agrochimie Report n°: 9467 Doc n°433184 and 435031 Date: 15 June 1993 GLP – Yes Published - No	
IIA, 2.1.7			See point 2.1.6./02	
IIA, 2.1.8			See also points 2.1.2/01 and 2.1.6/02	

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, 2.1.9.1/01	Piznik, M. Ziegelbein, J. Wargo, J.P.	1985	Hydrolysis of 14C Bromoxynil at pH 5, 7, 9 for 31 days at 25±1°C Generated by: Rhône-Poulenc Ag, USA Submitted by: Rhône-Poulenc Agrochimie Report n°: ASD 85/143 Date: 20 June 1985 GLP – Yes Published - No	
IIA, 2.1.9.1/02	Piznik, M. Ziegelbein, J. Wargo, J.P.	1986	Hydrolysis of 14C Bromoxynil heptanoate at pH 5, 7, 9 for 31 days at 25±1°C Generated by: Rhône-Poulenc Ag, USA Submitted by: Rhône-Poulenc Agrochimie Report n°: ASD 86/183 Doc n°433033 Date: 24 April 1986 GLP – Yes Published - No	
IIA, 2.1.9.1/03	Das, Y.T.	1990	Hydrolysis of (Phenyl(U)-14C) Bromoxynil Octanoate Solutions Buffered at pH 5, 7 and 9 Generated by: Innovative Scientific Services, Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 90040 Doc n°428900 and 41078 Date: 26 December 1990 GLP – Yes Published - No	
IIA, 2.1.9.1			See also point 2.1.6/02 and 7.2.1/01	
IIA, 2.1.9.2/01	Offizorz, P.	1992	Determination of the direct phototransformation of bromoxynil octanoate in water Generated by: RCC Umweltchemie, Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: 257207 Doc n°428417 Date: 24 February 1992 GLP – Yes Published - No	

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, 2.1.9.2/02	Offizorz, P.	1993	Determination of the direct phototransformation of bromoxynil octanoate in water. 1st Amendment to report. Generated by: RCC Umweltchemie, Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: 257207 Doc n°432563 Date: 7 June 1993 GLP – Yes Published - No	
IIA, 2.1.9./03	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 Doc n°431263 Date: 3 February 1993 GLP – Yes Published - No	
IIA, 2.1.9.3			See point 2.1.9.2//01/02/03/04	
IIA, 2.1.9.4/01	South, P.L. Schweitzer, M.G.	1993	Dissociation constants of bromoxynil in water Generated by: Battelle, USA Submitted by: Rhône-Poulenc Agrochimie Report n°: SC910121 Doc n°41057 Date: 7 June 1993 GLP – Yes Published - No	
IIA, 2.1.9.4/02	Duverney-Prêt P., Bascou J.Ph	1999	Bromoxynil octanoate - pH and dissociation Constant. Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Study 99-04, part B ; DOC n°445459 GLP – Yes Published - No	

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, 2.1.9.4/03	Duverney-Prêt P., Bascou J.Ph	1999	Bromoxynil heptanoate - pH and dissociation Constant. Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Study 99-03, part B ; DOC n°445458 GLP – Yes Published - No	
IIA, 2.1.9.5			See points 2.1.9.4/02/03	
IIA, 2.1.10	South, P.L	1993	Stability of Bromoxynil Octanoate Generated by : Battelle, USA Submitted by : Rhône-Poulenc Agrochimie Report n° : SC920212 Date : 17 March 1993 GLP – Yes Published - No	
IIA, 2.1.10			See also point 2.1.2/01 and 7.2.2/08	
IIA, 2.1.11.1/0 3	Bascou, J.Ph. François, J.M.	1998	Explosion properties, Oxidizing properties, flammability and ability for self heating of technical Bromoxynil. Generated by: Rhône-Poulence Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-188 Doc n°444664 Date: November 9, 1998 GLP – Yes Published - No	
IIA, 2.1.11.1/0 4	Bascou, J.Ph. François, J.M.	1998	Technical Bromoxynil heptanoate - Explosion properties, flammability, ability for self heating and oxidizing properties. Generated by: Rhône-Poulence Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-190 Doc n°444717 Date: November 30, 1998 GLP – Yes Published - No	

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, 2.1.11.1/0 5	Bascou, J.Ph. François, J.M.	1998	Technical Bromoxynil octanoate - Explosion properties, flammability, ability for self heating and oxidizing properties. Generated by: Rhône-Poulence Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-189 Doc n°444688 Date: November 18, 1998 GLP – Yes Published - No	
IIA, 2.1.11.2			See point 2.1.11/03/04/05	
IIA, 2.1.12			See point 2.1.11/01/02	
IIA, 2.1.13			See point 2.1.11/03/04/05	
IIA, 2.1.14/01	Kochian C., Cousin J.	1995	Bromoxynil Active substance - Surface tension Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Study 95-40, part B ; DOC n°438263 GLP – Yes Published - No	
IIA, 2.1.14			See also points 2.1.1.1/04/05	
IIA, 2.1.15/01	South, P.J.	1992	Oxidation:reduction properties of bromoxynil octanoate Generated by: Rhône-Poulenc Agrochimie Submitted by: Rhône-Poulenc Agrochimie Report n°: 41376 Doc n°41376 Date: 19 January 1992 GLP – Yes Published - No	
IIA, 2.1.15			See also points 2.1.11.1/03/04/05	
IIA, 4.1.1/01	unknown	2001	Active substance Bromoxynil octanoate: MOA and Validation Position document of January 20, 2001 GLP – No Published - No	

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, 4.1.1/02	Buddle G.C., Mills, E.A., Patel M.T. and Warren T.F.	1989.	Hydroxybenzonnitriles : bromoxynil heptanoate - analytical examination of Batches Generated by: Rhône-Poulenc -UK. Submitted by: Rhône-Poulenc Agrochimie Report n°: D.Ag.1290 Date: 3july 1989.	
IIA, 4.1.1/03	Communal, P Duchene, P	1994	Method for evaluating bromoxynil residues in sweet corn (seeds). Report No.: CFP/BRO/94011 Date: 16 February 1994 Generated by: CFPI Submitted by: CFPI Report no : CFP/BRO/94011	
IIA, 4.1.1/04	Doust R.H.	1982	Analytical method for the determination of bromoxynil octanoate and ioxynil octanoate in the formulation OXYTRIL CM. Generated by: Rhône-Poulenc - Agriculture Submitted by: Rhône-Poulenc Agrochimie Report n°: Ag. Tech. 148 Date: January 1982	
IIA, 4.1.1./05	Robles J.M.	1995	Bromoxynil, technical grade active ingredient, HPLC determination of active ingredient content Analytical method B-804-04-95 Study 95-23 May 17th, 1995 Generated by : Rhône Poulenc Agrochimie Submitted by : Aventis CropScience GLP – Yes Published - No	
IIA, 4.1.1/06	Fonte, M.	1999	Determination of Bromoxynil Octanoate in CA1216. Validation of theAOAC 980.05 method Date: 25 february Generated by: CFPI Submitted by: CFPI Reference No.: OT 09/C/2680 GLP – No Published - No	

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, 4.1.1/07	Gomez F	1995	Bromoxynil technical grade active ingredient analysis and certification of product ingredients Generated by: Rhône-Poulenc - Agrochimie Submitted by: Rhône-Poulenc Agrochimie Report n°: R&D/CRLD/AN/9516314. Date: 28 november 1995 GLP – Yes Published - No	
IIA, 4.1.1./08	Robles J.M.	1995	Bromoxynil, technical grade active ingredient, HPLC determination of organic impurities Analytical method B-812-06-95 Study 95-23 September 13th, 1995 Generated by : Rhône Poulenc Agrochimie Submitted by : Aventis CropScience GLP – Yes Published - No	
IIA, 4.1.1./09	Bowen T.	2000	Analytical method Bromoxynil (AE F025943). Determination of organic impurities in technical grade and pure active ingredient by HPLC Report C010204 December 14th, 2000 Generated by : Aventis CropScience Submitted by : Aventis CropScience GLP – Yes Published - No	
IIA, 4.1.1./10	Bowen T.	2000	Validation of the Analytical method AL038/00-00 for the determination organic impurities in bromoxynil Report C010203 December 14th, 2000 Generated by : Aventis CropScience Submitted by : Aventis CropScience GLP – Yes Published - No	

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, 4.1.1./11	Clarisse B	2001	Technical bromoxynil octanoate - analysis and certified limits of the different components - report 09/V/3058 -, 2001 Generated by CFPI Nufarm Submitted by Aventis CropScience GLP – Yes Published - No	
IIA, 4.1.1./111	Gabay P	2002	Determination of Bromoxynil octanoate contents in formulation by GC - Reference method : C-organique-00498 - TA – february 21, 2002 Generated by : Nufarm S.A. Submitted by : Aventis Crop Science GLP – Yes Published - No	
IIA, 4.1.1./112	Clarisse B.	2002	Emblem WP Nufarm method : C-Organique-00498-TA and CIPAC method : 87.3 oct/TC/(M)- (GLC method 1) Discrepancies and justification March 2002 Generated by : CFPI Nufarm Submitted by : CFPI Nufarm GLP – No Published - No	
IIA, 4.1.1./1.1 3	Anonymous	1986	Bromoxynil Technical, free phenolic form (analytical method) generated by 1.Agan Chemical Manufacturers Ltd submitted by 2.Agan Chemical Manufacturers Ltd 3.BRX-ATF/2 4.September 1986	
IIA, 4.1.1./1.1 4	Weiss	1995	Bromoxynil phenol : determination of the active ingredient and main impurities in 5 impurities in 5 production batches generated by 1.Agan Chemical Manufacturers Ltd submitted by 2.Agan Chemical Manufacturers Ltd 3.AGM 30/950412 4.April 1995	

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, 4.1.1/15	Weiss	1996	Bromoxynil octanoate : determination of the active ingredient and main impurities in 5 impurities in 5 production batches generated by 1.Agan Chemical Manufacturers Ltd submitted by 2.Agan Chemical Manufacturers Ltd 3.AGM 33/950677 4.February 1996	
IIA, 4.1.1/16	Patel P.T. and Prebble K.A	1987.	Analytical method for the determination of bromoxynil heptanoate, bromoxynil octanoate and terbuthylazine in the formulation GARBODUC. Generated by: Rhône-Poulenc -UK. Submitted by: Rhône-Poulenc Agrochimie Report n°: D.Ag.427. Date: May 1987.	
IIA, 4.1.1/17	Schmit, C	1995	Determination of Bromoxynil Octanoate contents in formulations or in a Technical Bromoxynil Octanoate. Report No.: C-ORGANIQUE-00363-E-TA Date: 29 March 1995 Generated by: CFPI Submitted by: CFPI Reference No.: 5.1/01	
IIA, 4.1.1/18	Uceda L., Yslan F.	1996	Bromoxynil octanoate, ioxynil octanoate : detzermiation by GLC analysis in formulation EXP 03334C (EC) Generated by: Rhône-Poulenc - Agrochimie Submitted by: Rhône-Poulenc Agrochimie Study 9616619, DOC n° 441014 Date: 1996	
IIA, 4.1.1/19	Guzikevich G.	1997	Bromotril 225 EC Validation of the analytical method Date : november 1997 Generated by . Agan Chemical Manufacturers Ltd Submitted by .Agan Chemical Manufacturers Ltd Report No : project no 94-07 AV	

