

EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Pyraflufen-ethyl  
SANCO/3039/99-FINAL  
2 July 2002

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

Review report for the active substance pyraflufen-ethyl

Finalised in the Standing Committee on Plant Health at its meeting on 29 June 2001 in view of the inclusion of Pyraflufen-ethyl 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 pyraflufen-ethyl, 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 Belgian authorities received on 16 June 1997 an application from Nihon Nohyaku Co. Ltd., hereafter referred to as the applicant, for the inclusion of the active substance Pyraflufen-ethyl in Annex I to the Directive. Belgian authorities indicated to the Commission on 2 December 1997 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 Pyraflufen-ethyl 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 December 1997, 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 98/242<sup>1</sup> of 20 March 1998 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 Belgium 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.

Belgium submitted to the Commission on 8 July 1999 the report of its detailed scientific examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of Pyraflufen-ethyl in Annex I to the Directive.

On receipt of the draft assessment report, the Commission forwarded it for consultation to all the Member States as well as to Nihon Nohyaku Co. Ltd. being the applicant on 20 September 1999.

The Commission organised further an intensive consultation of specialised scientific experts from a representative number of Member States, to review the draft assessment report and the comments received thereon (peer review), in particular on each of the following disciplines :

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

The meetings for this consultation were organised on behalf of the Commission by the Pesticide Safety Directorate (PSD) in York, United Kingdom, from November 1999 to July 2000.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole applicant on 15 June 2001.

The dossier, draft assessment 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 July 2000 to June 2001, and was finalised in the meeting of the Standing Committee on 29 June 2001.

The present review report contains the conclusions of this final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the peer review as basic information for the final

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<sup>1</sup> OJ No L96, 28.03.1998, p.45.

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. The report of this Committee was formally adopted on 7 March 2001. (SCP/PYRA/final<sup>2</sup>).

## **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 2001/87/EC<sup>3</sup> concerning the inclusion of Pyraflufen-ethyl in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing Pyraflufen-ethyl 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 Pyraflufen-ethyl 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

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<sup>2</sup> Opinion of the scientific Committee on Plants regarding the inclusion of pyraflufen-ethyl in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market. Opinion adopted 7 March 2001.

<sup>3</sup> OJ L276, 19.10.2001, p.17

VI of Directive 91/414/EEC, for each Pyraflufen-ethyl containing plant protection product for which Member States will grant or review the authorisation.

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

- herbicide 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 which are highlighted in this evaluation**

##### **4.1 Residues of pyraflufen-ethyl in foodstuffs**

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 0.033 % 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.

##### **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 Ecotoxicology**

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 7 of this report.

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

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

The active substance shall have a minimum purity of 956 g/kg technical product.

The review has established that for the active substance notified by the applicant (Nihon Nohyaku Co. Ltd.), 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 pyraflufen-ethyl**

On the basis of the proposed and supported uses, the following particular issues have been identified as requiring particular and short term (within 12 months at the latest) attention from the 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 algae and aquatic plants and should apply, where appropriate, risk mitigation measures.
- The acid metabolite (designated as E1) has a potential for leaching which might require particular attention in vulnerable areas to ensure protection of groundwater.

## **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 Pyraflufen-ethyl 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 draft review report. 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**

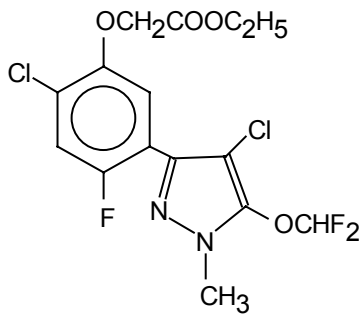
The technical information in this report may require periodic updating to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Such adaptations will be examined and finalised in the Standing Committee on

Plant Health, in connection with any amendment of the inclusion conditions for Pyraflufen-ethyl in Annex I of the Directive.

# APPENDIX I

## Identity, physical and chemical properties

### Pyraflufen-ethyl

<b>Common name (ISO)</b>	Pyraflufen-ethyl
<b>Chemical name (IUPAC)</b>	Ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetate
<b>Chemical name (CA)</b>	Ethyl 2-chloro-5-[4-chloro-(5-difluoromethoxy)-1methyl-1 <i>H</i> -pyrazol-3-yl]-4-fluorophenoxyacetate
<b>CIPAC No</b>	605
<b>CAS No</b>	129630-19-9
<b>EEC No</b>	Not allocated
<b>FAO SPECIFICATION</b>	No FAO specification
<b>Minimum purity</b>	956 g/kg
<b>Molecular formula</b>	C <sub>15</sub> H <sub>13</sub> Cl <sub>2</sub> F <sub>3</sub> N <sub>2</sub> O <sub>4</sub>
<b>Molecular mass</b>	413.18
<b>Structural formula</b>	

