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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

E1 - Plant health

flupyrsulfuron-methyl

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COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION SERVICES

FINAL

Review report for the active substance **flupyrsulfuron-methyl**

Finalised in the Standing Committee on Plant Health at its meeting on **27 April 2001** in view of the inclusion of flupyrsulfuron-methyl in Annex I of Directive 91/414/EEC.

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of the new active substance DPX KE 459 (flupyrsulfuron-methyl), made in the context of the work provided for in Articles 5 and 6 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.

In accordance with the provisions of Article 6(2) of Directive 91/414/EEC, the French authorities received on 26 October 1995 an application from DU PONT DE NEMOURS (France) SA, hereafter referred to as the applicant, for the inclusion of the active substance Flupyrsulfuron-methyl in Annex I to the Directive. The French authorities indicated to the Commission on 22 July 1996 the results of a first examination of the completeness of the dossier, with regard to the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive. Subsequently, and in accordance with the requirements of Article 6(2), a dossier on Flupyrsulfuron-methyl was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on Plant Health in the meeting of the working group 'legislation' thereof on 16 August 1996, during which the Member States confirmed the receipt of the dossier.

In accordance with the provisions of Article 6(3), which requires the confirmation at Community level that the dossier is to be considered as satisfying, in principle, the data and information requirements provided for in Annex II and, for at least one plant protection product containing the active substance concerned, in Annex III to the Directive and in accordance with the

procedure laid down in Article 20 of the Directive, the Commission confirmed in its Decision 97/164/EC¹ of 17 February 1997 that these requirements were satisfied.

Within the framework of that decision and with a view to the further organisation of the works related to the detailed examination of the dossier provided for in Article 6(2) and (4) of Directive 91/414/EEC, it was agreed between the Member States and the Commission that France would, as Rapporteur Member State, carry out the detailed examination of the dossier and report the conclusions of its examination accompanied by any recommendations on the inclusion or non-inclusion and any conditions relating thereto, to the Commission as soon as possible and at the latest within a period of one year.

France submitted to the Commission on 2 December 1997 the report of its detailed scientific examination, hereafter referred to as the draft report, including, as required, a recommendation concerning the possible inclusion of Flupyr-sulfuron-methyl in Annex I to the Directive.

On receipt of the draft report, the Commission forwarded it for consultation to all the Member States on 9 December 1997 as well as to Du Pont de Nemours (France) SA being the sole applicant on 18 December 1997.

The Commission organised further an intensive consultation of specialised scientific experts from a representative number of Member States, to review the draft 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 1998 to July 1998.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole applicant on 23 September 1998.

The dossier, draft report and the peer review report (i.e. full report) including in particular an outline resumé of the remaining technical questions, 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 December 1998 to April 2001, and was finalised in the meeting of the Standing Committee on 27 April 2001.

The present review report contains the conclusions of this final examination; given the importance of the draft report, the peer review report (i.e. full report) and the comments and

DPX KE 459 (flupyr-sulfuron-methyl)¹ OJ No L 64, 05.03.1997, p.17.

² Opinion of the scientific Committee on Plants regarding the inclusion of DPX KE 459 (flupyr-sulfuron-methyl) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market

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.

These documents were also submitted to the Scientific Committee for Plants for separate consultation on 15 July 1999. The report of this Committee was formally adopted on 30 November 2000³.

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 2001/49/EC concerning the inclusion of flupyrsulfuron-methyl in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing flupyrsulfuron-methyl 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 parallel with the provisions of Article 7(6) of Regulation 3600/92 for existing active substances, the Commission and the 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 the applicant.

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 possession of 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 Flupyrsulfuron-methyl 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 Flupyrsulfuron-methyl containing plant protection product for which Member States will grant or review the authorisation.

