

EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

E1 - Plant health

1.

Carfentrazone-ethyl

7473/VI/99-Final

10 April 2003

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

Review report for the active substance *carfentrazone-ethyl*

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 26 February 2003 in view of the inclusion of carfentrazone-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 carfentrazone-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 French authorities received on 14 February 1996 an application from FMC Europe NV (now FMC Chemical sprl), hereafter referred to as the applicant, for the inclusion of the active substance carfentrazone-ethyl in Annex I to the Directive. The French authorities indicated to the Commission on 25 October 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 carfentrazone-ethyl was distributed to the Member States and the Commission.

The Commission referred the dossier to the Standing Committee on the Food Chain and Animal Health in the meeting of the working group 'legislation' thereof on 19 December 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 97/362/EC¹ of 21 March 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 14 May 1998 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 carfentrazone-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 22 June 1998 as well as the sole applicant on 1 July 1998.

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 Biologische Bundesanstalt für Land und Forstwirtschaft (BBA) in Braunschweig, Germany, from September 1998 to January 1999.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States and the sole applicant on 18 May 1999.

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 the Food Chain and Animal Health, and specialised working groups of this Committee, for final examination, with participation of experts from the 15 Member States. This final examination took place from September 1999 to April 2003, and was finalised in the meeting of the Standing Committee on 11 April 2003.

These documents were also submitted to the Scientific Committee for Plants for separate consultation. The Committee was asked to comment on the relevance for humans of the elevated

¹ OJ NO L152, 11.06.1999, P.31.

levels of specific porphyrins detected in test animals. The Committee expressed the opinion² that the effects of the substance detected in test animals on porphyrin levels are relevant for humans but saw no evidence that humans are more sensitive to the effect than animals. In addition, the SCP noted that three unknown polar compounds were detected in a lysimeter. The notifier was therefore requested to comment on the relevance of these three metabolites. Additional information was subsequently provided by the notifier and evaluated by the Scientific Committee. In its assessment of the new data the Committee concluded that those metabolites will not cause an unacceptable ecotoxicological or toxicological risk via the groundwater.

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 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 2003/68/EC³ concerning the inclusion of carfentrazone-ethyl in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing carfentrazone-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.

² Opinion of the Scientific Committee on Plants regarding the Evaluation of carfentrazone-ethyl in the Context of Council Directive 91/414/EEC Concerning the Placing of Plant Protection Products on the Market. SCP/CARFEN/002-Final adopted 26 January 2001

³ OJ NO L177, 16.07.2003, P.12.

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 carfentrazone-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 VI of Directive 91/414/EEC, for each carfentrazone-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 against broad-leaved weeds and grasses in cereals with a maximum application rate of 0.02 kg a.s./ha

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 carfentrazone-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 < 1 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994). This low intake value reflects the 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 main identity and the physical/chemical properties of carfentrazone-ethyl are given in Appendix I.

The active substance shall have a minimum purity of 900 g/kg technical product.

The review has established that for the active substance notified by the applicant, 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 end points 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 carfentrazone-ethyl

On the basis of the proposed and supported uses, the following particular issues have been identified as requiring particular and short term 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 potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions.

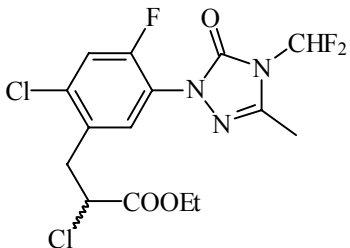
8. List of studies to be generated

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

9. 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 the Food Chain and Animal, in connection with any amendment of the inclusion conditions for for carfentrazone-ethyl in Annex I of the Directive.

APPENDIX I**Identity, physical and chemical properties****CARFENTRAZONE-ETHYL**

Common name (ISO)	Carfentrazone-ethyl
Development Code (for new actives only)	FMC 116426
Chemical name (IUPAC)	Ethyl (RS)-2-chloro-3-[2-chloro-5-(4-difluoromethyl-4,5-dihydro-3-methyl-5oxo-1 <i>H</i> 1,2,4-triazol-1-yl)-4-fluorophenyl]propionate
Chemical name (CA)	Ethyl α ,2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1 <i>H</i> -1,2,4-triazol-1-yl]-4-fluorobenzenepropanoate
CIPAC No	587
CAS No	128639-02.1
EEC No	Not allocated
FAO SPECIFICATION	Not allocated
Minimum purity	900 g/kg
Molecular formula	C ₁₅ H ₁₄ Cl ₂ N ₃ O ₃ F ₃
Molecular mass	412.19
Structural formula	