<b>Melting point</b>	126.4-127.2 °C (99.4% purity)
<b>Boiling point</b>	Not determinable due to decomposition above its melting point (99.4% purity).
<b>Appearance</b>	Fine white powder, without significant odour (99.4% purity); Fine cream coloured powder (some claying present), without significant odour (97.7% purity)
<b>Relative density</b>	1.565 at 24 °C (99.4% purity)
<b>Vapour pressure</b>	1.6 10 <sup>-8</sup> Pa (25°C) 4.3 10 <sup>-9</sup> Pa (20°C)
<b>Henry's law constant</b>	2.2 10 <sup>-5</sup> Pa.m <sup>3</sup> /mol (20°C)
<b>Solubility in water</b>	pH 7, 20°C: 0.082 mg/l
<b>Solubility in organic solvents</b>	at 20°C (97.7% purity): n-heptane: 234 mg/l p-xylene: 41.7 to 43.5 g/l 1,2-dichloromethane: 100 to 111 g/l methanol: 7.39 g/l acetone: 167 to 182 g/l ethyl acetate: 105 to 111 g/l
<b>Partition co-efficient (log P<sub>ow</sub>)</b>	pH 7, ambient temperature: log Pow = 3.49
<b>Hydrolytic stability (DT<sub>50</sub>)</b>	pH 4: hydrolytically stable pH 9: rapid hydrolysis (DT <sub>50</sub> at 50°C < 2.4 h) pH 7, 25°C: DT <sub>50</sub> = 13.1 d
<b>Dissociation constant</b>	Not applicable
<b>Quantum yield of direct photo-transformation in water at λ &gt; 290 nm</b>	f = 1.07%
<b>Flammability</b>	Not highly flammable.
<b>Explosive properties</b>	Not explosive.
<b>UV/VIS absorption (max.)</b>	λ = 203 nm : ε = 28700 l.mol <sup>-1</sup> .cm <sup>-1</sup> λ = 243 nm : ε = 12800 l.mol <sup>-1</sup> .cm <sup>-1</sup> λ = 291 nm : ε = 5900 l.mol <sup>-1</sup> .cm <sup>-1</sup> No further maxima between 291 and 700 nm.
<b>Photostability in water (DT<sub>50</sub>)</b>	pH 5, 20°C, Xenon lamp : DT <sub>50</sub> = 30 h



## APPENDIX II

### END POINTS AND RELATED INFORMATION

#### Pyraflufen-ethyl

#### 1 Toxicology and metabolism

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

Rate and extent of absorption:	Rapid, dose-dependent; 56 % ( urine + bile) after low dose within 2 days.
Distribution:	At 6 h, highest residues in GI tract, liver and excretory organs.
Potential for accumulation:	No accumulation
Rate and extent of excretion:	95-100 % in 24 h ( 70 % via feces ; 30% urinary)
Toxicologically significant compounds:	Parent compound, metabolites E1 and E9 Metabolism in plants and animals is similar.
Metabolism in animals:	Ester hydrolysis; N-demethylation < 1% absorbed dose eliminated unchanged

##### Acute toxicity

Rat LD50 oral:	> 5000 mg/kg bw
Rat LD50 dermal:	>2000 mg/kg bw
Rat LC50 inhalation:	> 5.03 mg/l
Skin irritation:	Non-irritant
Eye irritation:	Non-irritant
Skin sensitization (test method used and result):	Not sensitising (Maximisation test)

##### Short term toxicity

Target / critical effect:	Liver, kidney, red blood cells
Lowest relevant oral NOAEL / NOEL:	200 ppm (20 mg/kg bw/d) 90 day mouse (satellite group in 78 wk study)
Lowest relevant dermal NOAEL / NOEL:	No data, not necessary
Lowest relevant inhalation NOAEL / NOEL:	No data, not necessary

##### Genotoxicity

Not genotoxic
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##### Long term toxicity and carcinogenicity