³ Opinion of the scientific Committee on Plants regarding the inclusion of DPX KE 459 (flupyrsulfuron-methyl) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market

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

- Herbicide for use in cereals

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

4. Specific conclusions highlighted in this evaluation

4.1 Residues of DPX KE 459 (flupyr-sulfuron-methyl)

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) for a 60 kg adult is < 0.5 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). This low intake value reflects the current limited use pattern for this active substance.

For infants, toddler and child this figure was respectively 1.30%, 1.23% and 0.82% of the of the Acceptable Daily Intake (ADI)

4.2 Exposure of operators, workers and bystanders

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

4.3 Environment

The review has concluded that under the proposed and supported conditions of uses there are no unacceptable effects on the environment, as required in Article 4 (1)(b)(iv) and (v) of Council Directive 91/414/EEC, provided that certain conditions are taken into account as detailed in section 7 of this report.

5. Identity and Physical/chemical properties

The main identity and the physical/chemical properties of Flupyr-sulfuron-methyl are given in Appendix I.

The active substance shall have a minimum purity of 903 g/kg technical product.

The review has established that for the active substance notified by the applicant (Du Pont De Nemours (France) SA), none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

6. Endpoints and related information

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

7. 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 Flupyrsulfuron-methy

On the basis of the proposed and supported uses, the following particular issues have been identified which require particular and short term (within 12 months at the latest) attention from the Member States, in the framework of authorisations to be granted, varied or withdrawn, as appropriate:

- Leaching to groundwater: Particular attention should be given to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or extreme climatic conditions.

8. List of studies to be generated

- No further studies were identified which were considered at this stage, and under the current inclusion conditions necessary in relation to the inclusion of Flupyrsulfuron-methy in Annex I.

9. Information on studies with claimed data protection

For information of any interested parties, Appendix III gives information about the studies for which the applicant has claimed data protection and which are not present in the original dossier neither mentioned in the monograph. 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.

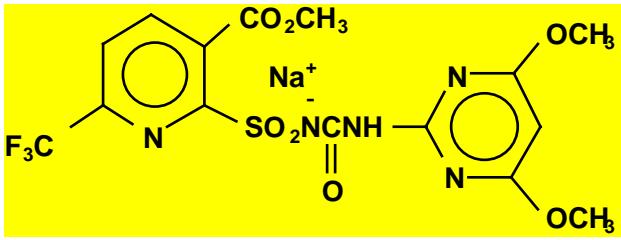
10. Updating of this review report

The technical information in this report may require periodic updating 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 flupyrsulfuron methyl in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

FLUPYRSULFURON-METHYL

Common name (ISO)	Flupyrsulfuron-methyl
Chemical name (IUPAC)	2-(4,6-dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)-6-trifluoromethylnicotinate monosodium salt
Chemical name (CA)	Methyl 2-[[[(4,6-dimethoxy-2-pirimidinyl)amino]carbonyl]-amino]sulfonyl]-6-(trifluoromethyl)-3-pyridinecarboxylate sodium salt
CIPAC No	577
CAS No	144740-54-5
EEC No	Not available
FAO SPECIFICATION	Not available
Minimum purity	903 g/kg
Molecular formula	C ₁₅ H ₁₃ F ₃ N ₅ O ₇ Na
Molecular mass	487.4
Structural formula	

