

European Commission  
Directorate-General Health & Consumer Protection  
Unit E.1: Legislation relating to crop products and animal nutrition

Fluroxypyr  
6848/VI/98-rev.13  
15 December 1999

## Review report for the active substance **fluroxypyr**

Finalised in the Standing Committee on Plant Health at its meeting on 30 November 1999 in view of the inclusion of fluroxypyr 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 fluroxypyr, 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<sup>(1)</sup> 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 1199/97<sup>(2)</sup>, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Fluroxypyr 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, Dow Elanco Europe on 9 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance fluroxypyr 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<sup>(3)</sup>, as last amended by Regulation (EC) No 2230/95<sup>(4)</sup>, designated Germany as rapporteur Member State to carry out the assessment of fluroxypyr on the basis of the dossiers submitted by the notifiers. In the same Regulation the Commission specified furthermore the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for fluroxypyr this deadline was 30 April 1995.

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<sup>1</sup> OJ No L 366, 15.12.1992, p.10

<sup>2</sup> OJ No L 170, 28.6.1997, p.19

<sup>3</sup> Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the rapporteur Member States for the implementation of Commission Regulation (EEC) No 3600/92. OJ No L 107, 28.4.1994, p.8.

<sup>4</sup> OJ No L 225, 22.9.1995, p.1

Dow Elanco Europe submitted to the rapporteur Member State a dossier which did not contain substantial data gaps, taking into account the supported uses. Information has furthermore been submitted by third parties, including the European Federation of Agricultural Workers, the Pesticide Action Network, the European Environmental Bureau and the Comité Regional Phyto (Université Catholique de Louvain, Belgium).

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Germany submitted on 27 September 1996 to the Commission the report of its examination, hereafter referred to as the monograph, including, as required, a recommendation concerning the possible inclusion of fluroxypyr 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 fluroxypyr from Dow Elanco Europe, on 6 January 1997.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the monograph to all the Member States on 25 October 1996 as well as to Dow Elanco Europe being the main data submitter, on 4 November 1996.

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

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

The meetings for this consultation were organised on behalf of the Commission by the Pesticide Safety Directorate (PSD) in York, United Kingdom, from January to April 1997.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the main data submitter on 10 April 1997 for comments and further clarification.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the monograph, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the Standing Committee on Plant Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from February to May 1998, and was finalised in the meeting of the Standing Committee on 30 November 1999.

These documents were also submitted to the Scientific Committee for Plants for a separate independent consultation.

The present review report contains the conclusions of this final examination; given the importance of the monograph, 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, have been developed and finalised in support of the Directive 2000/10/EC concerning the inclusion of fluroxypyr in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing fluroxypyr 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 fluroxypyr 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 plant protection product containing fluroxypyr for which Member States will grant or review the authorisation.

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

- **herbicide against broad leaved weeds in cereals, maize, apple trees, olive trees and sorghum.**

Extension of the use pattern beyond those described 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 0.22 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). Additional intake from water and products of animal origin are not expected to give rise to intake problems.

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

Given the results of the evaluation of the information submitted on fate and behaviour and ecotoxicology, particular conditions have been provided for as explained in section 6 of this report, which need short term attention from the Member States when granting new authorisations or varying existing authorisations. These conclusions were reached, in particular, for the methylheptylester of fluroxypyr, for which detailed information was submitted. Further studies, in particular bridging studies, may be necessary in relation to the acceptance of esters and salts of fluroxypyr other than the methylheptylester evaluated.

#### **4. Identity and Physical/chemical properties**

The main identity and the physical/chemical properties of fluroxypyr are given in Appendix I. The active substance shall comply with the specification mentioned in the inclusion Directive and there seem not to be reasons for deviating from that specification.

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

#### **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 are listed in Appendix II. For esters and salts of fluroxypyr other than the methylheptylester 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

On the basis of the proposed and supported uses, 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:

- on the basis of current information only a maximum application rate of 400 g a.s. (as acid)/ha, to be applied in the growing seasons, is acceptable. For higher application rates or for use in autumn further data will be required, in particular in the fields of ecochemistry and ecotoxicity,
- to support use on non-crop land, potential for ground water contamination as well as effects on biological sewage treatment would have to be investigated,
- to support uses on pasture and amenity, potential for ground water contamination would have to be investigated,
- intended uses in bulb vegetables (onions, garlic etc.) have to be supported by a plant metabolism study,
- suitable risk management to protect aquatic life has to be taken into account,
- uses in nordic countries may have to be supported by soil degradation data at low temperatures.

## 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 fluroxypyr in Annex I under the current inclusion conditions. However, the Scientific Committee on Plants, in its opinion provided on June 4, 1999 identified the need to confirm by additional data the environmental safety of certain breakdown products of fluroxypyr occurring in soil and water. This confirmatory data has to be provided to the Member States as outlined in Article 3 and the Annex of the inclusion Directive.

In addition, some endpoints may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under specific, local conditions. Additional studies, in particular bridging studies, may also be necessary in relation to the acceptance of esters and salts of fluroxypyr other than the methylheptylester evaluated.

Use rates higher than 400 g a.s. (as acid)/ha. and/or applications outside the growing season have to be supported by additional information in the fields of ecochemistry and ecotoxicity.

## 8. Information on studies with claimed data protection

For information of any interested parties, Appendix III lists the studies for which the main data 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. This list is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC in the Member States. It is based on the best information available to the Commission services at the time this review report was prepared; but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC neither does it commit the Commission.

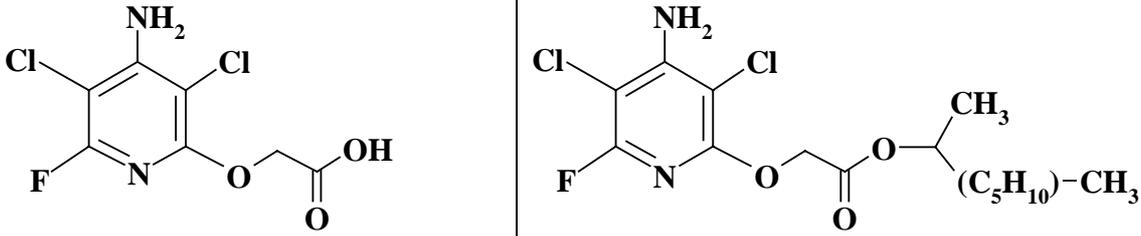
## **9. Updating of this review report**

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

## APPENDIX I

### Identity, physical and chemical properties

#### FLUROXYPYR

<b>Common name (ISO)</b>	Fluroxypyr	Fluroxypyr-meptyl
<b>Chemical name (IUPAC)</b>	4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetic acid	1-methylheptyl (4-amino-3,5-dichloro-6-fluoro-2-pyridyloxy)acetate
<b>Chemical name (CA)</b>	[(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetic acid	[(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetic acid, 1-methylheptyl ester
<b>CIPAC No</b>	431	431.214
<b>CAS No</b>	69377-81-7	81406-37-3
<b>EEC No</b>	---	279-752-9
<b>FAO SPECIFICATION</b>	---	---
<b>Minimum purity of the active substance as manufactured (g/kg)</b>	950	950
<b>Notable impurities (g/kg)</b>	---	---
<b>Molecular formula</b>	C <sub>7</sub> H <sub>5</sub> Cl <sub>2</sub> FN <sub>2</sub> O <sub>3</sub>	C <sub>15</sub> H <sub>21</sub> Cl <sub>2</sub> FN <sub>2</sub> O <sub>3</sub>
<b>Molecular mass</b>	255	367.3
<b>Structural formula</b>		