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, 4.2.1/01	Le Brun G.	1999	Development and validation of a method of analysis for the determination of Bromoxynil (phenol, heptanoate, octanoate) in cereals and cotton seeds - RPA/BROM/99001 (RPA study 99-69, method AR 201-99) - 29/10/1999 Generated by : GIRPA Submitted by : Aventis CropScience GLP Yes Published - No	
IIA, 4.2.3/01	Fuchsbichler G.	2000	ILV - Treated plants, plant products Independent laboratory validation of method of analysis AR 201-99 for the determination of Bromoxynil (phenol, heptanoate, octanoate) in cereals and cotton seed - Aventis CropScience study 00-02 (HVA 3/00) - 14 March 2000 generated by : Bayerische Hauptversuchsanstalt für Landwirtschaft submitted by : Aventis Crop Science GLP Yes Published - No	
IIA, 4.3.1/03	Le Brun G.	1999	Development and validation of a method of analysis for the determination of Bromoxynil (phenol, heptanoate, octanoate) in soils -RPA/ BROM/99002 (RPA study 99-71, method AR 203-99) - 23/09/1999 Generated by : GIRPA Submitted by : Aventis CropScience GLP – Yes Published - No	
IIA, 4.3.2/01	Gerault F., Le Brun G.	1999	Development and validation of a method of analysis for the determination of Bromoxynil, in water. Generated by : GIRPA Submitted by : Rhône-Poulenc Agro Report n° : 99-73 (Method AR 205-99) Doc n°446418 Date : September 29, 1999 GLP – Yes Published - No	

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, 4.3.2/02	Le Brun G.	1999	Development and validation of a method of analysis for the determination of Bromoxynil (phenol, heptanoate, octanoate) in waters -RPA/ BROM/99003 (RPA study 99-73, method AR 205-99) - 27/09/1999 Generated by : GIRPA Submitted by : Aventis CropScience GLP – No Published - No	
IIA, 4.3.3/01	Reichert, N.	1993.	Development of a method for the determination of bromoxynil, bromoxynil heptanoate and bromoxynil octanoate in air. Generated by: RCC Umweltchemie GmbH & Co. Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: RCC pPROJECT 411300. Doc n°435664 and 435325 and 435326 Date: 22 December 1993. GLP – Yes Published - No	
IIA, 4.4/01	Goller G.	2000	Development and validation of an analytical method for the determination of Bromoxynil (phenol, heptanoate, octanoate) and loxynil (phenol and octanoate) in blood – Study ACS 00-61 (Method AR 247-00) - 26/06/2000 generated by : ADME bioanalyses submitted by : Aventis Crop Science GLP – Yes Published - No	
IIA, 4.4.1/02	Bourgade, C., Faure, C., Guillet, M., Simonin, B.	1997	Bromoxynil : 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 131-96 Doc n°441340 Date : February 20, 1997 GLP – Yes Published - No	

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, 4.4.1/03	Yslan, F.	1999	Bromoxynil : 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 131-96 Doc n°441340 Date : February 8, 1999 GLP – Yes Published - No	
IIA, 4.4.1/04	Le Brun G.	1999	Development and validation of a method of analysis for the determination of Bromoxynil (phenol, heptanoate, octanoate) in foodstuffs of animal origin - AMENDED REPORT -Study 99-75 (Method AR 207-99) -13/12/1999 GLP – Yes Published - No	
IIA, 4.4.1/05	Class Th.	2000	ILV for animal origin Independant laboratory validation of Aventis CropScience analytical method AR 207-99 for the determination of Bromoxynil in foodstuffs of animal origin - Aventis CropScience study 00-04 (PTRL Europe study n° P 379 G, Report n° B 379G) - 03/03/2000 Generated by : PTRL europe Submitted by : Aventis Crop Science GLP – Yes Published - No	
IIA, 4.5.1.1/01	Adam C	2001	Determination of Bromoxynil octanoate impurity contents in technical by HPLC – Updated version of method C-organique-00483- Generated by CFPI Submitted by Aventis CropScience C-TA – January 23, 2001 GLP – Yes Published - No	
IIA, 4.5.1.1/02	Adam C	2001	Active substance Bromoxynil octanoate: MOA and Validation Position document of January 20, 2001 Generated by CFPI Submitted by Aventis CropScience GLP – No Published - No	

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, 4.5.1.1/03	Adam C	2001	Bromoxynil octanoate: Determination of active ingredient contents in technical by GC – Updated version of method C-organique-00484- Generated by CFPI Submitted by Aventis CropScience C-TA – January 12, 2001 GLP – Yes Published - No	
IIA, 4.5.1.1/04	Adam C	2001	Determination of Bromoxynil octanoate impurity contents in technical by GC – Updated version of method C-organique-00485- Generated by CFPI Submitted by Aventis CropScience C-TA – January 12, 2001 GLP – Yes Published - No	

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
IIA, 5.2.1/01	Denton S.M	2001	AE 0652991: Acute oral toxicity study in the rat Generated by : Covance Laboratories Ltd., Harrogate, GBR Submitted by Aventis CropScience S.A., FRA, 26 pages Report n°: C021612 Date: 2001 GLP Yes Published - No	
IIA, 5.2.2/01	Kuhn, O.J.	1989	Bromoxynil heptanoate technical: Acute dermal toxicity study in rabbits. Generated by: Stillmeadow, Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 6342-89 Doc n°435005 Date: 9 August 1989 GLP Yes Published - No	
IIA, 5.2.2/02	Manciaux, X.	1999.	BROMOXYNIL OCTANOATE Acute dermal toxicity study in rats Generated by : CIT - Centre International de Toxicologie, France. Submitted by : Rhône-Poulenc Agro Report 18528 TAR Date : July 30 th , 1999. GLP Yes Published - No	
IIA, 5.2.3/01	Holbert, S.M.	1991	Bromoxynil octanoate tech. Acute inhalation toxicity study in rats. Generated by: Stillmeadow, Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 8239-91 Doc n°431541 Date: 22 November 1991 GLP Yes Published - No	

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, 5.2.6/01	Manciaux, X.	1999	BROMOXYNIL OCTANOATE Skin sensitization test in Guinea-pigs Generated by : CIT - Centre International de Toxicologie, France. Submitted by : Rhône-Poulenc Agro Report 18531 TSG Date July 30 th , 1999 GLP Yes Published - No	
IIA, 5.2.6/02	Manciaux, X.	2002	Bromoxynil Phenol Skin sensitization test in guinea pigs Report : 22268TSG CIT, Evreux Centre Internationale de Toxicologie GLP Yes Published - No	
IIA, 5.3.1/01	Hendwood, S.M.	1992	3-Week dermal toxicity study with bromoxynil phenol in rabbits. Generated by: Hazleton Wis., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 6224-169 Date: 31 March 1992 GLP Yes Published - No	
IIA, 5.3.1/02	Hendwood, S.M.	1992	3- Week dermal toxicity study with bromoxynil octanoate in rabbits. Generated by: Hazleton Wis., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 6224-168 Date: 4 June 1992 GLP Yes Published - No	
IIA, 5.3.1/03	Bigot, D.	2000	Bromoxynil phenol 28-day toxicity study in CD-1 mice following dietary administration. Generated by : Aventis Submitted by : Aventis Report SA 98638 Date: December 18, 2000 GLP Yes Published - No	

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, 5.3.2/01	Hendwood, S.M.	1992	13-Week dietary toxicity study with bromoxynil octanoate in rats. Generated by: Hazleton Wis., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 6224-170 Doc n°445240 Date: 25 June 1992 GLP Yes Published - No	
IIA, 5.3.2/02	Williams, K.D.	1992	Subchronic toxicity study with bromoxynil phenol in mice. Generated by: Hazleton Wis., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 6224-167 Doc n°430290 Date: 12 October 1992 GLP Yes Published - No	
IIA, 5.3.2/03	Makin, A. Davies R E	1993	Bromoxynil octanoate. Toxicity to dogs by repeated oral administration for 13 weeks. Generated by: HRC, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: RNP 416/930670 Doc n°432876 Date: 27 May 1993 GLP Yes Published - No	
IIA, 5.4.1/01	Lawlor, T.E., Mecchi, M.S.	1991	Mutagenicity test on bromoxynil phenol in the Salmonella/mammalian-microsome reverse mutation assay (Ames test). Generated by: Hazleton Wash., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 12550-0-401 Doc n°426239 Date: 22 May 1991 GLP Yes Published - No	

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, 5.4.1/02	Dillon, D.M.	1993	Bromoxynil octanoate, batch n° HN 81536 testing for mutagenic activity with <i>Salmonella typhimurium</i> . TA1535, TA1537, TA1538, TA98 and TA100. Generated by: IRI, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: 9904 Doc n°436062 Date: 28 October 1993 GLP Yes Published - No	
IIA, 5.4.1/03	Mohammed, R., Downey, E., Craig, W.B.	1991	Bromoxynil octanoate technical: Assessment of genotoxicity in an unscheduled DNA synthesis assay using adult rat hepatocyte primary cultures. Generated by: IRI, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: 751110 Doc n°426695 Date: 5 July 1991 GLP Yes Published - No	
IIA, 5.4.1/04	Beevers C	2001	AE 0652991: Reverse mutation in five histidine-requiring strains of <i>Salmonella typhimurium</i> Generated by: Covance Laboratories Ltd., Harrogate, UK Submitted by Aventis CropScience S.A., FRA Report n°: C021608 Date: 2001 GLP Yes Published - No	
IIA, 5.4.2/01	Holmstrom, M., Innes, D., Craig, W.B.	1991	Bromoxynil phenol: Micronucleus test in bone marrow of CD-1 mice. Generated by: IRI, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: 751084 Doc n°426819 Date: 29 October 1991 GLP Yes Published - No	

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, 5.4.2/02	Holmstrom, M., Innes, D.	1991	Bromoxynil octanoate: Micronucleus test in bone marrow of CD-1 mice. Generated by: IRI, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: 751105 Doc n°425650 Date: 30 April 1991 GLP Yes Published - No	
IIA, 5.4.2/03	Golzio, L.	2001	Bromoxynil Unscheduled DNA Synthesis in rat liver cells In Vivo. RBM Laboratories. Submitted by : Aventis Report No. 990841 Date: March 16, 2001 GLP Yes Published - No	
IIA, 5.5.2/01	Williams, K.D.	1994	Oncogenicity study with bromoxynil phenol in mice. Generated by: Hazleton Wisc.Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 6224-174 Doc n°4411179 and 445225 Date: 9 May 1994 GLP Yes Published - No	
IIA, 5.5.2/02	Banas, D.	1994	Oncogenicity study with bromoxynil phenol in mice. Review of liver sections from male mice. Pathology report. Unpublished report of Experimental Pathology Laboratories, Inc.. Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Study N° 259-009 Date: 1994	