Melting point	Not determined because of decomposition of the active substance (decomposition at 165-170°C)													
Boiling point	Not required													
Appearance	white solid with chalk-like odour	(93.4 %)												
Relative density	1.55 (95 %)													
Vapour pressure	< 1x10 ⁻⁹ Pa at 20°C													
Henry's law constant	< 10 ⁻⁸ Pa m ³ mol ⁻¹ at pH 5 < 10 ⁻⁹ Pa m ³ mol ⁻¹ at pH 6													
Solubility in water	pH5 : 0.06 g/l at 20°C (93.4 %) pH6 : 0.61 g/l at 20°C pH7 : instability of the solution													
Solubility in organic solvents (g/l at 20 °C)	Acetone : 3.1 (93.4 %) Acetonitrile : 4.3 Benzene : 0.028 Dichloromethane : 0.60 Ethyl acetate : 0.49 Hexane : <0.001 Methanol : 5.0 n-octanol : 0.19													
Partition co-efficient (log P _{OW})	pH5 : 9.17 (Pow = 0.96)	(93.4 %)												
	pH6 : 1.16 (Pow = 0.06)													
Hydrolytic stability (DT ₅₀)	pH5 : DT ₅₀ = 44 days pH7 : DT ₅₀ = 12 days pH9 : DT ₅₀ = 0.42 days													
Dissociation constant	pKa = 4.94 (93.4 %)													
Quantum yield of direct photo-transformation in water at ε > 290 nm	1.59 10 ⁻³ mol x einstein ⁻¹ at pH7													
Flammability	not flammable													
Explosive properties	not explosive													
UV/VIS absorption (max.)	ε = 1.92 10 ⁴ l mol ⁻¹ cm ⁻¹ (95 %) No absorption >290 nm													
Photostability in water (DT ₅₀)	DT50 (days) DPX JE138 <table><tr><td></td><td>Sunlight</td><td>Photodegradation</td></tr><tr><td>pH5 :</td><td>40</td><td>470</td></tr><tr><td>pH7 :</td><td>8.7</td><td>33</td></tr><tr><td>pH9 :</td><td>0.39</td><td>5.4</td></tr></table>			Sunlight	Photodegradation	pH5 :	40	470	pH7 :	8.7	33	pH9 :	0.39	5.4
	Sunlight	Photodegradation												
pH5 :	40	470												
pH7 :	8.7	33												
pH9 :	0.39	5.4												

APPENDIX II

ENDPOINTS AND RELATED INFORMATION

FLUPYRSULFURON-METHYL

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	60 % in males within 120 h, based on urinary excretion.
Distribution:	Widely distributed.
Potential for accumulation:	Low potential.
Rate and extent of excretion:	> 90 % within 96 h mainly in urine.
Toxicologically significant compounds:	Parent compound, and its metabolites.
Metabolism in animals:	Metabolisation by cyclisation and cleavage of the molecule.

Acute toxicity

Rat LD ₅₀ oral:	> 5000 mg/kg bw
Rat LD ₅₀ dermal:	> 2000 mg/kg bw
Rat LC ₅₀ inhalation:	> 5.8 mg/l
Skin irritation:	Non-irritant
Eye irritation:	Non-irritant
Skin sensitization:	Not a sensitiser (Magnusson and Kligman)

Short term toxicity

Target / critical effect:	Indications of low toxicity: body-weight gain and food efficiency (Rat), liver (Rat)
Lowest relevant oral NOEL:	12 - month oral dog : 500 ppm (13.6 mg/kg bw/day).
Lowest relevant dermal NOAEL/NOEL	no study required.
Lowest relevant inhalation NOAEL/NOEL	no study required.

Genotoxicity

Negative in vitro and in vivo.

Long term toxicity and carcinogenicity

Target / critical effect:

Indications of liver toxicity

Lowest relevant NOAEL:

18-month oral mouse : 25 ppm (3.51 mg/kg bw/day)

Carcinogenicity:

(Liver tumours in mice)

Reproductive toxicity

Target/critical effect - Reproduction:

Decrease pup weight at parental toxicity dose level

Lowest relevant reproductive
NOAEL/NOEL:

1 500 ppm (84 mg/kg bw/day) , two generations rat study

Target/critical effect - Developmental
toxicity

Reduced foetal weight, retarded ossification

Lowest relevant developmental NOEL:

20 mg/kg bw/day (rat)

Delayed neurotoxicity

No evidence of neurotoxicity in standard toxicity tests and functional observation battery test.

Other toxicological studies

No other studies submitted (not necessary).

Medical data

No case of intoxication reported (New substance).