<b>Melting point</b>	232 - 233 °C	58.2 - 60 °C
<b>Boiling point</b>	No boiling point observed up to 360 °C	No boiling point observed up to 360 °C
<b>Appearance</b>	White crystalline solid	White crystalline solid
<b>Relative density</b>	1.09	1.322
<b>Vapour pressure</b>	$3.78 \cdot 10^{-9}$ Pa at 20 °C	$1.3 \cdot 10^{-6}$ Pa at 20 °C
<b>Henry's law constant</b>	$1.06 \cdot 10^{-8}$ Pa·m <sup>3</sup> ·mol <sup>-1</sup>	$5.5 \cdot 10^{-3}$ Pa·m <sup>3</sup> ·mol <sup>-1</sup>
<b>Solubility in water</b>	pH 5: 5.7 g/l pH 7: - pH 9: 7.3 g/l	0.0813 mg/l 0.109 mg/l hydrolysis
<b>Solubility in organic solvents</b>	At 25 °C: - hexane: 0.002 g/l - methanol: 35 g/l - 2-propanol: 9 g/l -dichloromethane: 0.15 g/l -ethylacetate: 11 g/l -toluene: 0.77 g/l - xylene: 0.3 g/l acetone: 9.2 g/l	At 25 °C: - hexane: 45 g/l - methanol: 469 g/l - 2-propanol: 288 g/l; - xylene, toluene, dichloromethane, acetone, ethylacetate: >500 g/l
<b>Partition co-efficient (log P<sub>ow</sub>)</b>	2.0	4.5
<b>Hydrolytic stability (DT<sub>50</sub>)</b>	pH 5: stable pH 7: stable pH 9: stable	pH 5: 9.8 d pH 7: 17.5 d pH 9: 10.2 d
<b>Dissociation constant</b>	pKa (25 °C) = 2.94	no dissociation in water
<b>UV/VIS absorption (max.)</b>	Absorption in the range of 210 to 218 nm, only	No maximum between 290 and 900 nm
<b>Photostability (DT<sub>50</sub>)</b>	---	63 d in water
<b>Flammability</b>	Not available	Non-flammable Not-autoflammable
<b>Explosive Properties</b>	Not available	non-explosive

## APPENDIX II

### END POINTS AND RELATED INFORMATION

#### FLUROXYPYR

### 1 Toxicology and metabolism

#### Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	~100 %; < 0.5 d; oral [acid, MHE]
Distribution:	Highest residues: Gastro-intestinal-tract and kidneys [acid, MHE]
Potential for accumulation:	No indication of accumulation after repeated administration [MHE]
Rate and extent of excretion:	Efficiently eliminated within 2 days: urine (91 - 94 %); faeces (4 - 6 %) [acid, MHE]
Toxicologically significant compounds:	MHE; rapidly and completely hydrolysed to fluroxypyr; sodium salt; unchanged excreted

#### Acute toxicity

Rat LD <sub>50</sub> oral:	> 2000 mg/kg bw [MHE]
Rat LD <sub>50</sub> dermal:	> 2000 mg/kg bw [MHE]
Rat LC <sub>50</sub> inhalation:	>1.0 mg/l (highest attainable concentration) [MHE]
Skin irritation:	Not irritating [MHE]
Eye irritation:	Not irritating [MHE]
Sensitization:	Not sensitising [MHE]

#### Short term toxicity

Target / critical effect:	Kidney [acid, MHE]
Lowest relevant NOAEL:	80 mg/kg bw/d; 13 weeks; oral; mouse and rat [acid] NOEL 300 mg/kg bw/d; dermal [MHE]

**Genotoxicity**

No evidence of genotoxicity [acid]

**Long term toxicity and carcinogenicity**

Target / critical effect:

Kidney [acid]

Lowest relevant NOAEL:

80 mg/kg bw/d; 2 y; oral; rat (Wistar) [acid]

Carcinogenicity:

No evidence of carcinogenicity [acid]

**Reproductive toxicity**

Reproduction:

No conclusive adverse effects [acid]

NOAEL 150 mg/kg bw/d for reproductive and maternal toxicity [acid]

Developmental toxicity:

No evidence of teratogenicity in rats or rabbits [acid]

**Delayed neurotoxicity**

Not a primary neurotoxin, delayed neurotoxicity studies are not required [acid, MHE]

**Other toxicological studies**

None of toxicological relevance

**Medical data**

No reports of adverse effects in humans [acid, MHE]

**Summary**

ADI:

0.8 mg/kg bw; SF=100; 2 y rat [acid]

AOEL:

0.8 mg/kg bw/d (oral); SF=100; 2 y rat [acid]

ARfD:

Not allocated – not necessary

**Dermal absorption**

Default value of 10% dermal absorption based on the physical chemical properties of this active ingredient [acid, MHE]

## 2 Fate and behaviour in the environment

### 2.1 Fate and behaviour in soil

#### Route of degradation

##### Aerobic:

Mineralization after 100 days:

Up to 65 % at 20 °C

Non-extractable residues after 100 days:

Up to 29.7 % at 20 °C

Relevant metabolites above 10 % of applied active substance: name and/or code

4-Amino-3,5-dichloro-6-fluoro-2-pyridinol (metabolite II) up to 11.5 % after 7 d

% of applied rate (range and maximum)

4-Amino-3,5-dichloro-6-fluoro-methoxypyridine (metabolite III) up to 17.8 % after 28 d

##### Supplemental studies

##### Anaerobic:

Mineralization < 0.1%, non-extractables up to 33.5 % (after 56 d, 25 °C)

Relevant metabolites: metabolite III, up to 12 % after 112 d

##### Soil photolysis:

DT<sub>50</sub> = 153 d [MHE]

#### Rate of degradation

##### Laboratory studies

DT<sub>50lab</sub> (20 °C, aerobic):

3 - 55 d at 20 - 22 °C [acid]<sup>5</sup>

DT<sub>90lab</sub> (20 °C, aerobic):

15 – 40 d [acid]; 53 - 220 d [MHE plus acid]

DT<sub>50lab</sub> (10 °C, aerobic):

No data available, if use required in Nordic region then data will be required.

DT<sub>50lab</sub> (20 °C, anaerobic):

91 - 210 d at 25 °C [acid]

##### Field studies (country or region)

Canada, UK

<sup>5</sup> Metabolite II, DT<sub>50</sub> = 21 - 53 d  
Metabolite III, DT<sub>50</sub> = 20 - 429 d

Under worst case conditions, metabolite III exceeds the DT<sub>50</sub> trigger value.