Melting point	- 22.1°C (purity 97 %)
Boiling point	350 - 355 °C (purity 97%)
Appearance	Yellow viscous liquid
Relative density	1.46 at 20 °C (purity 97 %) as density
Vapour pressure	$7.2 \cdot 10^{-6}$ Pa at 20 °C
Henry's law constant	$2.5 \cdot 10^{-4}$ Pa·m ³ ·mol ⁻¹
Solubility in water	pH 7.0 at 20°C: 12 mg/l pH 7.0 at 25 °C: 22 mg/l pH 7.0 at 30 °C: 23 mg/l
Solubility in organic solvents	At 20 °C: acetone : > 2000 g/l acetonitrile : > 2000 g/l toluene : 900 g/l dichloromethane : > 2000 g/l hexane : 30 g/l ethanol : > 2000 g/l ethyl acetate : > 2000 g/l
Partition co-efficient (log P_{ow})	3.36 at 20 °C
Hydrolytic stability (DT₅₀)	At 20 °C: pH 7: 13.7 d pH 9: 5.1 h pH 5: stable
Dissociation constant	No dissociation constant
Quantum yield of direct photo-transformation in water at $\epsilon > 290$ nm	$9 \cdot 10^{-2}$ mol · einstein ⁻¹
Flammability	Not flammable
Explosive properties	Not explosive
UV/VIS absorption (max.)	209 nm ϵ : $20.5 \cdot 10^3$ l·mol ⁻¹ ·cm ⁻¹ 244 nm ϵ : $10.8 \cdot 10^3$ l·mol ⁻¹ ·cm ⁻¹ 275.5 nm ϵ : $2.25 \cdot 10^3$ l·mol ⁻¹ ·cm ⁻¹ No absorption after 290 nm
Photostability (DT₅₀)	5.4 to 10.4 d (sunlight exposure) for acid metabolite 8.3 d at pH 5 (sunlight exposure) for carfentrazone-ethyl

APPENDIX II

END POINTS AND RELATED INFORMATION

CARFENTRAZONE-ETHYL

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapidly, 72-81 % based on urinary excretion over 7 d
Distribution:	Widely distributed
Potential for accumulation:	No potential for accumulation
Rate and extent of excretion:	Rapidly and almost complete in 7 days, mainly via urine
Toxicologically significant compounds:	Parent compound
Metabolism in animals:	Extensively metabolised; hydrolysis of the ester moiety and hydroxylation

Acute toxicity

Rat LD ₅₀ oral:	> 5000 mg/kg bw
Rat LD ₅₀ dermal:	> 4000 mg/kg bw
Rat LC ₅₀ inhalation:	> 5.09 mg/l
Skin irritation:	Non-irritant
Eye irritation:	Non-irritant
Skin sensitization (test method used and result):	Non-sensitising (M & K)

Short term toxicity

Target / critical effect:	Haematotoxicity (heme synthesis), liver, kidney
Lowest relevant oral NOAEL / NOEL:	90-d rat: 1000 ppm (58 mg/kg bw/d)
Lowest relevant dermal NOAEL / NOEL:	21-d rat: > 1000 mg/kg bw/d
Lowest relevant inhalation NOAEL / NOEL:	No data, no study required

Genotoxicity

Overall no genotoxic potential (<i>in vitro</i> CHO chromosomal aberration test without S9 positive)

Long term toxicity and carcinogenicity

Target / critical effect:

Haematotoxicity (heme synthesis), liver

Lowest relevant NOAEL:

2 y rat: 50 ppm (3 mg/kg bw/d)

Carcinogenicity:

No carcinogenic potential

Reproductive toxicity

Target / critical effect - Reproduction:

No reproductive toxicity

Lowest relevant reproductive NOAEL / NOEL:

1500 ppm (120 mg/kg bw/d)

Target / critical effect - Developmental toxicity:

(Reversible) skeletal variations at maternal toxic doses

Lowest relevant developmental NOAEL / NOEL:

Rabbit: 40 mg/kg bw/d

maternal NOAEL: 150 mg/kg/day in rabbits (TO BE CHECKED)
foetal NOAEL: > 300 mg/kg/day in rabbits**Delayed neurotoxicity**

Not relevant

Other toxicological studies

Carfentrazone-ethyl-benzoic acid (soil metabolite) and 3-desmethyl-carfentrazone-ethyl chloropropionic acid (plant metabolite) showed low oral acute toxicity and a negative Ames test

Medical data

Limited data, new compound

Summary

	Value	Study	Safety factor
ADI:	0.03 mg/kg bw	rat, 2 y study	100
AOEL systemic:	0.6 mg/kg bw/d	rat, 90-d study	100
ARfD (acute reference dose):	Not allocated – no relevant acute effects.		

Dermal absorption

No data, 10 % default value considered adequate

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:

< 3 % (phenyl and carbonyl moieties)

Non-extractable residues after 100 days:

Phenyl moiety : max. 14.5 %

Carbonyl moiety : max. 15 %

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

4 soils, 2 moisture contents, 2 labels

F8426-chloropropionic acid max. 49.3 - 86.6 % (1.5 - 16 d)

F8426-propionic acid max. 21.7 % (180 d)

F8426-cinnamic acid max. 21.4 - 47.1 % (8 - 102 d)

F8426-benzoic acid max. 17.2 % (365 d)

Supplemental studies

Anaerobic:

F8426-chloropropionic acid max. 95.9 % (7 d)

F8426-propionic acid max. 27.3 % (180 d)

Soil photolysis:

Not significant

Remarks:

none

Rate of degradation

Laboratory studies

DT_{50lab} (20 °C, aerobic):

DT _{50lab} (20°C, aerobic):				
Soil type	OC %	pH	DT ₅₀ (days)	
			Carfent.	Chloroprop.
Loamy sand	2.0	4.5	< 1.3	11.3
Speyer 2.2	2.3	5.8	< 0.5	85.6
Silt loam	3.0	5.6	< 0.1	24.8
Clay loam	3.4	5.7	< 0.1	23.1

DT_{90lab} (20 °C, aerobic):