Target / critical effect:	Red blood cells and liver in mice, urinary and biliary tract in rats.
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Lowest relevant NOAEL:	200 ppm (20 mg/kg bw/d ) 2 year mice study 400 ppm ( 20 mg/kg bw/d) 2 year rat study
Carcinogenicity:	Increased incidence of hepatocellular adenomas in mice at hepatotoxic doses, not carcinogenic in rats. Classification and labelling not appropriate.
<b>Reproductive toxicity</b>	
Target / critical effect - Reproduction:	Reduced body weight gain of pups during lactation at parental toxic doses.
Lowest relevant reproductive NOAEL / NOEL:	NOAEL <sub>syst.tox</sub> = 1000 ppm (70.8 mg/kg bw/d) NOAEL <sub>reprotox</sub> = 1000ppm ( 70.8 mg/kg bw/d)
Target / critical effect - Developmental toxicity:	Implantation loss and retardations in rabbits at maternally toxic doses (mortality).
Lowest relevant developmental NOAEL / NOEL:	20 mg/kg bw/d
<b>Delayed neurotoxicity</b>	No data, not necessary
<b>Other toxicological studies</b>	Accumulation of porphyrins in all organs except skin and Harderian glands. Inhibitor of some liver P450 dependent activities ; inhibitor of catalase. Induction of liver single cell necrosis followed by mitosis.
<b>Medical data</b>	No detrimental effects on health were found in participating personnel in manufacturing of pyraflufen-ethyl.

**Summary**

	Value	Study	Safety factor
ADI:	0.2 mg/kg bw/d	NOAEL from 2 year rat, mice study	100
AOEL systemic:	0.112 mg/kg bw/d	90 day satellite groups of 78 wk mouse carcinogenicity study	100 x 56%
AOEL inhalation:	Not necessary		
AOEL dermal:	Not necessary		
ARfD (acute reference dose):	0.2 mg/kg bw/d	Same basis as ADI and AOEL supported by rabbit teratogenesis study.	100

**Dermal absorption**

No studies; dermal absorption not higher than oral absorption (56%).
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**2 Fate and behaviour in the environment****2.1 Fate and behaviour in soil****Route of degradation****Aerobic:**

Mineralization after 100 days:

2.53%

Non-extractable residues after 100 days:

17%

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

E-1 (max 94% at d 1),  
E-2 (max 14-19%),  
E-3 (max 56-69%),

Structure of unknown2 (10%) is rather similar to the a.s. and the 3 main metabolites.

**Supplemental studies****Anaerobic:**E-1 major degradation product (max 99%)  
E-2 (max 28%)  
2.04% bound residue  
0.2% mineralization**Soil photolysis:**

No photodegradation : DT50 = 299 d

**Remarks:**

None

**Rate of degradation****Laboratory studies**

DT50lab (20 °C, aerobic):

a.s.: < 0.5 d (4 values)  
E-1: 16-53 d (4 values)  
E-2: 6-11 d (3 values)  
E-3: 153-496 d (3 values)

DT90lab (20 °C, aerobic):

a.s.: 0.8-4.0 d (4 values)  
E-1: 52-175 d (4 values)  
E-2: 20-36 d (3 values)  
E-3: 509-1648 d (3 values)

DT50lab (10 °C, aerobic):

a.s.: 1 d (1 value)  
E-1: 328 d (1 value)

DT50lab (20 °C, anaerobic):

a.s.: 1 d (1 value)  
E-1: 191 d (1 value)  
E-2: 392 d (1 value)

**Field studies (country or region)**

DT50f from soil dissipation studies:

a.s., spring: 1-7 d (4 sites in FR, UK, DE) a.s., fall: 1-3 d (4 sites in FR, UK, DE) E-1, spring: 11-44 d (4 sites in FR, UK, DE) E-1, fall: 35-71 d (4 sites in FR, UK, DE)
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DT90f from soil dissipation studies:

a.s., spring: 3-23 d (4 sites in FR, UK, DE) a.s., fall: 3-10 d (4 sites in FR, UK, DE) E-1, spring: 121-345 d (4 sites in Fr, UK, DE) E-1, fall: 115-236 d (4 sites in Fr, UK, DE) Max level E-2: 0.01 mg /kg soil Max level E-3: 0.01-0.05 mg /kg soil
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Soil accumulation studies:

Not required
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Soil residue studies:

Not required
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**Remarks:**

e.g. effect of soil pH on degradation rate

None
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**Adsorption/desorption**

Kf / Koc:

Koc (a.s., HPLC) = 1949
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Kd

Kf (E-1, 3 soils) = 2.21-3.02; Koc = 81-197 Kf (E-2, 3 soils) = 26.15-52.68; Koc = 1424-2179 Kf (E-3, 3 soils) = 52.24-114.62; Koc = 3098-4354
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pH dependence:

No
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**Mobility****Laboratory studies:**

Column leaching:

0.2 % RR in the leachate
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Aged residue leaching:

0.5 % RR in the leachate
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**Field studies:**

Lysimeter/Field leaching studies:

Not required
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**Remarks:**

None
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**2.2 Fate and behaviour in water****Abiotic degradation**

Hydrolytic degradation:

a.s. (pH 7, 25°C): 13.1 d  
a.s. hydrolytically stable at pH 4, rapidly hydrolyzed at pH 9.