DT <sub>50f</sub> from soil dissipation studies:	< 3 d [MHE] 34 - 68 d [acid] 11 - 38 d [acid, MHE]
DT <sub>90f</sub> from soil dissipation studies:	Metabolite II: 3 - 16 %, but not detectable after 16 months Metabolite III: 9 - 43 % after 16 months
Soil accumulation studies:	No data available
Soil residue studies:	UK, Italy, Germany: [MHE plus acid] - spring wheat: 0.12 mg/kg (74 d) - winter wheat, bean, turnip: 0.025 mg/kg (404 d) - soft wheat, winter barley, durum wheat each: < 0.01 mg/kg (88, 72, 101 d) - summer wheat 0.018 mg/kg (95 d) - winter rye, winter barley each: < 0.01 mg/kg (92, 75 d)/0-5, 10, 20 cm

**Remarks**

e.g. effect of soil pH on degradation rate

In general, as soil pH decreases then DT<sub>50</sub> increases**Adsorption/desorption**K<sub>oc</sub> / K<sub>om</sub>:K<sub>oc</sub> of adsorption: MHE: 6200 - 43000  
acid: 51 - 81

Soil type, pH, OC/OM content:

Silt loam (pH 5.9, OC 2.2 %)  
Sandy loam (pH 7.5, OC 0.2 %)  
Loam (pH 6.8, OC 3.1 %)  
Clay (pH 7.0, OC 1.3 %)**Mobility****Laboratory studies:**

Column leaching:

MHE: < 2 % in leachate  
Acid: 18 - 74 % (as equivalents) in leachate

Aged residue leaching:

60 d ageing (approximately equivalent to the worst case DT<sub>50</sub>) at 22 °C:  
Acid: 10% in leachate  
Metabolite II: not detected at 5 µg/l  
Metabolite III : not looked for

**Field studies:**

Lysimeter/Field leaching studies:

Lysimeter studies:  
Single spring application (200 and 400 g (as acid)/ha):  
MHE: not detected  
Acid: 0.008 and 0.0034 µg/l (2 y averages),  
0.034 and 0.008 µg/l (maximum).  
Metabolite II: 0.0009 and < 0.0001 µg/l  
(2 y averages)  
0.0038 and 0.001 µg/l (maximum)  
Metabolite III: 0.0003 and 0.0002 µg/l  
(2 y averages)  
0.0009 and 0.0006 µg/l (maximum)

**Remarks:**

Lysimeter studies would be more useful if results were presented separately for each year rather than as 2 year averages.

Field leaching data submitted was not acceptable as the limit of detection was too high.

## 2.2 Fate and behaviour in water

### Abiotic degradation

Hydrolytic degradation:

	MHE:	acid:
DT <sub>50</sub> at pH 4/5:	stable*	stable*
7:	stable*	stable*
9:	3.2 d	stable*
*no significant degradation during study period of 30 d		
None		
Molar absorption coefficient < 10 l·mol <sup>-1</sup> ·cm <sup>-1</sup> f wavelengths ≥ 290 nm [MHE]		

Relevant metabolites:

Photolytic degradation:

### Biological degradation

Ready biological degradability:

Water/sediment study:

No	
DT <sub>50</sub> (water): immediately release the	The MHE was found after application in the Hydrolysis occurred to more soluble acid in the water.
DT <sub>50</sub> (whole system): MHE: 2 d, acid: 24 d	
Metabolite II	IV <sup>6</sup> (25 °C, aerobic, dark)
44	17.9
14	28
13.2	6.5
7	28
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Relevant metabolites

- residues in the water phase (% of applied)  
maximum at day ....  
at the end of the study at day....
- residues in the sediment (% of applied)  
maximum at day....  
at the end of the study at day....

Accumulation in water and/or sediment:

**Degradation in the saturated zone** No data available

Remarks:

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<sup>6</sup> 4-Amino-3-chloro-6-fluoro-2-pyridinol  
20 °C: 4-Amino-3,5-dichloro-6-fluoro-2-pyridone  
(tentatively identified), maximum 13 % (4 - 13 weeks) and 45 % (8 weeks)(whole systems),  
DT<sub>50</sub>: 28 and 34 d (whole systems)

## 2.3 Fate and behaviour in air

### Volatility

Vapour pressure:

MHE: $1.3 \cdot 10^{-6}$ Pa at 20 °C
Acid: $3.8 \cdot 10^{-9}$ Pa at 20 °C

Henry's law constant:

MHE: $5.5 \cdot 10^{-3}$ Pa·m <sup>3</sup> ·mol <sup>-1</sup>
Acid: $1.06 \cdot 10^{-8}$ Pa·m <sup>3</sup> ·mol <sup>-1</sup>

### Photolytic degradation

Direct photolysis in air:

Molar absorption coefficient $< 10 \text{ l}\cdot\text{mol}^{-1}\cdot\text{cm}^{-1}$ for wavelengths $\geq 290 \text{ nm}$ [MHE]
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Photochemical oxidative degradation in air DT<sub>50</sub>:

MHE: 3.3 - 9.8 h
Acid: 4.5 - 13.4 h

Remarks:

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### 3 Ecotoxicology

#### Effects on terrestrial vertebrates

(Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

	Endpoint	Acid	MHE
Acute toxicity to mammals	LD <sub>50</sub>	---	> 2000 mg/kg bw
Acute toxicity to birds	LD <sub>50</sub>	> 2000 mg/kg bw	> 2000 mg/kg bw
Dietary toxicity to birds	LC <sub>50</sub>	> 5000 ppm	> 5000 ppm
Reproductive toxicity to birds	NOEL	---	500 ppm
Short term oral toxicity to mammals	NOEL	---	200 mg/kg bw/d

#### Effects on aquatic organisms

(Annex IIA, point 8.2, Annex IIA, point 10.2)

Group	Duration	Endpoint	Acid	MHE	Metabolit II Fluroxypyr Pyridinol	formulated product Starane 180
				Toxicity (mg/l)		
<b>Acute Toxicity</b>						
<i>L. macrochirus</i>	96 h	LC <sub>50</sub>	14.3			
<i>O. mykiss</i>	96 h	LC <sub>50</sub>		> 0.2	39	3.5
<i>D. magna</i>	48 h	EC <sub>50</sub>	> 100	> 0.2	> 49	0.8
<i>S. capricornutum</i>	120 h	LC <sub>50</sub>	49.8		> 45	
<i>S. subspicatus</i>	72 h	LC <sub>50</sub>		> 0.5		1.8
<i>L. gibba</i>	14 d	LC <sub>50</sub>	12.3			
<b>Chronic Toxicity</b>						
<i>O. mykiss</i>	21 d	NOEC	100	0.2	---	0.25
<i>D. magna</i>	21 d	NOEC	56	0.1	---	0.007

#### Chronic Toxicity sediment dwelling organisms:

Not relevant

#### Bioconcentration:

Bioconcentration factor (BCF)

Not relevant

**Effects on honeybees** (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Acute oral toxicity

Acute contact toxicity

MHE	
LD <sub>50</sub>	Hazard Quotient
> 100 µg/bee	< 3.6
> 100 µg/bee	< 3.6

**Effects on other arthropod species**

(Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species	Stage	Test Substance (Starane 180)	Effect lethal/sublethal %
<b>Laboratory test</b>			
Aphidius rhopalosiphi	adult	578 g as/ha*	100
Typhlodromus pyri	adult	578 g as/ha*	33.3
Aleochara bilineata	adult	360 g as/ha**	7
Paradosa spp.	adult	360 g as/ha**	0
Poecilus cupreus	adult	360 g as/ha*	9.1
<b>Extended laboratory test</b>			
Aphidius rhopalosiphi	adult	439 g as/ha*	0