DT _{90lab} (20°C, aerobic):				
Soil type	OC %	pH	DT ₉₀ (days)	
			Carfent.	Chloroprop.
Loamy sand	2.0	4.5	220-299	-
Speyer 2.2	2.3	5.8	9-17	-
Silt loam	3.0	5.6	< 0.5	-
Clay loam	3.4	5.7	0.6-1.2	-

DT_{50lab} (10 °C, aerobic):DT_{50lab} (10°C, aerobic):
0.1 d (Speyer 2.2)F8426-chloropropionic acid
DT₅₀ 92.4 d (Speyer 2.2)DT_{50lab} (20 °C, anaerobic):DT_{50lab} (20°C, anaerobic):
< 1 d (Speyer 2.2)F8426-chloropropionic acid DT₅₀ > 100 d**Field studies (country or region)**DT_{50f} from soil dissipation studies:DT_{50f}: Germany (3 sites, bare soil), UK (2 sites, bare soil), southern France (4 sites, wheat), 2 x 100 g as/ha (winter + spring applications, 5 times normal rate)

a.s. only in traces (LOD 1 µg/kg)

F8426-chloropropionic acid

max. 14 - 51.6 µg/kg (0 - 7 d)

DT_{50f} 3 - 14 d (27 d, 1 UK site, spring)

F8426-cinnamic acid

max. 2 - 15.7 µg/kg (0 - 56 d)

DT_{50f} 5 - 29 d (n=8 ; 3 G - 1 UK - 2 F sites)

F8426-benzoic acid

max. 1 - 12 µg/kg (0 - 56 d)

DT_{50f} 11 - 31 d (n=4 ; 1 G - 1 UK - 2 F sites)

F8426-propionic acid

max. < 3.8 µg/kg (0 - 30 d)

DT_{50f} not determined ; no residue after 57 d

Total residues

DT_{50f} 15 - 49 dDT_{90f} from soil dissipation studies:DT_{90f}: same conditions

F8426-chloropropionic acid : 11 - 47 d (88 d, 1 UK site)

F8426-cinnamic acid : 17 - 97 d

F8426-benzoic acid : 37 - 104 d

Total residues : 49 - 162 d

Soil accumulation studies:

Not relevant

Soil residue studies:

Not relevant

Remarks:

e.g. effect of soil pH on degradation rate

No pH dependence

Adsorption/desorption K_f / K_{OC} : K_d

pH dependence:

Active substance : not applicable due to degradation

F8426-Chloropropionic acid

Soil type	OC (%)	pH	K_f^*	slope*	K_{oc}^*
Loamy sand	2.3	6.0	0.35	0.90	15.3
Silt loam	2.7	6.1	0.45	0.86	16.8
Sandy clay loam	3.4	5.7	0.26	0.89	7.4
Loamy sand	1.9	4.8	0.59	0.91	31.3
Loamy sand	0.2	6.4	0.11	0.88	46.4
mean			-	-	23.4

* mean of 2 experiments

F8426-Benzoic acid

Soil type	OC (%)	pH	K_f	slope	K_{oc}
Loamy sand	2.3	6.0	0.15	0.77	6
Silt loam	2.7	6.1	0.24	0.90	9
Sandy clay loam	3.4	5.7	0.12	0.86	4
Loamy sand	2.3	4.6	0.58	1.01	25
Loamy sand	0.2	6.4	0.09	0.87	41
mean			-	-	17

F8426-Cinnamic acid

Soil type	OC (%)	pH	K_f	slope	K_{oc}
Loamy sand	2.3	6.0	1.38	1.12	60
Silt loam	2.7	6.1	3.26	1.14	121
Sandy clay loam	3.4	5.7	1.51	1.10	44
Loamy sand	2.3	4.6	7.77	1.14	333
Loamy sand	0.2	6.4	0.35	1.06	151
mean			-	-	142

F8426-Propionic acid

Soil type	OC (%)	pH	K_f	slope	K_{oc}
Loamy sand	2.3	6.0	1.17	1.19	51
Silt loam	2.7	6.1	1.89	1.13	70
Sandy clay loam	3.4	5.7	0.92	1.18	27
Loamy sand	2.3	4.6	6.07	1.20	260
Loamy sand	0.2	6.4	0.19	1.34	83
mean			-	-	98

Chloropropionic acid and benzoic acid:

no effect of pH (4.6-6.4)

Cinnamic acid and Propionic acid: adsorption
increases at pH < 5.7Methyl triazole: Kdoc 27-94 (lysimeter soil), no
significant effect of pH (4-8)Sulfonate: Kdoc 15-119 (lysimeter soil), adsorption
tends to increase at pH < 4.

Mobility

Laboratory studies:

Column leaching:

No data provided, not required

Aged residue leaching:

Incubation 10 days (20° C)

508 mm over 1 d

Soil type	OC	pH	RA in leachates (%)				
			Carfen	Chlorop.	Cinn.	Benz.	Total
Loamy sand	2.3	6.0	nd	nd	3.5	22.8	43.8
Silt loam	2.7	6.1	nd	0.25	0.5	9.8	17.5
Sandy cl. l.	3.4	5.7	nd	nd	5.5	23.5	41.8
Loamy sand	2.1	4.8	nd	nd	nd	nd	8.8
Loamy sand	0.2	6.4	nd	66.0	13.7	8.6	91.5

R.A. lost during storage for loamy sand (pH 6.0) and sandy clay loam soils

Field studies:

Lysimeter/Field leaching studies:

Sandy soil (OC 1.32 %, pH 5.6) in Munster (Germany). Application rate 13-16 g/ha ¹⁴C-carbonyl carfentrazone ethyl. Rainfall 930 and 837 mm. Recharge 385-389 mm (year 1), 246-262 mm (year 2).