Summary

ADI

Value	Study	Safety factor
0.035 mg/kg	18 month mouse	100
0.08 mg/kg	1 year dog	100, corrected by 60 % oral absorption
Not allocated (not necessary)		
Not allocated (not necessary)		
Not allocated (not necessary)		

AOEL systemic :

AOEL inhalation

AOEL dermal

ARfD (Acute Reference Dose)

Dermal absorption

10 % default value (no study required)

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

mineralization after 100 days:

non-extractable residues:

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

% of applied (range and maximum)

< 2 % (both labels)

29 % (pyridine label, 90 days) - 41 % (1 year)

39 % (pyrimidine label, 90 days) - 34 % (1 year)

IN-JV460 max. 24 %

IN-KY374 max. 32 %

Supplemental studies

Anaerobic:

IN-JV460 max. 42.1 %

IN-KV996 max. 11.8 %

Bound residue max. 30 %

Soil photolysis:

IN-JE127 max. 13.1 %

No significant effect of light

Remarks:

None

Rate of degradation

Laboratory studies:

DT₅₀lab (20 °C, aerobic):

Lab. : first order (R^2 not reported)

Field : non linear regression ($R^2 = 0.74 - 0.90$)

soil	sa. l. (UK)	l. (G)	sa. l. (F)	si. l. (F)	cl. l. (UK)
OM %	2.6	2.2	1.2	2.2	3.3
pH	6.5	6.1	7.6	6.4	7.1
DT50	26/24	16/16	8/8	16/18	10/9
(days at 50/70 % MWHC)					
Metabolites - first approach					
IN-JV460 : 373 days (UK sandy loam soil)					
IN-KC576 : 248 days (UK sandy loam soil)					
Metabolites – modelling					
IN-JV460 : 120 days (UK sandy loam soil)					
IN-KC576 : 30 days (UK sandy loam soil)					

DT_{90lab} (20 °C, aerobic):

soil	sa. l. (UK)	l. (G)	sa. l. (F)	si. l. (F)	cl. l. (UK)
	85/80	53/53	27/27	52/60	32/30

(days at 50/70 % MWHC)

DT_{50lab} (10°C, aerobic):

58 days (UK sandy loam soil, 50 % MWHC)

DT_{50lab} (20°C, anaerobic):

31 days (UK sandy loam soil)

Field studies (country or region):

DT_{50f} from soil dissipation studies:

DT_{50f}:

10 d UK site (cl. l. soil , 1.9% OC, pH 7.3), Dec. appl.
 11 d UK site, April appl.
 6 d F site (sa. si. l. soil, 1.1% OC, pH 7.6), Dec. appl.
 6 d US Delaware site (si. l. soil, 2.1% OC, pH 5.8),
 May appl.

Metabolites

IN-JV460 : 49 / 231 d (UK site, Dec. / April appl.),
 128 d (F site), 180 d (US site).
 max. amounts 13-27 %

IN-KC576 : 150 d

only significant at the US site, max. 58 %

No other significant metabolites

DT_{90f} from soil dissipation studies:

DT_{90f}:

104 - 70 - 35 – 123 d (same conditions as above)

Soil accumulation studies:

- DT_{50lab} for IN-JV460 estimated to be 120 d in the UK sandy loam by modelling (instead of 373 d, first approach). Max. concentration 4 µg/kg after 65 d (modelling PRZM3, 10 g as/ha). For yearly application, estimated accumulation would be < 1 µg/kg (lower plateau level).

- DT_{50lab} for IN-KC576 estimated to be 30 d in the UK sandy loam by modelling (instead of 248 d, first approach). DT_{50f} not reliable (R² 0.37). Accumulation not relevant.