\* MHE

\*\* acid

**Effects on earthworms** (Annex IIA, point 8.4, Annex IIIA, point 10.6)

	Acid	MHE	Metabolit III*	formulated product (Starane 180)
	LC <sub>50</sub> mg as/kg			
Acute toxicity	---	> 1000	313	49.7
Reproductive toxicity	---	---	---	---

**Effects on soil micro-organisms**

(Annex IIA, point 8.5, Annex IIIA, point 10.7)

	<i>Testing was carried out using a herbicide containing fluroxypyr and another active substance</i>	Metabolite III (Fluroxypyr Methoxypridin)
Nitrogen mineralization	No negative effects up to 2 kg as/ha	---
Carbon mineralization	No negative effects up to 2 kg as/ha	---
Soil respiration	---	No negative effects up to 495g as/ha
Nitrogen mineralisation	---	No negative effects up to 495g as/ha

## Appendix III

### FLUROXYPYR

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<sup>7</sup>.

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 <sup>8</sup> on previous use in granting national authorisations
IIA, 1.9	Hummel, R. A.	1988	Assay of fluroxypyr 1-methylheptyl ester, AGR 248743, (A55) owner: DowElanco ML-AL 88-030273	
IIA, 1.10	Cowlyn, T. C.	1994	STARANE F: Determination of unknown impurities (A56) owner: DowElanco GHE-P-3949	
IIA, 1.10	Moreland, J.	1995	Confirmation of identity and quantitation of an unknown impurity in STARANE F Herbicide Ex-Drusenheim (A58) owner: DowElanco GHE-P-4147	
IIA, 1.10 IIA, 2.4	Moreland, J., Ghosh, D. and Peacock, J.	1993	Characterisation of STARANE F Herbicide (Batch 42 Ex-Drusenheim) (A35) owner: DowElanco GHE-P-3210	
IIA, 1.11 IIA, 4.1.1 IIA, 4.1.2	Comb, A. L.	1994	STARANE F: Five-batch Characterisation of Starane F herbicides (A53) owner: DowElanco GHE-P-3948	

<sup>7</sup> List based on a detailed analysis from Germany in its submission of XX/XX/XX (background document C).

<sup>8</sup> Reports received from Member States at the date of finalisation of the present review report (not exhaustive).

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 <sup>8</sup> on previous use in granting national authorisations
IIA, 2.1 IIA, 2.2 IIA, 2.6 IIA, 2.8 IIA, 2.11 IIA, 2.13 IIA, 2.15	O'Connor, J.	1991	Fluroxypyr 1-methylheptyl ester: Determination of Physico-Chemical Properties (A11) owner: DowElanco Report No. GHE-P-2473	FR: The study has been used for authorisation January 1996 (09.01.96) SE: The study has been used for authorisation in December 1991
IIA, 2.3	Schuurman, I. P.	1989	Determination of the autoflammability of STARANE 180 formulation (EF 1018) (Q6) owner: DowElanco report No. GHE-P-2029	FI: The study has been used for authorisation in April 1992 (22.4.1992) NL: Date of national decision: 01.04.1994
IIA, 2.3	Watson, P. A.	1994	Fluroxypyr 1-methylheptyl ester: Calculation of Henry's Law Constant (A39) owner: DowElanco HLC/2-4/94	
IIA, 2.4	Sydney, P.	1994	STARANE F; Determination of physico-chemical properties (A45) owner: DowElanco Report No. GHE-P-3735	
IIA, 2.5	Knowles, S.	1995	Generation of Spectral Data (UV-VIS) for fluroxypyr MH Ester pure, AGR 228289 (A57) owner: DowElanco Report No. GEHE-P-4231	
IIA, 2.5	Knowles, S. J., Peacock, G. and Portwood, D.	1991	Determination of Spectral Data for Starane F, Fluroxypyr 1-Methylheptyl Ester (Technical), VE 270 BX680 (A21) owner: DowElanco Report No. GHE-P-2457	
IIA, 2.5	Knowles, S. J., Peacock, G. and Portwood, D.	1991	Determination of Spectral Data of Fluroxypyr acid (Analytical), AGR 218256 (A24) owner: DowElanco Report No. GHE-P-2474	
IIA, 2.5 IIA, 2.9	Knowles, S. J., Peacock, G. and Portwood, D.	1991	Determination of Spectral Data for Fluroxypyr 1-Methylheptyl Ester (Analytical), AGR 228289 (A22) owner: DowElanco Report No. GHE-P-2458	SE: The study has been used for authorisation in December 1991
IIA, 2.7	Oliver, P. and Hamilton, A.	1992	STARANE 180 Herbicide: EC 1018 Packaging Stability data (Q8) owner: DowElanco Report No. GHE-P-2029	

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 <sup>8</sup> on previous use in granting national authorisations
IIA, 2.8	O'Connor, J.	1991	Fluroxypyr: Determination of Partition Coefficient (A23) owner: DowElanco GHE-P-2475	
IIA, 2.9 IIA, 7.3.1.3.2	Lehmann, R. G.	1988	Formation of fluroxypyr from fluroxypyr-MHE by soil catalysis. (K34) Dow Chemical Company GH-C 2068	FI: The study has been used for authorisation in April 1992 (22.4.1992) SE: The study has been used for authorisation in December 1991 IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991
IIA, 2.9 IIA, 7.2.1.2	Cleveland, C. B. and Holbrook, D. L.	1992	Aqueous photolysis of fluroxypyr methylheptyl ester and fluroxypyr (acid) in natural sunlight. (K51) owner: DowElanco GH-C 2758	
IIA, 2.10	Müller, M.	1995	Estimation of the atmospheric half-life of Fluroxypyr (A59) owner: DowElanco Report No. GHE-P-4738	
IIA, 2.10	Müller, M.	1995	Estimation of the atmospheric half-life of Fluroxypyr-1-methylheptyl ester owner: DowElanco (A60) Report No. GHE-P-4736	
IIA, 3.5	Puvanesarajah, V. and Steward, C.	1991	Metabolism of <sup>14</sup> C-fluroxypyr MHE in wheat. (L2) owner: DowElanco REPORT #38701	SE: The study has been used for authorisation in December 1991
IIA, 4.1 IIA, 5.1	Anonymous	1991	Analytical method: STARANE EC Multimethod (O85) owner: DowElanco Report No: EU-AM-90-38 (DOWM 10098 8-DE 91A)	
IIA, 4.2.1	Anonymous	1990	Determination of fluroxypyr residues in grass and hay, ERC 86.1 (O30) owner: DowElanco	DE: The study has been submitted in 1987 in a national authorisation IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991