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, 5.6.1/01	Higgins, C.	1989	Bromoxynil: Effects upon reproductive performance of rats treated continuously throughout two successive generations. Generated by: LSR, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: 89/MBL091/0343 Doc n°418589 and 418590 and 418591 Date: 20 June 1989 GLP Yes Published - No	
IIA, 5.6.1/02	Hoberman, A.M.	1990	Male reproductive effects of bromoxynil octanoate after dermal administration. Generated by: Argus Res. Lab., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 218-010 Doc n°425595 Date: 19 October 1990 GLP Yes Published - No	
IIA, 5.6.2/03	Hoberman, A.M.	1988	Developmental toxicity (embryo-fetal toxicity and teratogenic potential) study of bromoxynil phenol administered percutaneously to CrI:CD (SD) BR presumed pregnant rats. Generated by: Argus Res. Lab., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 310-003 Doc n°438869 Date: 20 September 1988 GLP Yes Published - No	
IIA, 5.6.2/04	Hoberman, A.M.	1989	Developmental toxicity (embryo-fetal toxicity and teratogenic potential) study of bromoxynil octanoate administered percutaneously to CrI:CD (SD) BR presumed pregnant rats. Generated by: Argus Res. Lab., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 218-005 Doc n°424206 Date: 3 July 1989 GLP Yes Published - No	

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, 5.6.2/05	Hoberman, A.M.	1988	Developmental toxicity (embryo-fetal toxicity and teratogenic potential) study of bromoxynil phenol administered percutaneously to New Zealand White rabbits. Generated by: Argus Res. Lab., USA Submitted by: Rhône- Doc n°416572 and 424203Poulenc Agrochimie Report n°: 310-001 Date: 13 December 1988 GLP Yes Published - No	
IIA, 5.6.2/06	Hoberman, A.M.	1990	Developmental toxicity (embryo-fetal toxicity and teratogenic potential) study of bromoxynil octanoate administered percutaneously to New Zealand White rabbits. Generated by: Argus Res. Lab., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 218-006 Doc n°423157 and 424207 Date: 27 April 1990 GLP Yes Published - No	
IIA, 5.8.1/01	Dange, M.	1998	3,5-Dibromo-4-Hydroxybenzoic acid (DBHA) : 90-day toxicity study in the rat by gavage. Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: SA 97330 Doc n°603073 Date: June 17, 1998 GLP Yes Published - No	

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, 6.1.1/01	Wootton, M. Johnson, T.	1992	Metabolic Fate and Distribution of ¹⁴ C-Bromoxynil Octanoate in Sweet Corn Generated by: PTRL East Inc., USA, Rhône-Poulenc Agrochimie, France Submitted by: Rhône-Poulenc Agrochimie Report n°: PTRL 1410 (+ supplement) Doc n°437683 Date: 31 July 1992 GLP Yes Published - No	
IIA, 6.1.2/01	K.L. Huhtanen and B.K. Smith.	1985	Brominal: Distribution of Residues and Metabolism of ¹⁴ C-Bromoxynil Octanoate in Foliar Treated Alfalfa. Generated by: Union Carbide Agricultural Products Co. Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 33771. Doc n°431412 and 33771 Date: 28 June 1985 GLP No Published - No	
IIA, 6.1.2/02	Yenne, S.P. Macy, L.J.	1993	Metabolic Fate and Distribution of ¹⁴ C-Bromoxynil Octanoate on Cotton and Genetically Modified Cotton Generated by: Rhône-Poulenc Ag.CO., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 41370 Doc n°431310 and 41370 Date: 8 February 1993 GLP Yes Published - No	

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, 6/01	Koktavy, K.,	1994	Storage stability of Bromoxynil on frozen raw agricultural commodity substrates spiked with Bromoxynil Octanoate. Generated by: McKenzie Laboratories, Inc. US Submitted by: Rhône-Poulenc Agrochimie Report n°: EC-91-179 Doc n°044295 Date: January 21, 1994 GLP Yes Published - No	
IIA, 6/02	Yang, J.	1997	Storage stability of Bromoxynil Phenol Residues and its metabolite, 3,5-dibromo-4-hydroxybenzoic acid residues in cottonseed, gin trash and seed processed fractions. Generated by: Rhône-Poulenc Agriculture, US Submitted by: Rhône-Poulenc Agrochimie Report n°: EC-96-344 Date: june 26, 1997 GLP Yes Published - No	
IIA, 6.3.1/01	M.-A. Muller	1996	DFF-Bromoxynil-Mecoprop-P; Formulation EXP 31315A (EC); essai France 1995; Résidus dans le blé tendre d'hiver; étude de décroissance Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-520 Date: May 07, 1996 GLP Yes Published - No	

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, 6.3.1/02	M.-A. Muller	1996	DFF-Bromoxynil-loxynil; Formulation EXP 30035A(SC); essai France 1995; Residues in soft winter wheat (grain & straw) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-515 Date: January 31, 1996 GLP Yes Published - No	
IIA, 6.3.1/02	M.-A. Muller	1996	DFF-Bromoxynil; Formulation EXP 30088B(EC); trial Greece 1995; Residues in durum winter wheat (grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-697 Date: January 15, 1996 GLP Yes Published - No	
IIA, 6.3.1/03	M.-A. Muller	1995	DFF-Bromoxynil; Formulation EXP 30088B(EC); trial Greece 1994; Residues in soft winter wheat (grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 94-682 Date: June 22, 1995 GLP Yes Published - No	
IIA, 6.3.1/04	M.-A. Muller	1994	DFF-Bromoxynil; Formulation EXP 30088B(EC); trial Greece 1993; Residues in winter wheat (grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 93-738 Date: November 30, 1994 GLP Yes Published - No	

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, 6.3.1/05	M.-A. Muller	1994	DFF-Bromoxynil-Diclofop-methyl; Formulation EXP 04344A(EC); trial Greece 1993; Residues in winter wheat (grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 93-700 Date: October 19, 1994 GLP Yes Published - No	
IIA, 6.3.1/06	M. Maestracci	1997	Bromoxynil; Formulation EXP 31438A(EC); trial France 1996; Residues in durum winter wheat (plant, grain, straw). Decline study Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 96-693 Date: November 21, 1997 GLP Yes Published - No	
IIA, 6.3.1/07	M. Maestracci	1996	Bromoxynil; Formulation EXP 31438A(EC); trial France 1996; Residues in soft winter wheat. Decline study Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 96-591 Date: December 30, 1996 GLP Yes Published - No	
IIA, 6.3.2/01	M.-A. Muller	1996	DFF-Bromoxynil-Mecoprop-P; Formulation EXP 31315A (EC); essai France 1995; Résidus dans l'orge d'hiver; étude de décroissance Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-522 Date: May 13, 1996 GLP Yes Published - No	

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, 6.3.2/02	M.-A. Muller	1996	DFF-Bromoxynil-Mecoprop-P; Formulation EXP 31315A (EC); essai France 1995; Résidus dans l'orge d'hiver (grain & paille) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-521 Date: May 06, 1996 GLP Yes Published - No	
IIA, 6.3.2/03	M.-A. Muller	1996	DFF-Bromoxynil-loxynil; Formulation EXP 30035A(SC); essai France 1995; Residues in winter barley (grain & straw) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-516 Date: January 23, 1996 GLP Yes Published - No	
IIA, 6.3.3/01	M.-A. Muller	1996	Bromoxynil-Aclonifen; Formulation EXP 31206A(SC); trial France 1995; Résidus dans le maize(ensilage et grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 95-534 Date: July 02, 1996 GLP Yes Published - No	
IIA, 6.3.3/02	M. Maestracci	1998	Bromoxynil as Bromoxynil octanoate and RPA084966 (metabolite); Formulation EXP 31122A(WP); trial Italy 1997; Residues in maize(silage & grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: 97-668 Date: August 04, 1998 GLP Yes Published - No	

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	England, D.A. and Savage, E.A.	1986.	Bromoxynil: Identification of Soil Metabolites Generated by: May & Baker Ltd.,UK Submitted by: Rhône-Poulenc Agrochimie Report n°: D.Ag. 37 Doc n°409449 Date: 5 August 1986. GLP No Published - No	
IIA, 7.1.1/02	Williams C.M.	1984	Bromoxynil: Metabolism in Sandy Loam and Loam Soils under Aerobic Conditions. Generated by: May & Baker Ltd.,UK Submitted by: Rhône-Poulenc Agrochimie Report n°: Ag. Tech 421. Doc n°406657 Date: 27 January 1984. GLP Yes Published - No	
IIA, 7.1.1/03	B.D. Cameron, B.E. Hall and J.A. Mackie	1991	[¹⁴ C]-Bromoxynil octanoate: Metabolism in Soil under Aerobic Conditions Generated by: Inveresk Research International., UK Submitted by: Rhône-Poulenc Agrochimie Report n°: IRI 142021 Doc n°431386 and 431406 Date: 8 April 1991. GLP Yes Published - No	
IIA, 7.1.1/04	Hardy, I.A.J., Priestly, D.B., Savage, E.A.	1990	Bromoxynil Octanoate: Spectroscopic Investigation of Metabolites from a [¹⁴ C]-Bromoxynil Octanoate Aerobic Soil Metabolism Study. Generated by: Rhône-Poulenc Agriculture UK Submitted by: Rhône-Poulenc Agrochimie Report n°: D. Ag. 1565. Doc n°424408 Date: 14 December 1990. GLP Yes Published - No	

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, 7.1.1/05	Greenslade D., J. Ward, R. Hopkins	1983.	A Study of the Aerobic Metabolism of [¹⁴ C] Ring-Labelled 3,5-Dibromo-4-hydroxybenzamide in Two Soils. Generated by: Hazleton Laboratories, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: 3155-18/4 Doc n°415441 Date: 11 January 1983. GLP No Published - No	
IIA, 7.1.1/06	Williams C.M., Savage, E.A.	1984.	Bromoxynil: Metabolism in Soil under Anaerobic Conditions. Generated by: May & Baker Ltd., UK Submitted by: Rhône-Poulenc Agrochimie Report n°: Ag. Tech. 494. Doc n°406734 Date: 24 April 1984. GLP Yes Published - No	
IIA, 7.1.1/07	B.D. Cameron, B.E. Hall, M. Phillips.	1990	[¹⁴ C]-Bromoxynil Octanoate: Soil Photolysis. Generated by: Inveresk Research International, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: IRI 7473 Doc n°424410 and 431384 Date: 3 October 1990. GLP Yes Published - No	
IIA, 7.1.1/08	Das Y.T.	1991	Photodegradation of [¹⁴ C]-Bromoxynil Octanoate on soil under artificial sunlight. Generated by: Innovative Scientific Services Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: ISSI 91011 Doc n°437817 Date: 19th May 1991 GLP No Published - No	