Relevant metabolites:

The only hydrolysis product E-1 is stable at pH 4-7-9.

Photolytic degradation:

a.s. (20°C): 30 h (major degradate : PD1)  
E-1 (25°C): 22.1 h  
E-2 (25°C): 8.7 h  
E-3 (25°C): 29.1 h

Relevant metabolites:

E-1, E-2

**Biological degradation**

Readily biodegradable:

No

Water/sediment study:

DT50 water:

a.s.: 1-2 h,  
E-1 = 50-100 d,

DT90 water:

a.s.: 4-7 h

DT50 whole system:

a.s.: 2-2h

DT90 whole system:

a.s.: 6-7 h

Distribution in water / sediment systems  
(active substance)

a.s. mainly in water phase

Distribution in water / sediment systems  
(metabolites)E-1: mainly in water phase (83-94% after 1 d, 11-42% after 100 d)  
E-2: mainly in sediment phase (20-54% after 100 d)  
E-3: mainly in sediment phase (6-7% after 100 d)

Accumulation in water and/or sediment:

No

**Degradation in the saturated zone**

Not required

**Remarks:**

None

## 2.3 Fate and behaviour in air

### Volatility

Vapour pressure:

1.6 10 <sup>-8</sup> Pa (25°C)
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4.3 10 <sup>-9</sup> Pa (20°C)
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Henry's law constant:

2.2 10 <sup>-5</sup> Pa.m <sup>3</sup> /mol (20°C)
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### Photolytic degradation

Direct photolysis in air:

DT50 : 11.3 h
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Photochemical oxidative degradation in air

Latitude: 52° N    Season: June    DT50 : 33 h
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DT50:

Volatilisation:

No volatilisation from plant surfaces or soil.
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Remarks:

None
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### 3 Ecotoxicology

#### Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 > 5000 mg/kg bw
Acute toxicity to birds:	LD50 > 2000 mg/kg bw
Dietary toxicity to birds:	LC50 > 5000 mg/kg food
Reproductive toxicity to birds:	NOEC = 50 mg a.s./kg food
Reproductive toxicity to mammals:	NOAEL= 1000 mg a.s./kg food (70.8 mg/kg bw/d)

#### Aquatic Organisms

Acute toxicity fish:	a.s.: LC50 > 100 µg/l (96 h; <i>Oncorhynchus mykiss</i> ) E-1: LC50 > 100 000 µg/l (96 h; <i>Lepomis macrochirus</i> ) EXP31279A*: LC 50 > 60 000 µg/l (96 h; <i>Oncorhynchus mykiss</i> )
Long term toxicity fish:	E-1: NOEC = 10 000 µg/l (36 d; <i>Pimephales promelas</i> )
Bioaccumulation fish:	a.s.: BCF is not relevant (DT50 = 2h) E-1: BCF = 2.4
Acute toxicity invertebrate:	a.s. : EC50 > 100 µg/l (48 h; <i>Daphnia magna</i> ) E-1: EC50 > 120 000 µg/l (48 h; <i>D. magna</i> ) EXP31279A*: EC50 > 15 000 µg/l (48 h; <i>D. magna</i> )
Chronic toxicity invertebrate:	E-1: NOEC = 100 000 µg/l (21 d; <i>D. magna</i> )
Acute toxicity algae:	a.s. : EC50 = 0.23 µg/l (72 h; <i>Selenastrum capricornutum</i> ) E-1: EC50 = 2.2 µg/l (72 h; <i>S. capricornutum</i> ) E-2: EC50 = 0.16 µg/l (72 h; <i>S. capricornutum</i> ) EXP31279A*: EC50 = 0.48 µg/l (72 h; <i>S. capricornutum</i> )
Chronic toxicity sediment dwelling organism:	Not required
Acute toxicity aquatic plants:	E-1: EC50 = 2.6 µg/l (14 d; <i>Lemna gibba</i> )

\*EXP31279A (SC containing 9 g/l pyraflufen-ethyl and 500 g/l bifenoX)