<b>Annex point / reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not</b>	<b>Reports<sup>8</sup> on previous use in granting national authorisations</b>
IIA, 4.2.1	Butcher, S. M.	1994	Determination of fluroxypyr residues in olives, ERC 94.9 (O40) owner: DowElanco	
IIA, 4.2.1	Butcher, S. and Hastings, M.	1992	Determination of fluroxypyr residues in wheat and barley grain and straw, ERC 92.1 (O31) owner: DowElanco	DE: The study has been submitted in 1994 in a national authorisation
IIA, 4.2.1	Dawson, J.	1990	Determination of fluroxypyr residues in grapes, ERC 86.4 (O36) owner: DowElanco	SE: The study has been used for authorisation in December 1991
IIA, 4.2.1	Dawson, J.	1990	Determination of fluroxypyr residues in maize fractions, ERC 86.3 (O35) owner: DowElanco	BE: Date of national decision: 05.03.1992
IIA, 4.2.1	Maycock, R. C.	1991	Determination of fluroxypyr residues in apples and onions, ERC 89.2 (O37) owner: DowElanco	FR: The study has been used for authorisation March 1994 (17.03.94) SE: The study has been used for authorisation in December 1991
IIA, 4.2.1	Maycock, R. C. and Teasdale, R.	1990	Determination of fluroxypyr residues in maize plant and kernels, ERC 89.5 (O38) owner: DowElanco	BE: Date of national decision: 05.03.1992 DE: The study has been submitted in 1990 in a national authorisation
IIA, 4.2.1	Teasdale, R. J.	1994	Independent method validation of DowElanco Analytical Method ERC 92.1: Determination of Fluroxypyr residues in wheat and barley grain and straw (O32) owner: DowElanco GHE-P-3392	
IIA, 4.2.1	Teasdale, R. J.	1995	Independent method validation of DowElanco Analytical Method ERC 92.1 for the Determination of Fluroxypyr residues in wheat and barley immature plant (O32A) owner: DowElanco GHE-P-4190	
IIA, 4.2.1	Teasdale, R. J.	1995	Independent method validation of DowElanco Analytical Method ERC 90.3 for the Determination of Fluroxypyr residues in pasture (O33B) owner: DowElanco GHE-P-4648	

<b>Annex point / reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not</b>	<b>Reports<sup>8</sup> on previous use in granting national authorisations</b>
IIA, 4.2.1	Teasdale, R. J.	1995	Independent validation of DowElanco Analytical Method ERC 89.5 for the Determination of Fluroxypyr residues in maize plant and cob (O38A) owner: DowElanco GHE-P-4647	
IIA, 4.2.2	Gill, J. P.	1995	Determination of residues of fluroxypyr, the 3,5-Dichloropyri- dinol and 2-methoxy- pyridine in soil, ERC 94.31 (O20D) owner: DowElanco	
IIA, 4.2.2	Van Dyke, M. E.	1991	Determination of residues of fluroxypyr methylheptyl-ester in soil by gas chromatography/mass spectrum (O20A) owner: DowElanco	
IIA, 4.2.3	Butcher, S. M.	1992	Determination of residues of the methoxy- pyridine and pyridinol metabolites of fluroxypyr in Drinking Water, ERC 92.17 (O16A) owner: DowElanco	DE: The study has been submitted in 1992 in a national authorisation
IIA, 4.2.4	Long, T. and Balluff, M.	1994	Development and validation of a low level air monitoring method for fluroxypyr 1-MHE (O45A) owner: DowElanco GHE-P-4045	
IIA, 4.2.4	Long, T. and Balluff, M.	1994	Development and validation of a low level air monitoring method for fluroxypyr (O46A) owner: DowElanco GHE-P-4046	
IIA, 4.2.4	Long, T. and Balluff, M.	1995	Monitoring low levels of fluroxypyr 1-MHE in air, ERC 94.24 (O45) owner: DowElanco	
IIA, 4.2.4	Long, T. and Balluff, M.	1995	Monitoring low levels of fluroxypyr in air, ERC 95.17 (O46) owner: DowElanco	
IIA, 4.2.5	Anonymous	1990	Determination of fluroxypyr residues in milk, ERC 87.11 include. Addendum (O25) owner: DowElanco	DE: The study has been submitted in 1989 in a national authorisation
IIA, 4.2.5	Anonymous	1991	Determination of fluroxypyr residues in urine, ERC 87.14 (O22) owner: DowElanco	
IIA, 4.2.5	Anonymous	1991	Determination of fluroxypyr residues in kidney, liver and muscle, ERC 87.13 include. Addendum (O23) owner: DowElanco	DE: The study has been submitted in 1989 in a national authorisation

<b>Annex point / reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not</b>	<b>Reports<sup>8</sup> on previous use in granting national authorisations</b>
IIA, 4.2.5	Anonymous	1991	Determination of fluroxypyr residues in peritoneal and subcutaneous fat, ERC 87.12 (O24) owner: DowElanco	DE: The study has been submitted in 1989 in a national authorisation
IIA, 4.2.5	Woods, J. S. and Yeakle	1990	Determination of fluroxypyr in eggs, chicken muscle, liver, and fat tissues by gas chromatography ACR 90.4 (O39) owner: DowElanco	FI: The study has been used for authorisation in April 1992 (22.4.1992) SE: The study has been used for authorisation in December 1991
IIA, 5.2.1	Jones, J. R.	1994	STARANE F: Acute oral toxicity (Limit test) in the Rat (B11) owner: DowElanco	
IIA, 5.2.2	Jones, J. R.	1994	STARANE F: Acute dermal toxicity (Limit test) in the Rat (B12) owner: DowElanco	
IIA, 5.2.5	Jones, J. R.	1994	STARANE F: Acute dermal eye irritation test in the rabbit (B13) owner: DowElanco	
IIA, 5.2.6	Jones, J. R.	1994	STARANE F: Magnusson and Kligman Maximisation study in the Guinea pig (B14) owner: DowElanco	
IIA, 5.3.2	Cosse, P. F., Vedula, U. and Crissman, J. W.	1991	Fluroxypyr methylheptyl ester: 13-week dietary toxicity study and 5-week Recovery study in Fischer 344 rats (D14) owner: DowElanco DECO-HET K-137992-004	
IIA, 5.3.3	Cosse, P. F., Crissman, J. W. and Vedula, U.	1991	Fluroxypyr Methylheptyl Ester: Dermal Probe Study and 21-Day Dermal Toxicity Study in New Zealand White Rabbits (D13) owner: DowElanco DECO-HET K-137992-003	SE: The study has been used for authorisation in December 1991
IIA, 5.5	Cosse, P. F., Crissman, J. W., Markham, D. A. and Corley, R. A.	1993	Fluroxypyr: 18-month dietary oncogenicity study in CD-1 Mice (I5) owner: DowElanco K-129976-004	
IIA, 5.6.1	Dreef-van der Meulen, H. C.	1991	Oral Multigeneration Reproduction study with Dowco 433 Acid in Rats; Additional Pathology (F5) owner: DowElanco	SE: The study has been used for authorisation in December 1991