Soil residue studies:

See above

Remarks:

e.g. effect of soil pH on degradation rate:

None

Adsorption/desorption

K_f / K_{oc} :

K_d

Koc derived from Kf (or from Kd)						
Soil	OC %	pH	a.s.	KC576	JV460	KY374
sa. l. (UK)	1.5	7.4	15	19	196	(39)
sa. l. (F)	0.7	8.8	19	26	148	(12)
si. l. (F)	1.3	7.4	22	-	-	-
cl. l. (UK)	1.9	8.1	23	(48)	(106)	(4)
Speyer 2.2	2.3	5.8	22	(22)	(79)	(17)
l. (G)	1.3	6.6	(55)	21	202	(3)
si. l. (G)	0.9	8.0	(34)	-	-	-
sa. l. (F)	2.1	7.9	(30)	-	-	-
si. l. (US)	1.8	5.7	-	(40)	(65)	(24)

Mobility

Laboratory studies:

- Column leaching:

No data required

- Aged residue leaching:

UK sandy loam, 17 d incubation
 leachates IN-JV460 32 %
 a.s. 5.7 %
 others < 5 % each

Field studies:

Lysimeter/Field leaching studies:

Field dissipation studies
F site (Nambenheim) and UK site (Alconbury)
 15 - 30 cm < 13.5 % AR (a.s. < 2 %)
 30 - 60 cm max. 5.7 - 9.8 % AR (20 % one
 sample)
 60 - 90 cm 2 samples with 2.4 and 15.2 % AR
USA site (Newark, Delaware)
 0 - 5 % AR in 15 - 30 cm, 30 - 60 cm and 60 - 90
 cm

Remarks:

None

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation :

pH = 5 (20° C) DT50 = 44 d
 metabolites: IN-KT982 (15.1 %),
 IN-JV460 (30.7 %),
 IN-JE127 (12.5 %),
 IN-J290 (11.4 %)

pH = 7 (20° C) DT50 = 12 d
 metabolites : IN-JV460 (78 %), stable

pH = 9 (20° C) DT50 = 0.4 d
 metabolite : IN-JV460 (96.7 %),
 stable (DT50 = 320 d)

Relevant metabolites:

IN-JV460 (hydrolysis)

Photolytic degradation:

pH = 5 (20° C) DT50 = 40 d
 metabolites : IN-KT982 (< 10 %),
 IN-JV460 (< 10 %)

pH = 7 (20° C) DT50 = 8.7 d
 metabolites : IN-KV994 (10.3 %),
 IN-KF526 (21 %)

pH = 9 (20° C) DT50 = 0.39 d
 metabolites : IN-JV460 (DT50 = 4.5 d)

Relevant metabolites

IN-KF526 and IN-KV994 (photolysis)

Biological degradation

Readily biodegradable:

No

Degradation in - DT₅₀ water

3-6 d

water/sediment - DT₉₀ water

20-36 d

- DT₅₀ whole system

3-6 d

- DT₉₀ whole system

25-46 d

Distribution in water / sediment systems
 (active substance)

mainly in water, < 9.1 % in sediment

Distribution in water / sediment systems
 (metabolites)

IN-JV460 max. 69 % (after 30 d) in water, 24 %
 (after 100 d) in sediment

Accumulation in water and/or sediment:

IN-JV460 < 0.005 µg/l in water and < 0.0003 µg/kg
 in sediment (EXAMS II, 10 g as/ha, spray drift 0.6 %
 at 5 m). Simple calculation based on data from water-
 sediment studies would give < 0.014 µg/l (69 %) and

< 0.019 µg/kg (24 %)

Degradation in the saturated zone

no data available, not required

Remarks:

no particular remarks

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

< 10 ⁻⁹ Pa (20° C)

Henry's law constant:

< 10 ⁻⁸ Pa m ³ mol ⁻¹ at pH 5
--

< 10 ⁻⁹ Pa m ³ mol ⁻¹ at pH 6
--

Photolytic degradation

Direct photolysis in air:

No data required

Photochemical oxidative degradation in air (DT₅₀):

0.053 d

Volatilisation:

from plant surfaces : 0.1%

from soil : 2.8%

Remarks:

None

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals
Acute toxicity to birds:
Dietary toxicity to birds:
Reproductive toxicity to birds:
Long term oral toxicity to mammals.