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, 7.1.1/09	Savage, E.A.	1983	Bromoxynil: Rate of Degradation in Four Soils under Aerobic Conditions Generated by: May & Baker Ltd., UK Submitted by: Rhône-Poulenc Agrochimie Report n°: Ag. Tech 307 Doc n°405440 and 406157 Date: 6 January 1983 GLP No Published - No	
IIA, 7.1.1/10	Savage, E.A.	1983	Bromoxynil: Rate of Degradation in Four Soils under Aerobic Conditions at 10°C. Generated by: May & Baker Ltd., UK Submitted by: Rhône-Poulenc Agrochimie Report n°: Ag. Tech 308 Doc n°405438 and 406166 Date: 6 January 1983 GLP No Published - No	
IIA, 7.1.1/11	Fisher, P.J., Koundakjian, P.P. and Savage E.A.	1986	Bromoxynil Octanoate: Rate of Degradation in Soil under Aerobic Conditions at 10°C and 22°C Generated by: May & Baker Ltd., UK Submitted by: Rhône-Poulenc Agrochimie Report n°: D.Ag 22 Doc n°409433 and 431029 Date: 21 July 1986. GLP Yes Published - No	
IIA, 7.1.1/12	Norris, F.A.	1989.	A Small Scale Field Soil Dissipation Study with Bromoxynil, the Active Ingredient of Buctril® Brand Herbicide. Generated by: Rhône-Poulenc Ag. Co., USA Submitted by Rhône-Poulenc Agrochimie Report n°: 40640: Doc n°40640 Date: 28 November 1989. GLP Yes Published - No	

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, 7.1.1/13	Ingram, G.H. and Pullin, E.M.	1974	Persistence of Bromoxynil in Three Soil Types Generated by: May & Baker Ltd., UK Submitted by: Rhône-Poulenc Agrochimie Report n°: Doc n°430932 Date: 5 March 1974. GLP No Published - No	
IIA, 7.1.1.2.1/ 01	Clarke, D.E.	1998	[¹⁴ C]-3,5-dibromo-4-hydroxybenzoic acid : rate of aerobic degradation in three soil types at 20°C. Generated by: Rhône-Poulenc Agro Ltd, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: 15099 Doc n°201802 Date: July 30, 1998 GLP Yes Published - No	
IIA, 7.1.1.2.1/ 02	Clarke, D.E.	1998	[¹⁴ C]-3,5-dibromo-4-hydroxybenzamide : rate of aerobic degradation in three soil types at 20°C. Generated by: Rhône-Poulenc Agro Ltd, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: 14896 Doc n°201788 Date: July 27, 1998 GLP Yes Published - No	
IIA, 7.1.2/01	C.M. Williams.	1982	Bromoxynil: Sorption Study with Four Soils. Generated by: May & Baker Ltd., UK Submitted by: Rhône-Poulenc Agrochimie Report n°: Ag. Tech. 157. Doc n°404014 and 410078 Date: 10 February 1982 GLP No Published - No	

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	Parkins, M.D. and Heintzelman, R.W.	1982	The Adsorption Coefficient of Bromoxynil Octanoate on Sandy Loam Soil. Generated by: Union Carbide Agricultural Products, USA Submitted by: Rhône-Poulenc Agrochimie Report n°: BRO/M28 Doc n°415434 and 29831 Date: 3 February 1982. GLP No Published - No	
IIA, 7.1.2/03	McMillan-Staff, S.L.	1998	[¹⁴ C]-3,5-dibromo-4-hydroxy-benzoic acid : absorption/desorption to and from four soils. Generated by: Rhône-Poulenc Agro Ltd, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: 14897 Doc n°201789 Date: July 29, 1998 GLP Yes Published - No	
IIA, 7.1.2/04	McMillan-Staff, S.L.	1998	[¹⁴ C]-3,5-dibromo-4-hydroxybenzamide : absorption/desorption to and from four soils. Generated by: Rhône-Poulenc Agro Ltd, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: 15100 Doc n°201799 Date: July 24, 1998 GLP Yes Published - No	
IIA, 7.1.2/05	Rosenwald J	2002	(14C)-Bromoxynil octanoate: Adsorption/desorption in soil Covance Laboratories GmbH, Münster, Germany, 53 pages Report n°: C022853 GLP Yes Published - No	

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, 7.1.2/06	Laabs V	2002	(14C)-Bromoxynil octanoate: Stability in Aqueous Soil Suspensions used for Adsorption/desorption Studies. Generated by: Covance Laboratories GmbH, Münster, Germany, Submitted by: Bayer CropScience Report n°: No 1905-074 C028009 Date: 2002. GLP Yes Published - No	
IIA, 7.1.2/07	Reinken G	2002	Estimation of the Bromoxynil Octanoate K_{oc} Soil Adsorption Coefficient using the PCKOCWIN Model Generated by: Bayer CropScience, Monheim Submitted by: Bayer CropScience Report n°: MR 524/02 C028576 Date: 2002. GLP Yes Published - No	
IIA, 7.1.3/01	C.M. Williams.	1983.	Bromoxynil: Leaching study with four soils. Generated by: May & Baker Ltd., UK Submitted by: Rhône-Poulenc Agrochimie Report n°: Ag. Tech. 334 Doc n°405533 Date: 17th February 1983. GLP No Published - No	
IIA, 7.1.3/02	Dr Wirotama	1983.	Bromoxynil formulated as Oxytril M. Generated by: Natec, Institut, Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: NA Date: 17 January 1983. GLP No Published - No	
IIA, 7.1.3/03	Prof. Dr. Habil. H. Maler-Bode.	1975	Bromoxynil - Oxytril M BBA Leaching Study. Generated by: Prof. Dr. Habil. H. Maler-Bode, Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: Doc n°437804 Date: 30 August 1975. GLP No Published - No	

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, 7.1.3/04	Parsons, A.H.	1981	Bromoxynil Potassium Salt: Leaching Study. Generated by: G.C. Laboratories Ltd., UK Submitted by: Rhône-Poulenc Agrochimie Report n°: J 3677. Doc n°445228 Date: 30 December 1981. GLP No Published - No	
IIA, 7.1.3/05	Grau, J.T. and Fitzmaurice M.J.	1992	[ring- ¹⁴ C]-Bromoxynil Octanoate: Leaching Study with Four Soils. Generated by: Rhône-Poulenc Agriculture Limited., UK Submitted by: Rhône-Poulenc Agrochimie Report n°: P91/046. Doc n°428392 Date: 31 March 1992. GLP Yes Published - No	
IIA, 7.1.3./06	Cooper, J.D.L., Jones, M.K., Lowden, P., McMillan-Staff, S.L	1995	herbicides : Bromoxynil Octanoate : aged leaching in four soils and a sediment. Generated by: Rhône-Poulenc Agro Ltd, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: P 95/089 Doc n°200996 Date: August 18, 1995 GLP Yes Published - No	
IIA, 7.2.1/01	Hart G.F.J.	1983	Bromoxynil and Ioxynil Hydrolysis Studies According to Merkblatt 55. Generated by: G.C. Laboratories Ltd., Submitted by: Rhône-Poulenc Agrochimie Report.n°: BRO/C45 J3766 Doc n°426809 Date: 25 May 1983 GLP No Published - No	

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	M. Piznik, J. Ziegelbein and J P Wargo	1986	The hydrolysis of [¹⁴ C] Bromoxynil Heptanoate at pH levels of 5, 7 and 9 for 30 days at 25°C ± 1°C. Generated by: Rhône-Poulenc Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 86/183 Doc n°433003 Date: April 1986. GLP Yes Published - No	
IIA, 7.2.1/03	Y.T. Das.	1990	Hydrolysis of [phenyl U- ¹⁴ C] Bromoxynil Octanoate in Aqueous solution buffered at pH 5, 7 and 9. Generated by: Innovative Scientific Services Inc. USA Submitted by: Rhône-Poulenc Agrochimie Report n°: ISSI 90040 Doc n°428900 and 41078 Date: 26 December 1990 GLP Yes Published - No	
IIA, 7.2.1/04	J. Kochany, G.G. Choudhry, G.R. Barrie Webster.	1990	Photochemistry of Halogenated Benzene Derivating Part IX Environmental Aquatic Phototransformation of Bromoxynil (3,5- Dibromo-4-hydroxybenzotrile). Generated by: Pesticide Research Laboratory, Canada Submitted by: Rhône-Poulenc Agrochimie Report n°: None Date: 1990 GLP No Published - Yes	
IIA, 7.2.1/05	Offizorz, P.	1993	Determination of the Direct Phototransformation of Bromoxynil Heptanoate in Water. Generated by: RCC Umweltchemie GmbH and Co., Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: RCC327306 Doc n°431263 Date: 3 February 1993. GLP Yes Published - No	

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	Maestracci, M.	1993	Calculation of Environmental Photolytic Half-Life of Bromoxynil Heptanoate in Water. Generated by: Rhône-Poulenc Secteur Agro. Submitted by: Rhône-Poulenc Agrochimie Report n°: 9315286 Doc n°431237 Date: 2 February 1993. GLP No Published - No	
IIA, 7.2.1/07	Huhtanen K.	1985	Photolytic Degradation of Bromoxynil Octanoate in Buffered Aqueous Solution. Generated by: Union Carbide Agricultural Products, USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 33471 Doc n°33471 Date: 30 January 1985. GLP No Published - No	
IIA, 7.2.1/08	Offizorz, P.	1992	Determination of the Direct Phototransformation of Bromoxynil Octanoate in Water, plus Amendment. Generated by: RCC Umweltchemie GmbH and Co., Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: 257207 Doc n°428417 and 432563 Date: 24 February 1992.: GLP Yes Published - No	
IIA, 7.2.1/09	Maestracci, M.	1993	Calculation of Environmental Photolytic Half-Life of Bromoxynil Octanoate. Generated by: Rhône-Poulenc Secteur Agro. Submitted by: Rhône-Poulenc Agrochimie Report n°: Rand D/CRLD/AN/9316246. Doc n°431237 Date: 16 June 1993. GLP No Published - No	

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, 7.2.1/10	Greenwood J., Lucock A.	2002	(14C)-Bromoxynil Phenol – Quantum Yield Determination. Generated by: Covance Laboratories Ltd., Harrogate, UK Submitted by: Bayer CropScience Report n°: No 1849-029 C022857 Date: 2002 GLP Yes Published - No	
IIA, 7.2.1/11	Greenwood J., Lucock A.	2002	(14C)-Bromoxynil Phenol: Photodegradation in Sterile Aqueous Solution Generated by: Covance Laboratories Ltd., Harrogate, UK Submitted by: Bayer CropScience Report n°: No 1849-022 C022858 Date: 2002 GLP Yes Published - No	
IIA, 7.2.1/12	Greenwood J., Iriam S.	2002	(14C)-Bromoxynil Phenol: Characterisation of Aqueous Photolysis Degradates Generated by: Covance Laboratories Ltd., Harrogate, UK Submitted by: Bayer CropScience Report n°: No 1905/075-D2149 C028827 Date: 2002 GLP Yes Published - No	
IIA, 7.2.1/13	Gurman, M. and Cranor, W.	1990	Aerobic Aquatic Metabolism of [¹⁴ C]- Bromoxynil Octanoate in Flooded Sandy Loam Soil. Generated by: ABC Analytical Bio- Chemistry Laboratories Ltd., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: ABC Study Number 38288 Doc n°428910 Date: 8 February 1990 GLP Yes Published - No	