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Reports <sup>8</sup> on previous use in granting national authorisations
IIA, 5.9.1	Lines, S.	1995	Fluroxypyr 1-methylheptyl ester (STARANE F) :Employee Medical Record Evaluations (U1) owner: DowElanco	
IIA, 5.10	Thies, E. P.	1998	STARANE 180 and STARANE 200 Evaluation Table Point 4.1. Doc 6849/VI/97 (Operator Exposure 7.2.) (M1018) owner: DowElanco	
IIA, 6.1	Caley, C. Y., Hall, B. E.	1995	Comparative Metabolism of <sup>14</sup> C-fluroxypyr butoxypropyl ester and <sup>14</sup> C-fluroxypyr MHE in winter wheat – field study (L5) Source: Dow Elanco Report No.: 10592	DE: The study has been submitted in 1996 in a national authorisation
IIA, 6.1	Lickly, L. S. <i>et al</i>	1990	[ <sup>14</sup> C] Fluroxypyr-MHE: Confined accumulation study on rotational crops planted at 30, 120 and 366 days after soil treatment (N38) Source: Dow Elanco Report No.: GH-C-2401	
IIA, 6.1	Phillips, A. M.	1993	Determination of residues of fluroxypyr in wheat and barley receiving ground application of fluroxypyr methylheptyl ester (Canada) (N39) Source: Dow Elanco Report No.: GH-C-3168	
IIA, 6.1	Puvanesaraja, V., Steward, C.	1991	Metabolism of <sup>14</sup> C-fluroxypyr MHE in wheat (L2) Source: Dow Elanco Report No.: GH-C 2650	SE: The study has been used for authorisation in December 1991
IIA, 6.2	Yackovich, P. R., Lardie, T. S., Miller, J. H.	1989	Fate of <sup>14</sup> C labelled fluroxypyr fed to laying hens (N87) Source: Dow Elanco Report No.: GH-C-2148	
IIA, 6.2	Yackovich, P. R., Lardie, T. S., Miller, J. H.	1990	Fate of <sup>14</sup> C labelled fluroxypyr fed to lactating goats (H4) Source: Dow Elanco Report No.: GH-C 2297	UK: The study has been used in 06/1998 in a national authorisation
IIA, 6.3	Butcher, S. M., Teasdale, R.	1994	Residues of fluroxypyr in olives at harvest following basal application of STARANE 20 – Spain (N43A) Source: Dow Elanco Report No.: GHE-P-3750	ES: Date of national regulatory decision: February 1995
IIA, 6.3	Day, S. R., Flatt, S.	1988	Fluroxypyr residues in bulb onions following application of STARANE 2 – Holland (N65) Source: Dow Elanco Report No.: GHE-P-1838	

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 <sup>8</sup> on previous use in granting national authorisations
IIA, 6.3	Maycock, R.	1989	Fluroxypyr residues in bulb onions following application of STARANE 2 – UK (N66) Source: Dow Elanco Report No.: GHE-P-1934	
IIA, 6.3	Maycock, R.	1993	Fluroxypyr residues in apples following application of STARANE 2 – UK (N40) Source: Dow Elanco Report No.: GHE-P-1922	ES: Date of national regulatory decision: April 1997 FR: The study has been used for authorisation March 1994 (17.03.94) UK: The study has been used in 04/91 for a national authorisation.
IIA, 6.3	Teasdale, R.	1994	Residues of fluroxypyr in durum wheat at harvest and residues of fluroxypyr 1-methylheptl ester (MHE), fluroxypyr and two metabolites in soil following a single post-emergence application of STARANE (EF 1018). Italy (N22) Source: Dow Elanco Report No.: GHE-P-3912	
IIA, 6.3	Teasdale, R.	1995	Residues of fluroxypyr in soft wheat at harvest and residues of fluroxypyr 1-methylheptl ester (MHE), fluroxypyr and two metabolites in soil following a single post-emergence application of STARANE (EF 1018). Italy (N20) Source: Dow Elanco Report No.: GHE-P-3913	
IIA, 6.3	Teasdale, R.	1995	Residues of fluroxypyr in winter barley at harvest and residues of fluroxypyr 1-methylheptl ester (MHE), fluroxypyr and two metabolites in soil following a single post-emergence application of STARANE (EF 1018). Italy (N21) Source: Dow Elanco Report No.: GHE-P-3914	
IIA, 6.3	Teasdale, R.	1995	Residues of fluroxypyr in winter soft wheat and durum wheat at harvest following application of STARANE 20 (EF-689). Spain (N23) Source: Dow Elanco Report No.: GHE-P-4091	

<b>Annex point / reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not</b>	<b>Reports<sup>8</sup> on previous use in granting national authorisations</b>
IIA, 6.3	Teasdale, R.	1995	Residues of fluroxypyr in winter barley at harvest following application of STARANE 20 (EF-689). Spain (N24) Source: Dow Elanco Report No.: GHE-P-4092	
IIA, 6.3	Teasdale, R.	1995	Residues of fluroxypyr in winter wheat at intervals following application of STARANE 20 (EF-689). Spain (N25) Source: Dow Elanco Report No.: GHE-P-4093	
IIA, 6.3	Teasdale, R.	1995	Residues of fluroxypyr in winter barley at intervals following application of STARANE 20 (EF-689). Spain (N26) Source: Dow Elanco Report No.: GHE-P-4094	
IIA, 6.3	Teasdale, R.	1991	Fluroxypyr residues in apples following orchard floor application of STARANE 200 EC – France (N41) Source: Dow Elanco Report No.: GHE-P-2492	ES: Date of national regulatory decision: April 1997 FR: The study has been used for authorisation March 1994 (17.03.94)
IIA, 6.3	Teasdale, R., Maycock, R.	1990	Fluroxypyr residues in maize following application of STARANE 180 – Germany (N55) Source: Dow Elanco Report No.: GHE-P-2035	BE: Date of national decision: 05.03.1992 DE: The study has been submitted in 1990 in a national authorisation
IIA, 6.3	Teasdale, R., Maycock, R.	1990	Fluroxypyr residues in maize following application of STARANE 180 – Germany (N56) Source: Dow Elanco Report No.: GHE-P-1991	BE: Date of national decision: 05.03.1992 DE: The study has been submitted in 1990 in a national authorisation
IIA, 6.3	Teasdale, R.	1996	Frozen storage stability of fluroxypyr in wheat immature plant, grain and straw. (O32C) GHE-P-4830	