Total RA max. 1.5 µg/l, mean 0.70-0.76 µg/l (year 1) and 0.15-0.16 µg/l (year 2).

Carfentrazone and soil metabolites not detected (LOQ < 0.04 µg/l) except benzoic acid (max. mean 0.023 µg/l), M3=methyl triazole (0.116 µg/l) and M2= sulfonate (0.29 µg/l). Unknown M1 < 0.1 µg/l.

Remarks:

Mobility overcomes by rapid degradation in field. Confirmed by a lysimeter study reported in 1999 (sandy soil, 16 g/ha on May, Munster, Germany) Simulations using the FOCUS-PEARL scenarios with normalized spring (unfavourable) DT50 data sets from the field studies (8 sites) and the mean Koc values show that for autumn or spring application of carfentrazone ethyl at 20 g/ha to winter wheat, concentrations of chloropropionic acid, cinnamic acid and benzoic acid do not exceed 0.1 µg/l with one exception (benzoic acid, max. 0.126 µg/l, at Piacenza for unfavourable DT50 and autumn application).

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

pH 5 (20° C) Stable
pH 7 (20° C) DT50 13.7 d
pH 9 (20° C) DT50 5.1 hours

Relevant metabolites:

pH 7 (20° C)
metabolite : F8426-chloropropionic acid:
hydrolytically stable
pH 9 (20° C)
metabolite : F8426-chloropropionic acid
hydrolytically stable

Photolytic degradation:

Carfentrazone, pH 5 (25° C)
dark stable
light DT₅₀ 8.3 d

F8426-chloropropionic acid (pH 5-9, 25° C)
dark stable
light DT₅₀ 5.4 - 10.4 d

Relevant metabolites:

Carfentrazone, pH 5 (25° C)
metabolites : 5 hydroxy-derivates of carfentrazone
all > 10 %

F8426-chloropropionic acid (pH 5-9, 25° C)
metabolites 2,4-diOH-F8426-benzoic ac. (12%)
methyl triazole (46.5 %)

Biological degradation

Readily biodegradable:

Water/sediment study:

DT₅₀ water:DT₉₀ water:DT₅₀ whole system:DT₉₀ whole system:Distribution in water / sediment systems
(active substance)Distribution in water / sediment systems
(metabolites)

Accumulation in water and/or sediment:

No
<p>< 0.4 d (first order, water pH 7.85 - 8.07)</p> <p>< 1.2 d (id.)</p> <p>< 0.4 d (first order)</p> <p>< 1.2 d (id.)</p> <p>> 1 % in sediment</p> <p>F8426-chloropropionic acid, max. 93 % in water (1-2 d), 12 % in sediment (0 d), first order DT₅₀ : 44 - 89 d in water (mean 67 d), 46 - 112 d whole system (mean 79 d)</p> <p>F8426-cinnamic acid, max. 26 % in water (60 d), < 5 % in sediment</p> <p>F8426-benzoic acid, max. 32 % in water (100 d), < 5 % in sediment</p> <p>F8426-propionic acid, max. 7 % in water (60d), 5 % in sediment (60 d) at 20° C</p> <p>Not expected for Carfentrazone and F8426-chloropropionic acid</p>

Degradation in the saturated zone

No data

Remarks:

Leaching to the saturated zone not expected

2.3 Fate and behaviour in air

Volatility

Vapour pressure:

$7.2 \cdot 10^{-5}$ Pa at 20 °C

Henry's law constant:

$2.5 \cdot 10^{-4}$ Pa·m ³ ·mol ⁻¹
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Photolytic degradation

Direct photolysis in air:

No data provided, not required

Photochemical oxidative degradation in air

DT₅₀:

Latitude: Season: DT ₅₀ 4.6 hours
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Volatilisation:

From plant surfaces: 14.2 % (measured)
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From soil: 5 % (measured)

Remarks:

Low risk for air contamination

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3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 (rat) > 5 000 mg as/kg bw
Acute toxicity to birds:	LD50 (quail) > 2 250 mg as/kg bw
Dietary toxicity to birds:	LC50 (bobwhite quail) > 5 620 ppm LC50 (mallard duck) > 5 620 ppm
Reproductive toxicity to birds:	NOEC (bobwhite quail) = 1000 ppm NOEC (mallard duck) = 1000 ppm
Short term oral toxicity to mammals:	NOEL (rat, 90 d-oral) = 1 000 ppm