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, 7.2.1/14	R. Jackson, B.E. Hall, B.D. Cameron	1991	[¹⁴ C]-Bromoxynil Octanoate: Anaerobic Aquatic Metabolism. Generated by: Inveresk Research International, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: IRI 7601 Doc n°435004 Date: 5 April 1991. GLP Yes Published - No	
IIA, 7.2.1/15	Marshall, I.R., Hardy, I.A.J. and Savage, E.A.	1991	Bromoxynil Octanoate: Investigation into the Structure of the Metabolites Detected during an Anaerobic Aquatic Soil Study. Generated by: Rhône-Poulenc Agriculture Ltd., Submitted by: Rhône-Poulenc Agrochimie Report n°: D.Ag. 1619 Doc n°425519 Date: 24 April 1991 GLP Yes Published - No	
IIA, 7.2.1.3/01	Mackie, J.A.	1999	The aerobic degradation of [¹⁴ C]-Bromoxynil Octanoate in natural sediment/water systems. Generated by: Inveresk Research - Scotland Submitted by: Rhône-Poulenc Agrochimie report n°: IRI 15575 Date: March 3, 1999 GLP Yes Published - No	
IIA, 7.2.1.3/02	Kreuk, J.F., Kruyssen, M.H.H.M.	1991	The determination of bio-degradability of Bromoxynil in a sediment/water system. Generated by: MTI, Netherland Submitted by: Rhône-Poulenc Agrochimie report n°: R 90.16a/4/8025.02/91-02934 Date: July 18, 1991 GLP Yes Published - No	

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, 7.2.2/01	Maestracci, M.P.	1995.	Bromoxynil. 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/9416904 Doc n°437404 Date: January 1995. GLP Yes Published - No	
IIA, 7.2.2/02	Maestracci, M.P.	1995	Bromoxynil heptanoate. 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/9416906 Doc n°437406 Date: 23 January 1995. GLP Yes Published - No	
IIA, 7.2.2/03	Maestracci, M.P.	1995	Bromoxynil octanoate. 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/9416905 Doc n°437405 Date: January 1995. GLP Yes Published - No	

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, 7.2.2/04	Jendzejczak, N., Turier G, Maestracci, M.	1993	Soil Surface Volatility Study of Bromoxynil Octanoate Formulated as Buctril Emulsion Concentrate (EC) Containing 225g l ⁻¹ Bromoxynil Octanoate (Acid Equivalent). Generated by: Rhône-Poulenc Secteur Agro Submitted by: Rhône-Poulenc Agrochimie Report n°: R&D/CRLD/AN/9315851 Doc n°432479. Date: 8 April 1993 GLP Yes Published - No	
IIA, 7.2.2/05	Jendzejczak, N., Turier G, Maestracci, M.	1993.	Soil Surface Volatility Study of Bromoxynil Octanoate and Bromoxynil Heptanoate Formulated as Gardobuc: Suspo-Emulsion (SE) Containing 150g l ⁻¹ Bromoxynil (Octanoate and Heptanoate). Generated by: Rhône-Poulenc Secteur Agro Submitted by: Rhône-Poulenc Agrochimie Report n°: R&D/CRLD/AN/9315441. Doc n°431298 Date: 17 February 1993. GLP No Published - No	
IIA, 7.2.2/06	Jager, J. and Kubiak, R.	1993	Volatilisation of [¹⁴ C]-Bromoxynil octanoate formulated according to Buctril (EC) with a Content of 225g l ⁻¹ Bromoxynil Octanoate from Plant Surfaces under Laboratory Conditions. Generated by: Abt. Phytomedizin in LLFA, Germany Submitted by: Rhône- Poulenc Agrochimie Report n°: RPA 06. Doc n°431951 Date: 25 March 1993 GLP Yes Published - No	

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, 7.2.2/07	Jager, J. and Kubiak, R.	1993	Investigation of the Volatilisation of [¹⁴ C]-Bromoxynil Octanoate and [¹⁴ C]-Bromoxynil Heptanoate Formulated According to Gardobuc (SE) from Plant Surfaces under Laboratory Conditions. Generated by: Abt. Phytomedizin in LLFA, Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: RPA07 Doc n°431826 Date: 17 February, 1993. GLP Yes Published - No	
IIA, 7.2.2/08	Völkel, W.	1999	Estimation of the degradation of Bromoxynil by atmosphere oxidation. Generated by: RCC - Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: 720393 Doc n°444902 Date: January 19, 1999 GLP Yes Published - No	
IIA, 7.3/01	Reinken G	2002	Kinetic evaluation of the dissipation of bromoxynil octanoate, bromoxynil phenol and subsequent metabolites in aerobic water/sediment test systems using the TopFit 2.0 model Code: AE F065321, AE F025943, AE 0503455, AE B063193, AE 0503456, AE B058071, AE submitted by : Aventis CropScience GmbH, DEU Environmental Chemistry, Frankfurt, 79 pages Report n° C:016343 GLP Yes Published - No	
IIA, 7.3/02	Klein, M.	1993	Simulation of the fate of Bromoxynil-Octanoate and Bromoxynil-Phenol in the soil by PELMO 1.5 Generated by Fraunhofer-Institut für Umweltchemie und Ökotoxikologie, Schmallenberg, Germany Submitted by Rhone-Poulenc Agrochimie 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, 7.3/03	Reinken G	2002	Predicted environmental concentrations in soil (PECsoil) for bromoxynil octanoate, bromoxynil phenol and the two metabolites 2,3-dibromo-benzamide and 2,3-dibromo-acid Code: AE F065321, AE F025943, AE 0503455, AE B063193 Aventis CropScience GmbH, DEU Environmental Chemistry, Frankfurt, 33 pages Report n° C016342 GLP Yes Published - No	
IIA, 7.4.3.2	Reinken G	2002	Kinetic evaluation of the dissipation of bromoxynil octanoate, bromoxynil phenol and subsequent metabolites in aerobic water/sediment test systems using the TopFit 2.0 model Code: AE F065321, AE F025943, AE 0503455, AE B063193, AE 0503456, AE B058071, AE Aventis CropScience GmbH, DEU Environmental Chemistry, Frankfurt, 79 pages Report n°: C016343 GLP Yes Published - No	
IIA, 7.6.1	Reinken G	2002	Predicted environmental concentrations in groundwater (PECgw) for bromoxynil octanoate, bromoxynil phenol and the two metabolites 2,3-dibromo-benzamide and 2,3-dibromo-benzoic acid using the European FOCUS groundwater scenarios Code: AE F065321, AE F025943 Aventis CropScience GmbH, DEU Environmental Chemistry, Frankfurt, 58 pages Report n° C016341 GLP Yes Published - No	

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, 7.6.3	Reinken G.	2002	<p>Predicted environmental concentrations in surface water and sediment (PEC_{sw}, PEC_{sed}) for bromoxynil ocatanoate, bromoxynil phenol and five subsequent metabolites Code: AE F065321, AE F025943, AE 0503455, AE B063193, AE 0503456, AE B058071, AE C473621</p> <p>Aventis CropScience GmbH, DEU Environmental Chemistry, Frankfurt, 49 pages</p> <p>Report n° C016344 GLP Yes Published - No</p>	
IIA, 7.7.2	Diehl M.	2002	<p>Investigation of the volatilisation of (14)-bromoxynil phenol from soil and plant leaf surfaces Aventis Nufarm SA, Lyon, FRA, 50 pages</p> <p>RCC Ltd., Itingen, CHE Environmental Chemistry & Pharamalytics</p> <p>Report n° C022860 GLP Yes Published - No</p>	
IIA, 7.2.1.	Leake G	2003	<p>Response from Bayer CropScience Nufarm on Bromoxynil Fate and Behaviour Addendum 1 – 11/2002 Generated by: Bayer CropScience, Lyon Submitted by: Bayer CropScience, Lyon Report n°: HBN/EFATE/03/001 Date: 7/1/03 GLP N/A Published – No</p>	

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	Fletcher, D.W.	1985	Acute oral toxicity study with Bromoxynil Phenol in Bobwhite Quail Generated by: Bio-Life Associates Ltd., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 85 QD 51 Doc n°417641 Date: 15 June 1985 GLP Yes Published - No	
IIA, 8.1.1/02	Campbell, S.M. Beavers, J.B.	1993	Bromoxynil Heptanoate: An acute oral toxicity study with the Northern Bobwhite Generated by: Wildlife Int. Ltd., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 171-134 Doc n°445229 Date: 5 November 1993 GLP Yes Published - No	
IIA, 8.1.1/03	Fletcher, D.W.	1981	Acute oral toxicity study with Bromoxynil Octanoate, technical in Bobwhite Quail Generated by: Bio-Life Associates Ltd., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 81 QD 6 Doc n°417603 Date: 17 November 1981 GLP Yes Published - No	
IIA, 8.1.1/04	Fletcher, D.W.	1981	Acute oral toxicity study with Bromoxynil Octanoate, technical in Mallard Duck Generated by: Bio-Life Associates Ltd., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 81 DD 4 Doc n°417602 Date: 17 November 1981 GLP Yes Published - No	

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, 8.1.2/01	Fletcher, D.W.	1985	8-Day Dietary LC50 Study with Bromoxynil Phenol in Bobwhite Quail Generated by: Bio-Life Associates Ltd., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 85 QC 50 Doc n°417642 Date: 15 June 1985 GLP Yes Published - No	
IIA, 8.1.2/02	Fletcher, D.W.	1985	8-Day Dietary LC50 Study with Bromoxynil Phenol in Mallard Ducklings Generated by: Bio-Life Associates Ltd., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 85 DC 51 Doc n°417643 Date: 15 June 1985 GLP Yes Published - No	
IIA, 8.1.2/03	Campbell, S.M. Beavers, J.B.	1993	Bromoxynil Heptanoate: A dietary LC50 study with Northern Bobwhite Generated by: Wildlife Int. Ltd., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 171-133 Doc n°445230 Date: 10 November 1993 GLP Yes Published - No	
IIA, 8.1.2/04	Fletcher, D.W.	1981	8-Day Dietary LC50 Study with Bromoxynil Octanoate in Bobwhite Quail Generated by: Bio-Life Associates Ltd., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 81 QC 9 Doc n°417605 Date: 29 October 1981 GLP Yes Published - No	

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, 8.1.2/05	Fletcher, D.W.	1981	8-Day Dietary LC50 Study with Bromoxynil Octanoate in Mallard Ducklings Generated by: Bio-Life Associates Ltd., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 81 DC Doc n°4176049 Date: 28 October 1981 GLP Yes Published - No	
IIA, 8.1.3/01	Beavers, J.B. Sipler, O. Smith, G.J. Lynn, S.P. Jaber, M	1991	Bromoxynil Octanoate: A one-generation reproduction study with the bobwhite (<i>Colinus virginianus</i>) Generated by: Wild-life Int. Ltd., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 171-123 Doc n°426485 Date: 21 August 1991 GLP Yes Published - No	
IIA, 8.1.3/02	Beavers, J.B. Sipler, O. Smith, G.J. Lynn, S.P. Jaber, M	1991	Bromoxynil Octanoate: A one-generation reproduction study with the mallard (<i>Anas platyrhynchos</i>) Generated by: Wild-life Int. Ltd., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 171-124 Doc n°426486 Date: 21 August 1991 GLP Yes Published - No	
IIA, 8.2.1/01	Memmert, U. Knoch, E.	1991	Acute toxicity of Bromoxynil Phenol to Bluegill Sunfish (<i>Lepomis macrochirus</i>) in a semi-static test Generated by: RCC Umweltchemie Rosdorf, Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: 250356 Doc n°427060 Date: 11 November 1991 GLP Yes Published - No	