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 <sup>8</sup> on previous use in granting national authorisations
IIA, 6.4	Woods, J. S.	1990	Determination of residues of fluroxypyr in eggs, muscle, liver and fat tissues from chickens administered fluroxypyr herbicide (N86) Source: Dow Elanco Report No.: GH-C 2327	FI: The study has been used for authorisation in April 1992 (22.4.1992) SE: The study has been used for authorisation in December 1991
IIA, 7.1.1.1.1	Grant, R. K.	1992	Degradation and metabolism of fluroxypyr 1-rnethylheptyl ester in soil under aerobic conditions. (K22) owner: DowElanco Dow Elanco id GHE-P-2754	
IIA, 7.1.1.1.1	Lehmann, R. G.	1988	Extraction of fluroxypyr and its metabolites from aged soil. (K2) Dow Chemical Company GH-C 2048	
IIA, 7.1.1.1.1	Lehmann, R. G. and Miller, J. R.	1989	Aerobic soil metabolism study of fluroxypyr-MHE. (K6) Dow Chemical Company GH-C 2149R	BE: Date of national decision: 05.03.1992 SE: The study has been used for authorisation in December 1991 IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991 BE: Date of national decision: 05.03.1992 SE: The study has been used for authorisation in December 1991
IIA, 7.1.1.1.1	Lehmann, R. G. and Miller, J. R.	1989	Degradation of the methoxy pyridine metabolite of fluroxypyr in soils planted with grass. (K7) Dow Chemical Company GH-C 2256	BE: Date of national decision: 05.03.1992 SE: The study has been used for authorisation in December 1991
IIA, 7.1.1.1.1	Ballantine, L. G.	1993	Aerobic soil metabolism of <sup>14</sup> C-fluroxypyr – MHE. (K23) GH-C 3026	
IIA, 7.1.1.1.2	Batzer, F. R. and Lubinski, R. N.	1992	Soil photolysis of fluroxypyr 1-rnethylheptyl ester in natural sunlight (K50) owner: DowElanco Dow Elanco id GH-C 2717	
IIA, 7.1.1.2.2	Poletika, N. N., Roberts, D. W., Phillips, A. M. and Butter, I. W.	1994	Terrestrial field dissipation of fluroxypyr in Western Canada (K29) owner: DowElanco Dow Elanco id GH-C 3210	

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 <sup>8</sup> on previous use in granting national authorisations
IIA, 7.1.2	Lehmann, R. G.	1988	Adsorption/desorption study of fluroxypyr Dow Chemical Company (K3) Dow Elanco id GH-C 2124	BE: Date of national decision: 05.03.1992 DE: The study has been submitted in 1989 in a national authorisation SE: The study has been used for authorisation in December 1991 IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991
IIA, 7.1.3.3	Brumhard, B., Fuhr, F. and Baloch, R.	1993	Behaviour of [2,6- <sup>14</sup> C] fluroxypyr 1-methylheptyl ester in sandy pseudogley-braunerde after post-emergence application to spring barley (K17B) Institut. Fur Radioagron. Forsch. Julich Dow Elanco id GHE-P 2803	DE: The study has been submitted in 1995 in a national authorisation
IIA, 7.1.3.3	McGibbon, A. S.	1990	Dissipation of fluroxypyr-methylheptyl ester in Swedish Soils. (K16) Dow Chemical Company GHE-P-1993	BE: Date of national decision: 05.03.1992 SE: The study has been used for authorisation in December 1991
IIA, 7.2.1.3.2	Yon, D. A. and Cresswell, D. G.	1988	Degradation of <sup>14</sup> C fluroxypyr 1-MHE in ditch waters and their associated sediments 1987 Hazleton Laboratories (K20) Dow Elanco id GHE-P-1785	BE: Date of national decision: 05.03.1992 DE: The study has been submitted in 1995 in a national authorisation FI: The study has been used for authorisation in April 1992 (22.4.1992) NL: Date of national decision: 01.04.1994 IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991

Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Reports <sup>8</sup> on previous use in granting national authorisations
IIA, 7.2.1.3.2	Cleveland, C. B. and Miller, J. R.	1993	Aerobic aquatic metabolism of fluroxypyr MHE. (K25) owner: DowElanco GH-C 3008	
IIA, 7.2.1.3.2	Cleveland, C. B. and Miller, J. R.	1993	Anaerobic aquatic metabolism of fluroxypyr methylheptyl ester. (K26) owner: DowElanco GH-C 3033	
IIA, 8.1.2	Grimes, J. and Jaber, M.	1988	Fluroxypyr, 1-methylheptyl Ester: A dietary LC50 study with the mallard (J58)	SE: The study has been used for authorisation in December 1991
IIA, 8.1.2	Grimes, J., Lynn, S. P. and Smith, G.J.	1991	Fluroxypyr: A dietary LC50 study with the mallard (J66)	SE: The study has been used for authorisation in December 1991
IIA, 8.1.3	Beavers, J., Lloyd, D. and Jaber, M.	1988	Fluroxypyr 1-methylheptyl ester: ((4-amino-3,5-dichloro -6-fluoro-2-pyridinyl)oxy)acetic acid, 1-methylheptyl ester: A pilot reproduction study with the mallard ( <i>Anas platyrhynchos</i> ) (J61)	SE: The study has been used for authorisation in December 1991
IIA, 8.1.3	Beavers, J., Lloyd, D. and Jaber, M.	1988	Fluroxypyr, 1-methylheptyl ester: ((4-amino-3,5-dichloro -6-fluoro-2-pyridinyl)oxy)acetic acid, 1-methylheptyl ester: A pilot reproduction study with the bobwhite ( <i>Colinus virginianus</i> ) (J63)	SE: The study has been used for authorisation in December 1991
IIA, 8.1.3	Beavers, J. B., Hoxter, K. A., Nichols, L., Hawrot, R. and Jaber, M. J.	1989	Fluroxypyr 1-methylheptyl ester herbicide, ((4-amino-3,5-dichloro -6-fluoro-2-pyridinyl)oxy)acetic acid, 1-methylheptyl ester: A one-generation reproduction study with the mallard ( <i>Anas platyrhynchos</i> ) (J62)	SE: The study has been used for authorisation in December 1991 IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991
IIA, 8.1.3	Beavers, J. B., Hawrot, R. and Jaber, M. J.	1989	Fluroxypyr 1-Methylheptyl ester herbicide, ((4-amino-3,5-dichloro -6-fluoro-2-pyridinyl)oxy)acetic acid, 1-methylheptyl ester: A one-generation reproduction study with the bobwhite ( <i>Colinus virginianus</i> ) (J64)	SE: The study has been used for authorisation in December 1991
IIA, 8.2.1	Douglas, M. T., Stonehever, R. O. and Macdonald, I.	1989	Prolonged Toxicity of Fluroxypyr-1-Methyl Heptyl Ester to Rainbow Trout ( <i>Salmo gairdneri</i> ) (J9)	DE: The study has been submitted in 1995 in a national authorisation SE: The study has been used for authorisation in December 1991

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IIA, 8.2.1	Dill, D. C. and Bartlett, E. A.	1989	Fluroxypyr 1-Methylheptyl Ester: Evaluation of the Toxicity to the Bluegill ( <i>Lepomis macrochirus Rafinesque</i> ) (J7)	SE: The study has been used for authorisation in December 1991
IIA, 8.2.1	Sewell, I. G. and Bartlett, A. J.	1996	Fluroxypyr Pyridinol: Acute Toxicity to Rainbow trout ( <i>Oncorhynchus mykiss</i> ) (J260) owner: DowElanco Report No. 291/077	
IIA, 8.2.1	Weinberg, J. T., Richardson, C. H., Rick, D. L. and Piaseck, D. A.	1991	Fluroxypyr 1-Methylheptyl Ester: Evaluation of the acute toxicity to the Rainbow Trout ( <i>Oncorhynchus mykiss Walbaum</i> ) (J4) owner: DowElanco Report No. ES-DR-0186-1887-18	FR: The study has been used for authorisation January 1996 (09.01.96) SE: The study has been used for authorisation in December 1991
IIA, 8.2.1	Weinberg, J. T., Richardson, C. H., Rick, D. L. and Piaseck, D. A.	1991	Fluroxypyr: Evaluation of the acute toxicity to the Bluegill ( <i>Lepomis macrochirus Rafinesque</i> ). (J25) owner: DowElanco Report No. ES-DR-0170-8550	
IIA, 8.2.2	Douglas, M. T., Halls, R. W. S., Macdonald, I. A.	1989	The prolonged toxicity of Fluroxypyr acid to Rainbow trout ( <i>Salmo gairdneri</i> ) (J27)	DE: The study has been submitted in 1990 in a national authorisation FR: The study has been used for authorisation January 1996 (09.01.96) SE: The study has been used for authorisation in December 1991
IIA, 8.2.3	Ritter, A.	1989	Comments on the bioaccumulation study with 14C furoxypyr-1 MHE. (J10)	SE: The study has been used for authorisation in December 1991
IIA, 8.2.4	Weinberg, J. T., Milazzo, D. P., Servinski, R. F. and Rick, D. L.	1989	Fluroxypyr, 1-methylheptyl ester: Evaluation of the acute toxicity to the Water Flea, <i>Daphnia magna straus</i> . (J13)	DE: The study has been submitted in 1995 in a national authorisation FR: The study has been used for authorisation January 1996 (09.01.96)