Aquatic Organisms

Acute toxicity fish:	LC50 (trout, 96 h): 1.6 mg/l
Long term toxicity fish:	NOEC (trout, 28 d): 0.11 mg/l
Bioaccumulation fish:	Log Pow = 3.36 whole fish: 176; edible parts: 34; non-edible parts: 379 Clearance time CT ₅₀ : ca. 1 d CT ₉₀ : 14 d
Acute toxicity invertebrate:	EC50 (daphnid, 48 h): > 9.8 mg/l
Chronic toxicity invertebrate:	NOEC (daphnid, 21 d): 0.22 mg/l
Acute toxicity algae:	EC50 (<i>Anabaena flos-aquae</i> , 72 h): 0.012 mg/l
Effect on aquatic plant:	EC50 (<i>Lemna gibba</i> , 14 d): 0.0057 mg/l
Chronic toxicity sediment dwelling organism:	NOEC (<i>Chironomus riparius</i> , 21 d) 7.4 mg/l

Honeybees

Acute oral toxicity:	> 200 µg as /bee (WG 50% ¹)
Acute contact toxicity:	> 200 µg as/bee

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Other arthropod species*Test species**A. rhopalosiphi**T. pyri**P. cupreus**A. bilineata*

	% Effect
<i>A. rhopalosiphi</i>	0 % (mortality); -3% (fecundity) effect on adult (0.02 kg as/ha, WG 50%)
<i>T. pyri</i>	0 % (mortality); 0 % (fecundity) effect on protonymphs (0.02 kg as/ha, WG 50%)
<i>P. cupreus</i>	0 % (mortality); 0 % (consumption) effect on adult (0.025 kg as/ha, WG 50%)
<i>A. bilineata</i>	0 % (mortality); 17 % (parasitism) effect on adult (0.025 kg as/ha, WG 50%)

Earthworms

Acute toxicity:

Reproductive toxicity:

Acute toxicity:	LC50 > 820 mg as/kg soil
Reproductive toxicity:	no data

Soil micro-organisms

Nitrogen mineralization:

Carbon mineralization:

Nitrogen mineralization:	At 0.52 mg/kg max : effects (d 61) < ± 15%
Carbon mineralization:	At 0.52 mg/kg max : effects (d 28) < ± 15%

Appendix III

CARFENTRAZONE-ETHYL

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
A II, 2.14	Alvarez M.	1998	Surface Tension of carfentrazone-ethyl FMC Corporation, APG, Princeton, Report No. P-3363 GLP, unpublished report FMC EMEA filing No. 2.14/1
A II, 2.1.1; 2.1.2; 2.1.3; 2.2; 2.4.1; 2.4.2; 2.5.1.1-4; 2.6; 2.7	Alvarez M.	1999	Additional Physical properties of carfentrazone-ethyl metabolites FMC Corporation, APG, Princeton, Report P-3375 GLP, unpublished report FMC EMEA filing No. 2.1.1/1
A II, 2.3.1; 2.6; 2.8	Alvarez M.	1997	Select physical properties of F8426: Acid Metabolites FMC Corporation, APG princeton, Report P-3200 GLP unpublished report FMC EMEA filing No. : 2.3.2/2
A II, 2.9	Willut J.M. & al.	1991	Environmental fate Analysis F8426 and FMC 124161 FMC Corporation, APG Princeton, Report P-2560 GLP, unpublished report FMC EMEA filing No. 2.9.1/3
A II, 2.9	Willut J.	1995	Photodegradation of 14c-f8426-Chloropropionic acid in Buffered Aqueous Solution by Simulated Sunlight FMC Corporation, APG, Princeton, Report P-3051 GLP, unpublished report FMC EMEA filing No. 2.9.2/2
A II, 2.10	Dr. Völkel W.	1999	Estimation of the degradation of carfentrazone-chloropropionic acid by photo-oxidation in air, RCC CH-Ittingen, Report 723396 Unpublished report FMC Emea filing No. 2.10/2
AIII, 4.3	anonymous	1995	Cleanout test for KX 095 and KX 096 straight and in mixture with various mix partners

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
AII 5.3.3	Freeman C.	1996	F8426 Technical: 21-day repeated-dose dermal study in rats Study Number: A96-4439, FMC Corporation Princeton, US. GLP, unpublished report FMC EMEA Filing no. 5.3.3/1
AII-5.4.1	V. O. Wagner	2002	Bacterial Reverse Mutation Assay BioReliance, Study Number : A2002-5555 GLP, unpublished report FMC EMEA Study Number: 5.4.1/12
AII,.5.8	Freeman C Scubelek S	2001	FMC 233574 technical: Technical 28-day drinking water study in rats. FMC Corporation, Princeton Study Number: A2001-5367 GLP, unpublished report FMC EMEA Study Number: 5.3.1/5
AII,.5.8	Freeman C Scubelek S Watt B	2001	FMC 185655 (Methyl triazole) Technical - Ninety-Day Feeding Study in Study Number: A2000-5306 FMC Corporation, Princeton GLP, unpublished report FMC EMEA Study Number: 5.3.2/4
AII,.5.8	Gudi R Brown C	2001	<i>In Vitro</i> Mammalian Chromosome Aberration Test, Test Article FMC 185655 Study Number: A2001-5351, FMC Corporation , Princeton GLP, unpublished report FMC EMEA Study Number: 5.4.3/3
AII,.5.8	Gudi R Brown C	2001	<i>In Vitro</i> Mammalian Chromosome Aberration Test, Test article FMC 233574 Study Number: A2001-5377, FMC Corporation, Princeton GLP, unpublished report FMC EMEA Study Number: 5.4.3/2
AII,.5.8	San RHC Clarke JJ	2001	<i>In Vitro</i> Mammalian Cell Gene Mutation, (CHO/HGPRT) Test with an Independent Repeat Assay, Test article: FMC 185655 Study Number: A2001-5350, FMC Corporation, Princeton GLP, unpublished FMC EMEA Study Number: 5.4.1/9
AII,.5.8	San RHC Clarke JJ	2001	<i>In Vitro</i> Mammalian Cell Gene Mutation (CHO/HGPRT) Test with an Independent Repeat Assay, Test article FMC 233574 Study Number: A2001-5378, FMC Corporation, Princeton GLP, unpublished FMC EMEA Study Number: 5.4.1/10
AII,.5.8	Verdict B	2001	Carfentrazone-ethyl : Estimate of Exposure and Risk Assessment for the Polar Metabolites of Carfentrazone-ethyl, FMC Chemicals, -, unpublished report