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, 8.2.1/02	Bettencourt, M.J.	1993	Bromoxynil Heptanoate: Acute toxicity to bluegill sunfish (<i>Lepomis macrochirus</i>) under flow-through conditions Generated by: Springborn Lab. Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 93-10-5006 Doc n°445231 Date: 8 December 1993 GLP Yes Published - No	
IIA, 8.2.1/03	Croudace, C.P. Caunter, J.E. Grinell, A.J.	1992	Bromoxynil Octanoate: Acute toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) Generated by: ICI, Brixham, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: BL4607/B Doc n°431338 Date: 11 September 1992 GLP Yes Published - No	
IIA, 8.2.1/04	Sousa, J.V. LeBlanc, G.A.	1981	Acute toxicity of Bromoxynil Octanoate to bluegill (<i>Lepomis macrochirus</i>) Generated by: EG&G Bionomics, USA Submitted by: Rhône-Poulenc Agrochimie Report n°: BW-81-12-1063 Doc n°417606 Date: December 1981 GLP Yes Published - No	
IIA, 8.2.1/05	Dorgerloh M	2003	Bromoxynil Octanoate: Acute Toxicity To Fish (<i>Oncorhynchus Mykiss</i>) in a Water Sediment System Under Static Conditions Generated by: Bayer CropScience – Monheim Submitted by: : Bayer CropScience Nufarm Report n°: DOM 22079 C031955 Date: December 2003 GLP Yes Published - No	

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, 8.2.2/01	Memmert, U. Knoch, E.	1991	Toxicity of Bromoxynil Phenol to Rainbow Trout (<i>Oncorhynchus mykiss</i>) in a Prolonged Semi-Static Test (21 Days) Generated by: RCC Umweltchemie Rosdorf, Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: 250334 Doc n°427059 and 445630 Date: 11 November 1991 GLP Yes Published - No	
IIA, 8.2.2/02	Croudace, C.P. Caunter, J.E. Grinell, A.J.	1992	Bromoxynil Octanoate: The 28 day LC50 to rainbow trout (<i>Oncorhynchus mykiss</i>) Generated by: ICI, Brixham, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: BL4615/B Doc n°431337 Date: 17 December 1992 GLP Yes Published - No	
IIA, 8.2.2/03	Sousa, V.J.	1991	(Bromoxynil Octanoate): Toxicity to fathead minnow (<i>Pimephales promelas</i>) embryos and larvae Generated by: Springborn Lab., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 91-4-3719 Doc n°426346 Date: 21 June 1991 GLP Yes Published - No	

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, 8.2.3/01	Yenne, S.P. Macy, L.J. Andrawes, N.R.	1992	Uptake, Depuration and Bioconcentration of ¹⁴ C-Bromoxynil octanoate by Bluegill Sunfish (<i>Lepomis macrochirus</i>) Generated by: ABC Lab., USA, Rhône- Poulenc Ag. Company, USA Submitted by: Rhône-Poulenc Agrochimie Report n°: EC-91-144 Doc n°428977 and 41135 Date: 16 March 1992 GLP Yes Published - No	
IIA, 8.2.3/02	Parkins, M.D. Heinzelman, R.W.	1982	Uptake, Depuration and Bioconcentration of ¹⁴ C-Bromoxynil octanoate by Channel Catfish. Generated by: ABC Lab., USA, Rhône- Poulenc Ag. Company, USA Submitted by: Rhône-Poulenc Agrochimie Report n°: Doc n°30648 Date: 31 August 1982 GLP Not defined in report Published - No	
IIA, 8.2.4/01	Douglas, M.T. Pell, I.B. Almond, R.H.	1982	The acute toxicity of Bromoxynil to <i>daphnia magna</i> Generated by: HRC, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: M&B 149B/82326 Doc n°417649 Date: 13 August 1982 GLP Yes Published - No	
IIA, 8.2.4/02	Putt, A.E.	1993	Bromoxynil Heptanoate: Acute toxicity to Daphnids (<i>Daphnia magna</i>) under flow-through conditions Generated by: Springborn Lab., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 93-11-5050 Doc n°445232 Date: 7 December 1993 GLP Yes Published - No	

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, 8.2.4/03	Kent, S.J. Croudace, C.P. Penwell, A.J. Thompson, R.S.	1992	Bromoxynil Octanoate: Acute toxicity to <i>Daphnia magna</i> Generated by: ICI, Brixham, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: BL4636/B Doc n°431339 Date: 21 december 1992 GLP Yes Published - No	
IIA, 8.2.4/04	Ebeling. M. , Odin-Feurtet, M.	1998	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 98372 Doc n°603398 Date : October 20, 1998 GLP Yes Published - No	
IIA, 8.2.5/01	Memmert, U. Knoch, E.	1991	Influence of Bromoxynil Phenol on the Reproduction of <i>Daphnia magna</i> Generated by: RCC Umweltchemie, Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: 250312 Doc n°427057 Date: 6 November 1991 GLP Yes Published - No	
IIA, 8.2.5/02	Putt, A.E.	1991	(Bromoxynil Octanoate): Chronic toxicity to daphnids (<i>Daphnia magna</i>) under flow-through conditions Generated by: Springborn Lab., Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 91-4-3718 Doc n°426356 Date: 21 June 1991 GLP Yes Published - No	

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, 8.2.6/01	Douglas, M.T. Pell, I.B. Almond, R.H. Dawson, J.	1982	The Algistatic Effect of Bromoxynil Generated by: HRC, UK Submitted by: Rhône-Poulenc Agrochimie Report n°: M&B 149C/82483 Doc n°417647 Date: 6 August 1982 GLP Yes Published - No	
IIA, 8.2.6/02	Hoberg, J.R.	1993	Bromoxynil Heptanoate - Toxicity to the Frehwater Alga <i>Selenastrum capricornutum</i> Generated by: Springborn Lab. Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 93-11-5035 Doc n°445233 Date: 7 December 1993 GLP Yes Published - No	
IIA, 8.2.6/03	Hoberg, J.R.	1993	Bromoxynil Heptanoate - Toxicity to the Duckweed <i>Lemna gibba</i> Generated by: Springborn Lab. Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 93-11-5040 Doc n°445234 Date: 7 December 1993 GLP Yes Published - No	
IIA, 8.2.6/04	Oldersma, H. Hansveit, A.O.	1990	Effect of Bromoxynil Octanoate on the Growth of the Green Alga <i>Scenedesmus subspicatus</i> (OECD 201) Generated by: Springborn Lab. Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: R89/457 Date: 25 July 1990 GLP Yes Published - No	

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, 8.2.6/05	Giddings, J.M.	1990	Bromoxynil Octanoate Toxicity to the Freshwater Bluegreen Alga <i>Anabaena flos-aquae</i> Generated by: Springborn Lab. Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 90-8-3434 Doc n°424030 and 424363 Date: 16 August 1990 GLP Yes Published - No	
IIA, 8.2.6/06	Giddings, J.M.	1990	Bromoxynil Octanoate - Toxicity to the Freshwater Green Alga <i>Selenastrum capricornutum</i> Generated by: Springborn Lab. Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 90-8-3436 Doc n°424028 Date: 17 August 1990 GLP Yes Published - No	
IIA, 8.2.6/07	Giddings, J.M.	1990	Bromoxynil Octanoate - Toxicity to the Freshwater Diatom <i>Navicula pelliculosa</i> Generated by: Springborn Lab. Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 90-8-3431 Doc n°424029 and 424360 Date: 17 August 1990 GLP Yes Published - No	
IIA, 8.2.6/08	Giddings, J.M.	1990	Bromoxynil Octanoate - Toxicity to the Marine Diatom <i>Skeletonema costatum</i> Generated by: Springborn Lab. Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 90-8-3440 Doc n°424031 and 424361 Date: 17 August 1990 GLP Yes Published - No	

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, 8.2.6/09	Hoberg, J.R.	1998	Bromoxynil Octanoate - Toxicity to the Duckweed <i>Lemna gibba</i> Generated by: Springborn Lab. Inc., USA Submitted by: Rhône-Poulenc Agrochimie Report n°: 98-10-7506 Date: 1998 GLP Yes Published - No	
IIA, 8.2.6/10	Hoberg, J.R.	1998	Bromoxynil Phenol : toxicity to the freshwater diatom, <i>navicula pelliculosa</i> . Generated by : Springborn Laboratories AG Submitted by: Rhône-Poulenc Agrochimie Report n°: SLI 98-7-7389 Doc n°603434 Date: August 27, 1998 GLP Yes Published - No	
IIA, 8.2.7	Odin-Feurtet, M.	1998	Bromoxynil Octanoate : toxicity to the sediment dwelling chironomid larvae - 28 days - (<i>chironomus riparius</i>). Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Report n°: SA 97578 Doc n°603004 Date: May 20, 1998 GLP Yes Published - No	
IIA, 8.2.8/01	Hoberg, J.R.	1998	Bromoxynil Octanoate : toxicity to the duckweed (<i>Lemna gibba</i>). Generated by: Springborn Laboratories AG Submitted by: Rhône-Poulenc Agrochimie Report n°: SLI 98-10-7506 Date: October 23, 1998 GLP Yes Published - No	

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, 8.2.8/02	Hoberg, J.R.	1998	Bromoxynil Phenol : toxicity to the duckweed (<i>Lemna gibba</i>). Generated by: Springborn Laboratories, AG Submitted by: Rhône-Poulenc Agrochimie Report n°: SLI 98-7-7392 Doc n°603433 Date: September 2, 1998 GLP Yes Published - No	
IIA, 8.3.1/01	Hamon, N.M. Lacy, J.	1988	Bromoxynil - Toxicity determination of the toxicity of Bromoxynil to the adult honeybee <i>Apis mellifera</i> L. by direct contact and ingestion according to UK. approved protocols Generated by: May&Baker Ltd? UK Submitted by: Rhône-Poulenc Agrochimie Report n°: R.Ag. 416 Doc n°417756 Date: 7 December 1988 GLP No Published - No	
IIA, 8.3.1/02	Atkins, E.L., Greywood, E.A. Macdonald, R.L.	1975	Toxicity of Pesticides and other Agricultural Chemicals to Honey Bees. Laboratory Studies December 1975 GLP No Published - No	
IIA, 8.3.1./02	Schmitzer, S.	1998	Laboratory testing for toxicity (acute contact and oral LD ₅₀) of Bromoxynil Octanoate to honey bees (<i>apis mellifera</i> L.) (hymenoptera, apidae). Generated by: Ibacon GmbH Submitted by: Rhône-Poulenc Agrochimie Report n°: 4350036 Doc n°603438 Date: October 14, 1998 GLP Yes Published - No	