LD50 > 5 000 mg/kg
LD50 (quail/mallard duck) > 2 250 mg/kg bw
LC50 (quail/mallard duck) > 5 620 mg/kg bw
NOEC (mallard duck) = 200 ppm
NOAEL (90 d, rat) = 2 000 ppm

Aquatic Organisms

Active substance:

Acute toxicity fish:
Chronic toxicity fish

Bioaccumulation fish:

Acute toxicity invertebrate:
Chronic toxicity invertebrate:
Acute toxicity algae:

Aquatic plants:

Chronic toxicity sediment dwelling organism:

LC50 (trout): 470 mg/l
NOEC (trout, 28 d): 130 mg/l
NOEC (trout, 90 d): 9.2 mg/l
Not required
EC50 (daphnids): 721 mg/l
NOEC (daphnids, 21 d): 16 mg/l
EC50 (<i>S. capricornutum</i>): 0.0037 mg/l
EC50 (<i>A. flos-aquae</i>): 0.099 mg/l
EC50 (<i>L. gibba</i>): 0.0025 mg/l
not required

Preparation (WG 50%):

Acute toxicity algae:

EC50 (<i>S. capricornutum</i>): 0.0091 mg preparation/l

Metabolites:

Acute toxicity fish:

Acute toxicity invertebrate:

Acute toxicity algae:

LC50 (trout, IN-KF526): > 10 mg/l
LC50 (trout, IN-KV994): > 0.001 mg/l
EC50 (daphnids, IN-KF526): > 0.5 mg/l
EC50 (daphnids, IN-KV994): > 0.001 mg/l
EC50 (<i>S. capricornutum</i> , IN-JV460): > 0.0101 mg/l

Honeybees

Acute oral toxicity:

LD50 > 30 µg a.s./bee

Acute contact toxicity:

LD50 > 25 µg a.s./bee

Other arthropod species

*T. pyri*beneficial capacity: 7.1 % effect
(0.016 kg a.s./ha DPX-KV953 ¹)*A. rhopalosiphi*beneficial capacity: 41.1 % effect
(0.016 kg a.s./ha DPX-KV953 ¹)*A. rhopalosiphi*beneficial capacity: -6 % effect
(0.016 kg a.s./ha DPX-KS999 ²)*C. carnea*beneficial capacity: -56 % effect
(0.016 kg a.s./ha DPX-KV953 ¹)*P. cupreus*beneficial capacity: -9.9 % effect
(0.016 kg a.s./ha DPX-KV953 ¹)¹ DPX-KV953 50DF : 33.3% flupyrsulfuron-methyl + 16.7% metsulfuron-methyl² DPX-KS999 50DF : 16.7% flupyrsulfuron-methyl + 33.3% carfentrazone-ethyl

Earthworms

Active substance:

Acute toxicity:

LC50 > 1000 mg/kg

Reproductive toxicity:

not required

Metabolite:

Reproductive toxicity IN-JV460:

NOEC = 0.065 mg/kg soil

Soil micro-organisms

Nitrogen mineralization:

20 g a.s./ha: no effect

Carbon mineralization:

20 g a.s./ha: no effect

APPENDIX III**FLUPYRSULFURON-METHYL**

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	Reports ² on previous use in granting national authorizations
AII 2.2	Huntley, K; Edgar, L	1999	Determination of the Density of Flupyrsulfuron Methyl ABC Laboratories DuPont-1472 GLP/unpublished	
AII 2.5.1	Huntley, K; Ambroz, J	1999	Determination of the Ultraviolet-Visible Absorption of Flupyrsulfuron Methyl ABC Laboratories DuPont-1473 GLP/unpublished	
AII 2.10	Barefoot, AC; Schmuckler, ME	1996	Calculation of the Second-Order Rate Constant and Associated Half-Life T(1/2)E for the Reaction of DPX-KE459 in the Gas Phase in the Troposphere Using the Method of Atkinson DuPont Agricultural Products NA*/unpublished	
AII 2.11	Schmuckler, ME; LeSieur, LB	1994	Thermal Stability of DPX-KE459 DuPont Agricultural Products AMR 2727-93 GLP/unpublished	
AII 2.14	Huntley, K; Edgar, L	1999	Surface Tension Determination of Flupyrsulfuron Methyl ABC Laboratories DuPont-1471 GLP/unpublished	
AIII 2.7.1	Dejean, P	1998	Shelf Life Aging of 2 Years (DPX-KE459) DuPont Agricultural Products AMR 3503-95 GLP/unpublished	