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
			FMC EMEA Study Number: 5.10/2
AII.,5.8	Wagner VO Klug ML	2001	Bacterial Reverse Mutation Assay with an Independent Repeat Assay, Test article:FMC 185655 Study Number: A2001-5349, FMC Corporation, Princeton GLP, unpublished FMC EMEA Study Number: 5.4.1/8
AIIA-5.8	Wagner, V.O. Dakoulas, E.W.	2001	Bacterial Reverse Mutation Assay. Test article FMC 233574 (F8426 alpha-sulfo-deschloropropionic acid), Study Number A2001-5370 BioReliance, Rockville GLP, unpublished FMC EMEA Filing Number: 5.4.1/7
II.5.8	Wagner VO Klug ML	2001	Bacterial reverse mutation assay with FMC 233574 FMC study A2001-5392 BioReliance report AA47EX.502.BTL GLP, unpublished FMC EMEA Study Number: 5.4.1/11
AIIA-5.8	Steenwinkel, M- J.S.T.	2000	Gene mutation test at the TK-locus of L5178Y cells with Carfentrazone- benzoic acid. M-J.S.T. Study Number A2000-5207 TNO Nutrition and Food Research Institute, The Netherlands – GLP, unpublished report FMC EMEA Filing Number: 5.4.1/6
AII.,5.8	Weiner M	2001	Carfentrazone-ethyl Metabolites : Polarity Characteristics and Potential Toxicological Significance, Report Number : A2001-5380, FMC Corporation, Princeton -, unpublished report FMC EMEA Filing Number: 5.10/1
AIII 7.1.6	Allen D.J.	1996	F8426 50 WG: Magnusson & Kligman Maximisation Study in the Guinea pig Study number 240/147, Safepharm Lab. Ltd. UK GLP, unpublished report FMC EMEA Filing no. 7.1.6/2
AIII 7.1.6	Allen D.J.	1996	F8426 + IPU (0.75+50) WG: Magnusson & Kligman Maximisation Study in the Guinea pig Study number 240/148, Safepharm Lab. Ltd. UK GLP, unpublished report FMC EMEA Filing Number. 7.1.6/2

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
A II, 7.1.2	Alvarez M.	1999	Additional Physical properties of carfentrazone-ethyl metabolites FMC Corporation , APG, Princeton, Report P-3375 GLP, unpublished report FMC EMEA Filing No. 2.1.1/1
A II, 7.2.2	Dr. Völkel W.	1999	Estimation of the degradation of carfentrazone-chloropropionic acid by photo-oxidation in air, RCC CH-Ittingen, Report 723396 Unpublished report FMC EMEA Filing No. 2.10/2
A II 7.1.2	Baumann J.	2001	Adsorption characteristics of FMC 124161, FMC 125151, FMC 125165, FMC 097083, F8426 alpha-sulfodeschloropropionic acid (MII) and FMC 185655 (MIII) in a lysimeter soil. Battelle, Switzerland Study Number : E-17-01-52 GLP, unpublished report FMC EMEA Filing Number: 7.1.2/7
A II 7.1.3	Clayton R.	1999	¹⁴ C-F8426 : Lysimeter study according to BBA guideline IV, 4-3 (1990). Summary of Mass Spectroscopy. GLP, unpublished report Covance, Harrogate, England Subreport 73/106-D2146 of the report 1354-073-106 FMC EMEA Filing Number 7.1.3.3./6
A II 7.1.3	Clayton R. and Pethen S.	2001	¹⁴ C-F8426 : Lysimeter study according to BBA guideline IV, 4-3 (1990). Summary of LC/MS. GLP, unpublished report Covance, Harrogate, England Addendum to the subreport 73/106-D2146 of the report 1354-073-106 FMC EMEA Filing Number 7.1.3.3./6
A II, 7.1.3.3	Schnöder F.	1999	¹⁴ C-F8426:Lysimeter study According to BBA guideline IV, 4-3 (1990) Covance laboratories GmbH, D-Münster, CLE Study 073-106 – report 1354-073-106; FMC Study 84213896E1 – report FMC PC-290 GLP, unpublished report FMC EMEA Filing no. 7.1.3.3/1
A II 7.1.3	Schnöder F.	1999 2001	¹⁴ C-F8426 : Lysimeter study according to BBA guideline IV, 4-3 (1990). Revised Final Report 2. Covance, Munster, Germany GLP, unpublished report Report 1354-073-106 FMC EMEA Filing no.7.1.3.3/6
A II 7.1.3	Zheming Gu	2000	¹⁴ C-F8426 : Lysimeter study according to BBA guideline IV, 4-3 (1990). Subtitle : characterization and identification of metabolite (M-2) from leachate. Xenobiotic Lab. Inc., NJ Addendum RPT00631 to the report 1354-073-106 GLP, unpublished report FMC EMEA Filing no.7.1.3.3/5
A II 7.1.3	Zheming Gu	2000	¹⁴ C-F8426 : Lysimeter study according to BBA guideline IV, 4-3 (1990). Subtitle : characterization and identification of metabolite (M-1) from leachate. Xenobiotic Lab. Inc., NJ Addendum II RPT00667 to the report 1354-073-106 GLP, unpublished report FMC EMEA Filing number 7.1.3.3/5
AIIA-	Shaaban F. El	2000	F8426-Methyltriazole and F8426- α -Sulfodeschloropropionic