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, 8.3.2/01	Pietrzik, J.	1992	Assessment of the side effects of Buctril on the rove beetle <i>Aleochara bilineata</i> Gyll. using the laboratory test method of E. Naton Generated by: GAB Biotechnologie, Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: E-213/01-Ab Doc n°429232 Date: 20 July 1992 GLP Yes Published - No	
IIA, 8.3.2/02	Pietrzik, J.	1991	Assessment of the side effects of Buctril on the ground beetle <i>Poecilus cupreus</i> L. in the laboratory Generated by: GAB Biotechnologie, Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: E-213/01-Pc Doc n°427966 Date: 4 December 1991 GLP Yes Published - No	
IIA, 8.3.2/03	Kuhner, Ch.	1993	Side-effects of Buctril (RPA 3644 H) on <i>Trichogramma cacoeciae</i> Marschal (Hymenoptera, Trichogrammatidae) as a representative of the microhymenoptera in the laboratory (test on imagines) Generated by: GAB Biotechnologie, Germany Submitted by: Rhône-Poulenc Agrochimie Report n°: E-213/02.2-Tc Doc n°432764 Date: 19 April 1993 GLP Yes Published - No	

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, 8.3.2/04	Lürhs U.	1999	Effects of EXP 31122C on the predatory mites <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) - extended study Generated by: Ibacon GmbH Submitted by: Rhône-Poulenc Agrochimie Report n°: 6850062 Doc n°604369 Date: September 29, 1999 GLP Yes Published - No	
IIA, 8.3.2/05	Drexler A.	1999	Effects of CA1216 to the reproduction of the rove beetle <i>Aleochara bilineata</i> Gyll. (Coleoptera, Staphylinidae) in the laboratory Submitted by: CFPI IBACON Project 5651070 CFPI Report 540 GLP Yes Published - No	
IIA, 8.3.2/06	Gossmann A. Lührs U.	1999	Effects of CA 1216 on the Predatory Mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) in the laboratory. Submitted by: CFPI IBACON Project 5652063 GLP Yes Published - No	
IIA, 8.3.2/07	Gossmann A. Lührs U.	1998	Effects of CA 1216 on the Predatory Mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) – Extended laboratory study. Submitted by: CFPI IBACON Project 4410062 CFPI Report 504 GLP Yes Published - No	
IIA, 8.3.2/08	Klepka S.	1997	Effects of CA 1216 on the Parasitic Wasp <i>Aphidius rhopalosiphi</i> (Hymenoptera, Aphidiidae) in the laboratory. Submitted by: CFPI IBACON Project 1831003 CFPI Report 436 GLP Yes Published - No	

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, 8.3.2/09	Klepka S. Groer M.	1997	Effects of CA1216 to the carabid beetle <i>Poecilus cupreus</i> L. (Coleoptera, Carabidae) in the laboratory Submitted by: CFPI IBACON Project 1832006 CFPI Report 420 GLP Yes Published - No	
IIA, 8.3.2/10	Schmitzer S.	1997	Effects of CA 1216 on the Predatory Mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) in the laboratory. Submitted by: CFPI IBACON Project 1838063 CFPI Report 422 GLP Yes Published - No	
IIA, 8.3.2/11	Schmitzer S.	1997	Effects of CA1216 to the wolf spider <i>Pardosa spec.</i> (Araneae, Lycosidae) in the laboratory Submitted by: CFPI IBACON Project 1837065 CFPI Report 421 GLP Yes Published - No	
IIA, 8.3.3/01	Hamon, N. Lacy, J.	1985	Toxicity of the herbicide Bromoxynil to the earthworm (<i>Eisenia foetida</i>) Generated by: May&Baker Ltd. UK Submitted by: Rhône-Poulenc Agrochimie Report n°: RAG 204 Doc n°408673 and 417650 Date: October 1985 GLP No Published - No	
IIA, 8.4.1/01	Kühner C.	1993	Acute toxicity of Buctril (RPA 36440H) to earthworms <i>Eisenia foetida</i> using an artificial soil test Generated by: GAB Biotechnologie GmbH, Submitted by: Rhône-Poulenc Agrochimie Report N° GAB 213-Ef GLP Yes Published - No	

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, 8.4.1/02	Wetton PM	1999	Bromoxynil phenol: Acute toxicity to earthworms (<i>Eisenia foetida</i>) Generated by : Safepharm Laboratories, Derby, UK Submitted by: Rhône-Poulenc Agrochimie Report no. 282-568 Doc n°604108 Date : June 1999 GLP Yes Published - No	
IIA, 8.4.1/03	Wetton PM	1999	Bromoxynil heptanoate: Acute toxicity to earthworms (<i>Eisenia foetida</i>). Generated by : Safepharm Laboratories, Derby, UK Submitted by: Rhône-Poulenc Agrochimie Report no. no. 282-569 Doc n°604109 Date : June 1999 GLP Yes Published - No	
IIA, 8.3.4/01	Luscombe, B.M.	1983	Bromoxynil. Effects on soil respiration & nitrification Generated by: May&Baker Ltd. UK Submitted by: Rhône-Poulenc Agrochimie Report n°: R. AG 68 Doc n°405544 and 417654 Date: February 1983 GLP No Published - No	
IIA, 8.7	Hertl, J.	1998	Toxicity of Bromoxynil Octanoate to activated sludge in a respiration inhibition test. Generated by: Ibacon, GmbH Submitted by: Rhône-Poulenc Agrochimie Report n°: 4500170 Doc n°603440 Date: October 22, 1998 GLP Yes Published - No	

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
III A, 10.1 and 10.3	Ebeling, M.	2002	Refined long term risk assessment for birds and mammals Bromoxynil Code: AE F025943, AE F065321 Generated by Aventis CropScience GmbH, DEU Ecotoxicology, Frankfurt, Submitted by Aventis Nufarm Report n°: C022401 Date: 21/5/02 GLP N/A Published No	
III A, 10.2	Ebeling, M.	2003	Hypothetical Worst Case Risk Assessment for Aqueous Photometabolites of Bromoxynil Bayer CropScience, Frankfurt Generated by: Bayer CropScience, Frankfurt Submitted by: Bayer CropScience Nufarm Report n°: OE 03 / 008 Date: 31/1/03 GLP N/A Published - No	
III A, 10.3	Semino, G.	2002	Bromoxynil NOAEL proposal for long term risk assessment on wild mammals Code: AE F025943, AE F065321 Generated by Aventis CropScience S.A., FRA Regulatory Toxicology Submitted by: Aventis Nufarm Report n°: C022712 Date: 16/5/02 GLP N/A Published No	
III A, 10.1 and 10.3	Ebeling, M.	2003	Bromoxynil: Refined Long Term Risk Assessment in Birds and Mammals Confirmed by New Residue Data in Cereals. Generated by: Bayer CropScience, Frankfurt Submitted by: Bayer CropScience Nufarm Report n°: C029584 Date: 24/3/03 GLP N/A Published - No	

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
III A, 10.1 and 10.3	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 Generated by: Bayer CropScience, Frankfurt Submitted by: Bayer CropScience Nufarm Report n°: 02R266-C028055 Date: 5/122002 GLP Yes Published No	

APPENDIX IIIB**BROMOXYNIL**

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, 2.1.1	Contos, D.A. South, P.L.		Product chemistry of bromoxynil mixed ester manufacturing use product Generated by: Battelle, USA Submitted by: Rhône-Poulenc Agrochimie Report n°: SC910191 Doc n°428374 Date: August 1990 GLP – Yes Published - No
IIA, 2.1.10/	South, P.L.	1993	Stability of Bromoxynil Octanoate Generated by: Battelle, USA Submitted by: Rhône-Poulenc Agrochimie Report n°: SC920212 Doc n°431646 Date: 17 March 1993 GLP – Yes Published - No
IIA, 2.1.3..1	Françon B.	2001	Bromoxynil vapour pressure. Batettelle study No P-01-00-21 January 11, 2001 Generated by : Battelle Submitted by : Aventis Crop Science GLP – No Published - No
IIA, 2.1.3..1	Emeric, G.T.	2001	Bromoxynil heptanoate – active ingredient vapour pressure determination – Discussion on the influence of the purity of the test sample – OE 01/010 – January 18, 2001 Submitted by : Aventis Crop Science GLP – No Published - No

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, 2.1.3..1	Emeric, G.T.	2001	Bromoxynil octanoate – active ingredient vapour pressure determination – Discussion on the influence of the purity of the test sample – OE 01/009 – January 18, 2001 Submitted by : Aventis Crop Science GLP – No Published - No
IIA, 2.1.3..2	Bascou J.P.	2001	Bromoxynil : Henry's law constant Doc 448625 February 01,2001 Submitted by : Aventis Crop Science GLP – No Published - No
IIA, 2.1.9.4	Duverney-Prêt P., Bascou J.Ph	1999	Bromoxynil heptanoate - pH and dissociation Constant. Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agrochimie Study 99-03, part B ; DOC n°445458 GLP – Yes Published - No
IIA, 4.2.1	Le Brun G.	1999	Development and validation of a method of analysis for the determination of Bromoxynil (phenol, heptanoate, octanoate) in cereals and cotton seeds - RPA/BROM/99001 (RPA study 99-69, method AR 201-99) - 29/10/1999 Generated by : GIRPA Submitted by : Aventis CropScience GLP Yes Published - No
IIA, 4.2.3	Fuchsbichler G.	2000	ILV - Treated plants, plant products Independent laboratory validation of method of analysis AR 201-99 for the determination of Bromoxynil (phenol, heptanoate, octanoate) in cereals and cotton seed - Aventis CropScience study 00-02 (HVA 3/00) - 14 March 2000 generated by : Bayerische Hauptversuchsanstalt für Landwirtschaft submitted by : Aventis Crop Science GLP Yes Published - No
IIA, 4.3.2	Gerault F., Le Brun G.	1999	Development and validation of a method of analysis for the determination of Bromoxynil, (phenol, heptanoate, octanoate) in soils. Generated by : GIRPA Submitted by : Rhône-Poulenc Agro Report n° : 99-71 (Method AR 203-99) Doc n°446413 Date : September 24, 1999 GLP – Yes Published - No