² 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 ² on previous use in granting national authorizations
AII 4.2.1	Dubey, L	1995	Method Validation for the Determination of Residues of DPX-KE459 in Wheat Grain, Forage and Straw by HPLC-UV/CS Battelle Geneva A-11-94-04 GLP/unpublished	
AII 4.2.2	Goodenowe, DB; Orescan, DB; Babicki, WA	1999	Multianalyte Method for the Simultaneous Quantitation and Confirmation of 21 Sulfonylurea Herbicides in Soil Using Electrospray LC-Triple-Stage Quadrupole Mass Spectrometry DuPont Agricultural Products and Covance, UK AMR 4808-97 GLP/unpublished	
AII 4.2.4	Freeman, CJ	1995	Analytical Enforcement Method for the Determination of DPX-KE459 in Air DuPont Agricultural Products AMR 3657-95 GLP/unpublished	

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
No studies submitted.				

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
AII 6.1	Barefoot, AC; Christensen, O	1998	Metabolism of DPX-JE138 in Wheat DuPont Agricultural Products AMR 2391-92 Revision No. 1 GLP/unpublished	
AII 6.3	de Bernard, PA	1996	Freezer Storage Stability of Flupyrsulfuron Methyl in Wheat (Grain and Straw) DuPont Agricultural Products AMR 2887-93 GLP/unpublished	

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
AIII 9.1.3	Esterly, DM	1996	PRZM2 Assessment of the Potential Groundwater Concentrations of Flupyr-sulfuron Methyl (DPX-KE459) and its Major Soil Degradates under European Agricultural Practices DuPont Agricultural Products AMR 4204-96 NA*/unpublished	
AIII 9.1.3	Esterly, DM	1998	Model Assessment of the Potential Groundwater Surface Water and Pond Sediment Concentrations of Flupyr-sulfuron Methyl (DPX-KE459) and its Major Degradates under European Agricultural Practices DuPont Agricultural Products DuPont-1590 NA*/unpublished	
AIII 9.1.3	Esterly, DM	1999	Model Assessment of the Potential Groundwater Concentrations of Flupyr-sulfuron Methyl (DPX-KE459) and its Major Degradates for 32 Years of Continuous Use DuPont Agricultural Products DuPont-2741 NA*/unpublished	
AIII 9.1.3	Koch Singles, S	2000	Position paper for flupyr-sulfuron methyl : calculation of half-lives of IN-JV 460, the major soil degradate of flupyr-sulfuron methyl, under field conditions DuPont-3801 revision 1 NA*/Unpublished	

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
AII 8.2.6	Hughes, JS; Williams, TL	1998	IN-JV460 (Metabolite of Flupyr-sulfuron Methyl): Influence on Growth and Reproduction of <i>Selenastrum capricornutum</i> DuPont Agricultural Products AMR 4823-97 GLP/unpublished	
AII 8.2.6	Thompson, SG	1996	DPX-KE459 Technical: Influence on Growth and Reproduction of <i>Anabaena flos aquae</i> Wildlife International AMR 4206-96 GLP/unpublished	

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
AII 8.4.2	Lührs, U	2000	IN-JV460 (metabolite of flupyrsulfuron methyl) : Effects on Reproduction and Growth of the Earthworm, Eisenia fetida (Savigny 1826), in artificial soil. DuPont-3718 GLP/Not published	

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NA' GLP not applicable to position papers and modelling reports. The basic information used for these papers and reports are GLP compliant.