#### Honeybees

Acute oral toxicity:	LD50 > 100 µg/bee
Acute contact toxicity:	LD50 > 100 µg/bee



**Other arthropod species**

	1.33 l formulation /ha
<i>Aphidius rhopalosiphi</i>	Beneficial capacity: 2.1 % effect (adults; formulation, 1.33 l/ha)
<i>Typhlodromus pyri</i>	Beneficial capacity: 100 % effect (protonymphs; formulation, 1.33 l/ha)
<i>Pardosa amentata</i>	Mortality: 29.4 % (adults; formulation, 1.33 l/ha)
<i>Poecilus cupreus</i>	Mortality: 3.3 % (adults; formulation, 1.33 l/ha)
<i>Chrysoperla carnea</i>	Beneficial capacity: 32.6 % effect (24 h old larvae; formulation, 1.33 l/ha)
<i>Coccinella septempunctata</i>	Beneficial capacity: 33.04 % effect (3 d old larvae; formulation, 1.33 l/ha)
<i>Typhlodromus pyri</i>	Mortality: 42.7 % effect Reproduction: no effect (protonymphs; formulation, 5 % of 1.33 l/ha)
Extended laboratory test: <i>Hypoaspis aculeifer</i> (Acari, Laelapidae)	Mortality: 2 % Egg production: 25 % (protonymphs; formulation, 1.5 l/ha) Mortality: 4 % Egg production: 0.3 % (protonymphs; formulation, 4 % of 1.5 l/ha)

**Earthworms**

Acute toxicity:	LC 50 > 1000 mg a.s./kg soil
Reproductive toxicity:	Not required

**Soil micro-organisms**

Nitrogen mineralization:	Negligible effects at 20 and 100 g a.s./ha (1.5 and 7.4 times the application rate of 13.5 g a.s./ha)
Carbon mineralization:	Negligible effects at 20 and 100 g a.s./ha (1.5 and 7.4 times the application rate of 13.5 g a.s./ha)

**APPENDIX III**

## Pyraflufen-ethyl

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

New references submitted after completion of the monograph.

Author(s)	Year	Annex IIA Point Title Company, Report No.	GLP GEP Y/N	Published or not Y/N	Owner
Stumpf, K.	2000	Annex IIA.4.2.2 Proposed Analytical Method for Pyraflufen-ethyl (ET-751) and Metabolites E-1, E-2 and E-3 in Soil Using GC/NPD 26 April 2000 Aventis CropScience, report n°: PSR00/006	Y	N	ACS
Tran Thanh Phong, J.	1999	Annex IIA.2.15 Determination of the oxidizing properties of technical pyraflufen-ethyl- first amendment 25 November 1999 Rhone Poulenc, report n°: 99-267-EC	Y	Y	RPA
Ulf, Lührs	1999	Annex IIA.8.3.2 Effects of EXP 31279A on the predatory mite <i>Thyphlodromus pyri</i> Scheuten (Acari, Phytoseiidae) in the Laboratory 13 April 1999 Rhone Poulenc, report n°: C008209	Y	N	RPA
Pascual, Juan	1999	Annex IIA.8.3.2 An extended laboratory study to evaluate the effect of EXP31279A on the predaceous mite <i>Hypoaspis</i> <i>aculeifer</i> Canestrini (Acari, Laelapidae) 15 December 1999 Rhone Poulenc, report n°: RP001HAE	Y	N	RPA
Kudo, M.	1996	Annex IIA.1/IIIA.1 Identity of the active substance and plant protection product Nihon Nohyaku, Document J	Y	N	NN
Kudo, M.	1997	Annex IIA.1.11 Analytical Profile of Batches of ET-751 Technicals 12 February 1997 Nihon Nohyaku, report n°: GE-23 96- 0154	Y	N	NN

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Souvignet- bairrière, J. / Stumpf, K.	2000	Annex IIA.6.3 Storage stability in wheat grain and straw and wheat or barley shoot over a time period of 18 months at about - 18°C. Pyraflufen-ethyl (ET-751) code : AE F116624 report n°: PSROO/004	Y	N	ACS
Quintelas, G.	2000	Annex IIA.6.3 Stability of ET-751 in wheat (grain, straw and shoot) after storage at - 18°C. Study n° : RPA/P6-036	Y	N	RPA
Quintelas, G.	2000	Annex IIA.6.3 Stability of E-I in wheat (grain and straw) and barley (shoot) after storage at -18°C. Study n°: RPA/96-051	Y	N	RPA
Clarke, D.E.	1998	Annex IIA.6.6 [ <sup>14</sup> C]-ET-751 : A confined Rotational Crop Study using Radishes, lettuces and barley. Report n° : C007850	Y	Y	NN

The abbreviations ACS (Aventis Crop Sciences) , RPA (Rhône-Poulenc Agro), NN (Nihon Nohyaku) refer to one dossier (Joint submission of the dossier by RPA and NN, afterwards merging of RPA in ACS)