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, 4.3.1	Le Brun G.	1999	Development and validation of a method of analysis for the determination of Bromoxynil (phenol, heptanoate, octanoate) in soils -RPA/ BROM/99002 (RPA study 99-71, method AR 203-99) - 23/09/1999 Generated by : GIRPA Submitted by : Aventis CropScience GLP – Yes Published - No
IIA, 4.3.2	Gerault F., Le Brun G.	1999	Development and validation of a method of analysis for the determination of Bromoxynil, in water. Generated by : GIRPA Submitted by : Rhône-Poulenc Agro Report n° : 99-73 (Method AR 205-99) Doc n°446418 Date : September 29, 1999 GLP – Yes Published - No
IIA, 4.3.2	Le Brun G.	1999	Development and validation of a method of analysis for the determination of Bromoxynil (phenol, heptanoate, octanoate) in waters -RPA/ BROM/99003 (RPA study 99-73, method AR 205-99) - 27/09/1999 Generated by : GIRPA Submitted by : Aventis CropScience GLP – No Published - No
IIA, 4.4	Goller G.	2000	Development and validation of an analytical method for the determination of Bromoxynil (phenol, heptanoate, octanoate) and loxynil (phenol and octanoate) in blood – Study ACS 00-61 (Method AR 247-00) - 26/06/2000 generated by : ADME bioanalyses submitted by : Aventis Crop Science GLP – Yes Published - No
IIA, 4.4.1	Le Brun G.	1999	Development and validation of a method of analysis for the determination of Bromoxynil (phenol, heptanoate, octanoate) in foodstuffs of animal origin - AMENDED REPORT -Study 99-75 (Method AR 207-99) -13/12/1999 GLP – Yes Published - No

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, 4.4.1	Class Th.	2000	ILV for animal origin Independent laboratory validation of Aventis CropScience analytical method AR 207-99 for the determination of Bromoxynil in foodstuffs of animal origin - Aventis CropScience study 00-04 (PTRL Europe study n° P 379 G, Report n° B 379G) - 03/03/2000 Generated by : PTRL europe Submitted by : Aventis Crop Science GLP – Yes Published - No

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	Denton S.M	2001	AE 0652991: Acute oral toxicity study in the rat Generated by : Covance Laboratories Ltd., Harrogate, GBR Submitted by Aventis CropScience S.A., FRA, 26 pages Report n°: C021612 Date: 2001 GLP Yes Published - No
IIA, 5.3.1	Bigot, D.	2000	Bromoxynil phenol 28-day toxicity study in CD-1 mice following dietary administration. Generated by : Aventis Submitted by : Aventis Report SA 98638 Date: December 18, 2000 GLP Yes Published - No
IIA, 5.4.1	Beevers C	2001	AE 0652991: Reverse mutation in five histidine-requiring strains of Salmonella typhimurium Generated by: Covance Laboratories Ltd., Harrogate, UK Submitted by Aventis CropScience S.A., FRA Report n°: C021608 Date: 2001 GLP Yes Published - No

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, 5.4.2	Golzio, L.	2001	Bromoxynil Unscheduled DNA Synthesis in rat liver cells In Vivo. RBM Laboratories. Submitted by : Aventis Report No. 990841 Date: March 16, 2001 GLP Yes Published - No

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
--	------------------	-------------	--

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, 7.1.2/	Rosenwald J	2002	(14C)-Bromoxynil octanoate: Adsorption/desorption in soil Covance Laboratories GmbH, Münster, Germany, 53 pages Report n°: C022853 GLP Yes Published - No
IIA, 7.1.2	Laabs V	2002	(14C)-Bromoxynil octanoate: Stability in Aqueous Soil Suspensions used for Adsorption/desorption Studies. Generated by: Covance Laboratories GmbH, Münster, Germany, Submitted by: Bayer CropScience Report n°: No 1905-074 C028009 Date: 2002. GLP Yes Published - No
IIA, 7.1.2	Reinken G	2002	Estimation of the Bromoxynil Octanoate K_{oc} Soil Adsorption Coefficient using the PCKOCWIN Model Generated by: Bayer CropScience, Monheim Submitted by: Bayer CropScience Report n°: MR 524/02 C028576 Date: 2002. GLP Yes Published - No

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	Greenwood J., Lucock A.	2002	(14C)-Bromoxynil Phenol – Quantum Yield Determination. Generated by: Covance Laboratories Ltd., Harrogate, UK Submitted by: Bayer CropScience Report n°: No 1849-029 C022857 Date: 2002 GLP Yes Published - No
IIA, 7.2.1	Greenwood J., Lucock A.	2002	(14C)-Bromoxynil Phenol: Photodegradation in Sterile Aqueous Solution Generated by: Covance Laboratories Ltd., Harrogate, UK Submitted by: Bayer CropScience Report n°: No 1849-022 C022858 Date: 2002 GLP Yes Published - No
IIA, 7.2.1	Greenwood J., Iriam S.	2002	(14C)-Bromoxynil Phenol: Characterisation of Aqueous Photolysis Degradates Generated by: Covance Laboratories Ltd., Harrogate, UK Submitted by: Bayer CropScience Report n°: No 1905/075-D2149 C028827 Date: 2002 GLP Yes Published - No
IIA, 7.3	Reinken G	2002	Kinetic evaluation of the dissipation of bromoxynil octanoate, bromoxynil phenol and subsequent metabolites in aerobic water/sediment test systems using the TopFit 2.0 model Code: AE F065321, AE F025943, AE 0503455, AE B063193, AE 0503456, AE B058071, AE Aventis CropScience GmbH, DEU Environmental Chemistry, Frankfurt, 79 pages Submitted by: Bayer CropScience Report n° C:016343 GLP Yes Published - No

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, 7.3	Reinken G	2002	Predicted environmental concentrations in soil (PECsoil) for bromoxynil octanoate, bromoxynil phenol and the two metabolites 2,3-dibromo-benzamide and 2,3-dibromo-acid Code: AE F065321, AE F025943, AE 0503455, AE B063193 Aventis CropScience GmbH, DEU Environmental Chemistry, Frankfurt, 33 pages Submitted by: Bayer CropScience Report n° C016342 GLP Yes Published - No
IIA 7.4.3.2	Reinken G	2002	Kinetic evaluation of the dissipation of bromoxynil octanoate, bromoxynil phenol and subsequent metabolites in aerobic water/sediment test systems using the TopFit 2.0 model Code: AE F065321, AE F025943, AE 0503455, AE B063193, AE 0503456, AE B058071, AE Aventis CropScience GmbH, DEU Environmental Chemistry, Frankfurt, 79 pages Submitted by: Bayer CropScience Report n°: C016343 GLP Yes Published - No
IIA 7.6.1	Reinken G	2002	Predicted environmental concentrations in groundwater (PECgw) for bromoxynil octanoate, bromoxynil phenol and the two metabolites 2,3-dibromo-benzamide and 2,3-dibromo-benzoic acid using the European FOCUS groundwater scenarios Code: AE F065321, AE F025943 Aventis CropScience GmbH, DEU Environmental Chemistry, Frankfurt, 58 pages Submitted by: Bayer CropScience Report n° C016341 GLP Yes Published - No
IIA 7.6.3	Reinken G.	2002	Predicted environmental concentrations in surface water and sediment (PECsw, PECsed) for bromoxynil octanoate, bromoxynil phenol and five subsequent metabolites Code: AE F065321, AE F025943, AE 0503455, AE B063193, AE 0503456, AE B058071, AE C473621 Aventis CropScience GmbH, DEU Environmental Chemistry, Frankfurt, 49 pages Submitted by: Bayer CropScience Report n° C016344 GLP Yes Published - No

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 7.7.2	Diehl M.	2002	Investigation of the volatilisation of (14)-bromoxynil phenol from soil and plant leaf surfaces Aventis Nufarm SA, Lyon, FRA, 50 pages RCC Ltd., Itingen, CHE Environmental Chemistry & Pharamanalytics Submitted by: Bayer CropScience Report n° C022860 GLP Yes Published - No
XXX	Leake C	2003	Response from Bayer CropScience Nufarm on Bromoxynil Fate and Behaviour Addendum 1 – 11/2002 Generated by: Bayer CropScience, Lyon Submitted by: Bayer CropScience, Lyon Report n°: HBN/EFATE/03/001 Date: 7/1/03 GLP N/A Published – No

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, 8.2.1	Dorgerloh M	2003	Bromoxynil Octanoate: Acute Toxicity To Fish (<i>Oncorhynchus Mykiss</i>) in a Water Sediment System Under Static Conditions Generated by: Bayer CropScience – Monheim Submitted by: : Bayer CropScience Nufarm Report n°: DOM 22079 C031955 Date: December 2003 GLP Yes Published - No
IIIA, 10.1 and 10.3	Ebeling M	2002	Refined long term risk assessment for birds and mammals – Bromoxynil – Code: AE F025943, AE F065321 Generated by Aventis CropScience GmbH, DEU Ecotoxicology, Frankfurt, Submitted by Aventis Nufarm Report n°: C022401 Date: 21/5/02 GLP N/A Published – No

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
III A, 10.2	Ebeling M	2003	<p>Hypothetical Worst Case Risk Assessment for Aqueous Photometabolites of Bromoxynil</p> <p>Bayer CropScience, Frankfurt</p> <p>Generated by: Bayer CropScience, Frankfurt</p> <p>Submitted by: Bayer CropScience Nufarm</p> <p>Report n°: OE 03 / 008</p> <p>Date: 31/1/03</p> <p>GLP N/A</p> <p>Published - No</p>
III A, 10.3	Semino G	2002	<p>Bromoxynil - NOAEL proposal for long term risk assessment on wild mammals Code: AE F025943, AE F065321</p> <p>Generated by Aventis CropScience S.A., FRA</p> <p>Regulatory Toxicology</p> <p>Submitted by: Aventis Nufarm</p> <p>Report n°: C022712</p> <p>Date: 16/5/02</p> <p>GLP N/A</p> <p>Published - No</p>
III A, 10.1 and 10.3	Ebeling M.	2003	<p>Bromoxynil: Refined Long Term Risk Assessment in Birds and Mammals Confirmed by New Residue Data in Cereals.</p> <p>Generated by: Bayer CropScience, Frankfurt</p> <p>Submitted by: Bayer CropScience Nufarm</p> <p>Report n°: C029584</p> <p>Date: 24/3/03</p> <p>GLP N/A</p> <p>Published - No</p>
III A, 10.1 and 10.3	Sonder K	2002	<p>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</p> <p>Generated by: Bayer CropScience, Frankfurt</p> <p>Submitted by: Bayer CropScience Nufarm</p> <p>Report n°: 02R266 - C028055</p> <p>Date: 5/12/2002</p> <p>GLP Yes</p> <p>Published - No</p>

APPENDIX IV**List of uses supported by available data****BROMOXYNIL**

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, rye, triticale	EU	Oxytril	F	broad leaved weeds	EC	BO 200 + IO 200	spraying	2-3 leaves stage of crop till shooting (2 nodes)	1	-	-	200-400	0.4 *	60	*: expressed as bromoxynil equivalent (on young weeds up to 6 leaf stage, autumn or spring)
Spring cereals wheat (incl. durum), barley, oats, rye, triticale	EU	Oxytril	F	broad leaved weeds	EC	BO 200 + IO 200	spraying	2-3 leaves stage of crop till shooting (2 nodes)	1	-	-	200-400	0.3 *	60	*: expressed as bromoxynil equivalent (on young weeds up to 6 leaf stage)
Maize	EU	Emblem	F	broad leaved weeds	WP	BO 200	spraying	BBCH 19 (2-4 leaves) to BBCH 24 (4-6 leaves)	1	-	-	200-400	0.45 *	60	expressed as bromoxynil equivalent

Remarks: (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the (i) g/kg or g/l of bromoxynil octanoate (BO) and ioxynil octanoate (IO)

- (b) 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
- (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