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IIA, 8.2.5	Wüthrich, V.	1993	Influence of Fluroxypyr 1-Methylester on the Reproduction of <i>Daphnia magna</i> under Flow-through conditions at pH 7. (J14)	DE: The study has been submitted in 1993 in a national authorisation
IIA, 8.2.5	Sewell, I. G. and Bartlett, A. J.	1996	Fluroxypyr Pyridinol: Acute Toxicity to <i>Daphnia magna</i> . (J261) owner: DowElanco Report No. 291/076	
IIA, 8.2.6	Cowgill, U. M. Milazzo, D. P. and Murphy, P. G.	1988	Five-day toxicity of fluroxypyr (DOWCO 433) to <i>Selenastrum capricornutum prinz</i> , a freshwater green alga. (J33)	FR: The study has been used for authorisation January 1996 (09.01.96)
IIA, 8.2.6	Hughes, J. S., Alexander, M. M.	1991	The toxicity of Fluroxypyr 1-Methylheptyl ester to <i>Selenastrum capricornutum</i> (J16)	DE: The study has been submitted in 1993 in a national authorisation SE: The study has been used for authorisation in December 1991
IIA, 8.2.6	Douglas, M. T., Bell, G., Macdonald, I. A.	1992	The algistatic activity of Fluroxypyr 1-Methylheptyl Ester, tech. (J15)	DE: The study has been submitted in 1993 in a national authorisation FR: The study has been used for authorisation January 1996 (09.01.96) SE: The study has been used for authorisation in December 1991
IIA, 8.2.7	Sewell, I. G. and Bartlett, A. J.	1996	Fluroxypyr Pyridinol: Algal Inhibition Test. (J262) owner: DowElanco Report No. 291/075	
IIA, 8.2.8	Cowgill, U. M. Milazzo, D. P. and Murphy, P. G.	1988	The Fourteen-day toxicity of Fluroxypyr (DOWCO 433) to <i>Lemna gibba</i> L. G-3 (Duckweed). (J35)	DE: The study has been submitted in 1989 in a national authorisation UK: The study has been used in 02/98 for a national authorisation.

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IIA, 8.2.8	Kirk, H. D. et al	1999	Phytotoxicological evaluation of Starane 180 (EF-1463) on exposed aquatic plant, duckweed <i>lemna gibba</i> L G-3. (J144) Dow Chemical Company DECO-HET-DR-0360-2082-001	
IIA, 8.3.2	Heimbach, U.	1990	Effects of Starane 180 (EF1018) on the Carabid Beetle ( <i>Poecilus cupreus</i> ) using WPRS/IOBC Standard Laboratory Methods. (J79)	DE: The study has been submitted in 1995 in a national authorisation FI: The study has been used for authorisation in April 1992 (22.4.1992) IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991
IIA, 8.3.2	Samsoe-Petersen, L.	1990	Effects of Tristar (EF838), XRD-535 (EF1020) and Starane 180 (EF1018) on the Staphylinid Beetle ( <i>Aleochara bilineata</i> ) using a Standard WPRS/IOBC Laboratory Method. (J80)	DE: The study has been submitted in 1995 in a national authorisation FI: The study has been used for authorisation in April 1992 (22.4.1992) IRL: The study has been used as a basis for a national regulatory decision on 26 February 1991
IIA, 8.3.2	Heimann, D., Hof, A., Römbke, J., Vickus, P.	1992	Study of acute toxicity of STARANE 180 on <i>Pardosa spp. (Araneae)</i> (J82)	DE: The study has been submitted in 1995 in a national authorisation
IIA, 8.3.2	Mead-Briggs, M.	1996	A laboratory study to evaluate the side-effects of the herbicide fluroxypyr-BPE 400 EW (EF-1354) on the parasitic wasp <i>Aphidius rhopalosiphi</i> . (J118) GHE-P-4951	UK: The study has been used in 02/98 for a national authorisation.
IIA, 8.3.2	Miles, M.	1997	A laboratory test to evaluate the effects of Starane 2 EF-689 on the parasitic wasp <i>Aphidius rhopalosiphi</i> . (J141) Dow Elanco Europe GHE-P-6085	DE: The study has been submitted in 1998 in a national authorisation

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IIA, 8.3.2	Bienert, U.	1997	Effects of Starane 2 (EF-689) on predatory mites <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) in the laboratory. (J142) GHE-P-6879	DE: The study has been submitted in 1998 in a national authorisation
IIA, 8.3.2	Riches, M. N.	1999	An extended laboratory study on barley seedlings test to assess the side effects of Starane 2 EF-689 on the parasitic wasp <i>Aphidius rhopalosiphi</i> . (J141A) Dow AgroSciences GHE-P-7880	DE: The study has been submitted in 1999 in a national authorisation
IIA, 8.3.6	Knowles, S. and Jenkins, W. R:	1991	Ready biodegradability of fluroxypyr-1-methylheptyl ester (Modified Sturm Test). (K39) GHE-P-2439	
IIA, 8.4.1	Rees, P. B.	1996	Fluroxypyr Methoxypyridine: Acute toxicity study in the earthworm (Artificial soil test) (J252)	
IIA, 8.4.1	Johnson, A. J.	1994	Fluroxypyr methyl heptyl ester: Acute toxicity (LC50) to the Earthworm (J86A) owner: DowElanco Report No. DWC 692/932394	
IIA, 8.4.2	Meinerling, M., Lührs, U.	1999	Effects of Starane 180 (EF-1463) on reproduction and growth of earthworms <i>eisenia fetida</i> (Savigny 1826) in artificial soil (J143) GHE-T-909	
IIA, 8.5	Forster, J.	1996	A laboratory assessment of the effects of fluroxypyr methoxypyridine on soil microflora respiration and nitrogen turnover according to BBA guideline VI 1-1 (1990). (J251)	
IIA, 8.7	Barnes, S. P.	1998	Starane 180 (EF-1463) activated sludge – Respiration inhibition test. (J145) Dow Chemical Company GHE-T-883	