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
7.1.3.3	Naggar,		-Acid Metabolites : Polarity Characteristics and Impact on their ADME Behavior – -, unpublished report FMC EMEA Filing Number: 7.1.3.3/5
AIIA-7.1.3.3	Zheming Gu	2001	Addendum Report : ¹⁴ C-F8426 : Lysimeter Study According to BBA Guideline IV, 4-3 (1990) - Subtitle : Characterization of Metabolite (M-1) from Leachate Samples, XenoBiotic Laboratories, Inc., Plainsboro, NJ – Study Number: PC-290 GLP, unpublished report FMC EMEA Filing Number: 7.1.3.3/7
A III 9.2.1	Adrian P.	2001	Simulation of the leaching behaviour of Carfentrazone ethyl and its metabolites in Germany using PELMO 3.0 (version SP2) CEHTRA, Nice, France -, unpublished report FMC EMEA Filing Number: 9.2.1./3
A III 9.2.1	Adrian P.	2001	Carfentrazone-ethyl containing formulations in The Netherland – Evaluation of leaching potential using PEARL modelling -, unpublished report FMC EMEA Filing Number: 9.2.1./7
A III 9.2.1	Adrian P.	2002	Carfentrazone-ethyl containing formulations in the European Union – Evaluation of leaching potential using FOCUS groundwater scenarios CEHTRA, Nice, France -, unpublished report FMC EMEA Filing Number: 9.2.1/10
A III 9.2.1	Holihan J.C.	2002	Evaluation of the leaching potential of carfentrazone-ethyl polar metabolites using the FOCUS groundwater scenarios FMC Corporation, Princeton, US -, unpublished report FMC EMEA Filing Number: 9.2.1/11
A III 9.2.1	Holihan J.C.	2002	Predicted concentration of Carfentrazone benzoic acid, M2 and M3 in groundwater FMC Corporation, Princeton, US -, unpublished report FMC EMEA Filing Number: 9.2.1/12

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
AIIA-8.1.3	Pedersen, C. A.	1997	Avian reproductive toxicity study with F8426 technical in Bobwhite quail Bio-life Associates, Ltd., Neilsville US, report no.: A96-4402 FMC EMEA filing No. 8.1.3/1
AIIA-8.1.3	Pedersen, C. A.	1997	Avian reproductive toxicity study with F8426 technical in mallard ducks Bio-life Associates, Ltd., Neilsville US, report no.: A96-4403 FMC EMEA filing No. 8.1.3/2
AIIA-8.5	Jonas, W.	1997	Side-effects of the test substance Carfentrazone-ethyl 500 g/kg WG on the activity of soil microflora Natec Institute, Germany, report no.: NA 969409

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
			FMC EMEA filing No. 8.5/2
AIIA-8.2.1	Egeler, Ph. Enriquez, M.	2001	A study on the freshwater fish (rainbow trout) acute toxicity of methyl triazole according to the EEC Directive 92/69 method C.1., "Acute Toxicity for Fish"- Study Number : A-17-01-37 ECT Oekotoxikologie GmbH (Germany) and Battelle (Switzerland), GLP, unpublished report FMC EMEA Study Number: 8.2.1/8
AIIA-8.2.1	Egeler, Ph. Enriquez, M.	2001	A study on the freshwater fish (rainbow trout) acute toxicity of F8426 α -sulfodeschloropro-pionic acid according to the EEC Directive 92/69 method C.1., "Acute Toxicity for Fish" - Study Number : A-17-01-41 ECT Oekotoxikologie GmbH (Germany) and Battelle (Switzerland) GLP, unpublished report FMC EMEA Study Number: 8.2.1/9
AIIA-8.2.4	Egeler, Ph. Enriquez, M.	2001	A Study on the <i>Daphnia</i> Acute Toxicity - Methyl Triazole according to the EEC Directive 92/69 method C.2., "Acute Toxicity for <i>Daphnia</i> " Study Number : A-17-01-36 ; ECT Oekotoxikologie GmbH (Germany) and Battelle (Switzerland) ; GLP, unpublished report FMC EMEA Study Number: 8.2.4/8
AIIA-8.2.4	Egeler, Ph. Enriquez, M.	2001	A Study on the <i>Daphnia</i> Acute Toxicity of F8426 α -sulfodeschloropropionic acid according to the EEC Directive 92/69 method C.2., "Acute Toxicity for <i>Daphnia</i> " - Study Number : A-17-01-40 ; ECT Oekotoxikologie GmbH (Germany) and Battelle (Switzerland) ; GLP, unpublished report FMC EMEA Study Number: 8.2.4/9
AIIA-8.2.6	Egeler, Ph. Enriquez, M. Gilber, D.	2001	A Study on the Toxicity of Methyl Triazole to Algae (<i>Pseudokirchneriella subcapitata</i>) according to the EEC Directive 92/69 method C.3., "Algal Inhibition Test" - Study number: A-17-01-35 ECT Oekotoxikologie GmbH (Germany) and Battelle (Switzerland) GLP, unpublished report FMC EMEA Study Number: 8.2.6/13
AIIA-8.2.6	Egeler, Ph. Enriquez, M. Gilber, D.	2001	A Study on the Toxicity of F8426 alpha-sulfodeschloropropionic acid to Algae (<i>Pseudokirchneriella subcapitata</i>) according to the EEC Directive 92/69 method C.3., "Algal Inhibition Test" Study Number: A-17-01-39 ECT Oekotoxikologie GmbH (Germany) and Battelle (Switzerland) GLP, unpublished report FMC EMEA Study Number: 8.2.6/14
AIIA-8.4.1	Moser, Th.	2001	Methyl Triazole: acute toxicity to the earth-worm <i>Eisenia andrei</i> in an artificial soil test. - Study number. D13RA. ECT Oekotoxikologie GmbH (Germany). GLP, unpublished report FMC EMEA Study Number: 8.4.1/7
AIIA-8.4.1	Moser, Th.	2001	F8426 alpha-sulfo-deschloropropionic acid : Acute toxicity to the earthworm <i>Eisenia andrei</i> in an artificial soil test according to the OECD Guideline No.207 for the Testing of Chemicals "Earthworm, Acute Toxicity Tests" adopted April 4, 1984 Study no. D14RA. ECT Oekotoxikologie GmbH (Germany). GLP, unpublished report FMC EMEA Study Number: 8.4.1/8

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
AIIA-8.2.8	W. Kalsch M. Enriquez	2002	A study on the toxicity and growth inhibition of methyl –triazole to the freshwater aquatic plant (<i>Lemna minor</i> ST) according to the OECD proposal for a new guideline 221, “ <i>Lemna</i> sp. Growth inhibition test”, October 2000 - Study Number : A-17-02-39 Battelle, Switzerland GLP, unpublished report FMC EMEA Study Number: 8.2.8/2
AIIA-8.2.8	W. Kalsch M. Enriquez	2002	A study on the toxicity and growth inhibition of F8426 alpha sulfo deschloropropionic acid to the freshwater aquatic plant (<i>Lemna minor</i> ST) according to the OECD proposal for a new guideline 221, “ <i>Lemna</i> sp. Growth inhibition test”, October 2000 - Study Number : A-17-02-40 Battelle, Switzerland GLP, unpublished FMC EMEA Study Number: 8.2.8/3
AIIA-8.5	B. Förster M. Liebig M. Enriquez	2002	A study on the soil microorganisms toxicity of methyl triazole according to the OECD guideline for the testing of Chemicals No. 217 “soil microorganisms : carbon transformation test” and the OECD guideline testing of chemicals No. 216 “soil microorganisms : nitrogen transformation test” - Study Number: A-17-01-38 Battelle, Switzerland GLP, unpublished FMC EMEA Study Number: 8.5/5
AIIA-8.5	B. Förster M. Liebig M. Enriquez	2002	A study on the soil microorganisms toxicity of F8426 alpha-sulfodeschloropropionic acid according to the OECD guideline for the testing of chemicals No. 217 “soil microorganisms : carbon transformation test” and the OECD guideline for the testing of chemicals No. 216 “soil microorganisms : nitrogen transformation test” - Study Number: A-17-01-42 Battelle, Switzerland GLP, unpublished FMC EMEA Study Number: 8.5/7

APPENDIX IV

List of uses supported by available data

CARFENTRAZONE-ETHYL

(a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/ha min max	water l/ha min max	kg as/ha min max		
Winter (wheat, barley, rye, oats) Spring (wheat, barley) Durum Wheat	Northern and Southern Countries	Aurora Platform	F	Broad-leaved weeds	WG	50 %	broadcast, ground directed spraying	between crop stages : 2 leaves (Z12) and 2 nodes (Z32)	2			200-400	20g	do not treat later than Z32	
Winter wheat Winter barley		Affinity	F	Broad-leaved weeds and grasses	WG (water soluble granule)	0.75 % + 50 % IPU	broadcast, ground-directed spraying	between crop stages 2 meaves (Z12) and end tillering (Z29)	1			200-400	20.6 g	do not treat later than Z29	
Winter wheat Spring Wheat Durum wheat Winter barley Spring barley Winter oats		Aim Platform S	F	Broad-leaved weeds	SG (water soluble granule)	1.5 % + 60 % MCPP	broadcast ground-directed spraying	between crop stages : beginning tillering (Z21) and 2 nodes (Z32)	1			200-400	15 g	do not treat later than Z32	

Remarks:

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

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

(i) g/kg or g/l

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

- (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (k) season at time of application
- (l) The minimum and maximum number of application possible under practical conditions of use must be provided
- (m) PHI - minimum pre-harvest interval
- (n) Remarks may include: Extent of use/economic importance/restrictions