EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Florasulam

SANCO/1406/2001-rev. 6

18 September 2002

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

Review report for the active substance **florasulam**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 19 April 2002 in view of the inclusion of florasulam 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 florasulam, 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 2 February 1998 an application from Dow Agro Science, hereafter referred to as the applicant, for the inclusion of the active substance florasulam in Annex I to the Directive. Belgian authorities indicated to the Commission on 8 June 1998 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 florasulam 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 7 July 1998, 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 98/676/EC [1] of 16 October 1998 that these requirements were satisfied.

[1] OJ No L317, 26.11. 1998, p.47.

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, as rapporteur Member State would carry out the detailed examination of the dossier and report the conclusions of the 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 19 November 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 florasulam 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 Dow Agro Science being the sole applicant on 28 January 2000.

Further discussion between the Rapporteur Member State and experts form all other Member States were subsequently held in the working groups of the Standing Committee for Plant Health, to review and discuss the draft assessment report 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.

This final examination took place from October 2000 to April 2002, and was finalised in the meeting of the Standing Committee on the Food Chain and Animal Health on 19 April 2002.

The present review report contains the conclusions of this final examination; given the importance of the revised draft assessment report, and the comments and clarifications submitted after its distribution to the Member States 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. The Committee was asked to comment on the relevance of two degradation products of the active substance (ASTCA and DFP-ASTCA), and on the approach proposed to establish an acute reference dose. In its opinion[2] the Committee concluded that modelling results do not indicate potential groundwater contamination above a threshold of toxicological concern for the parent substance or its breakdown products. Neither metabolite appears to pose an unacceptable risk to non-target aquatic organisms. The Committee was further of the opinion that the allocation of an acute reference dose is not warranted.

[2] Opinion of the Scientific Committee on Plants regarding the inclusion of florasulam in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market SCP/FLORAS/002-Final adopted 29 October 2001

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 2002/64/EC of 18 July 2002 concerning the inclusion of florasulam in Annex I to Directive 91/414/EEC[3], and to assist the Member States in decisions on individual plant protection products containing florasulam 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 florasulam 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 florasulam 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.

[3] OJ L 189 18.07.2002 p45

4. Specific conclusions which are highlighted in this evaluation

4.1 Residues of florasulam 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 0.07 % 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 main identity and the physical/chemical properties of florasulam are given in Appendix I.

The active substance shall have a minimum purity of 970 g/kg technical product.

The review has established that for the active substance notified by the applicant (Dow Agro Science), 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 florasulam

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 should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures should be applied where appropriate.

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 florasulam in Annex I.

However, as outlined above, when granting authorisations Member States may require additional information to ensure protection of ground water resources. Furthermore Member States may require additional information on the effects on soil macro organisms.

9.

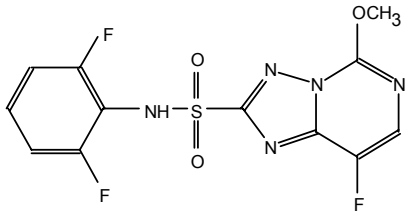
10. Updating of this review report

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 the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for florasulam in Annex I of the Directive.

APPENDIX I

Identity, physical and chemical properties

FLORASULAM

Common name (ISO)	Florasulam
Development Code (for new actives only)	DE-570
Chemical name (IUPAC)	2', 6', 8-Trifluoro-5-methoxy-[1,2,4]-triazolo [1,5-c] pyrimidine-2-sulfonanilide
Chemical name (CA)	N-(2,6-difluorophenyl)-8-fluoro-5 methoxy [1,2,4] triazolo [1,5-c] pyrimidine-2-sulfonamide
CIPAC No	616
CAS No	145701-23-1
EEC No	not available
FAO SPECIFICATION	not available
Minimum purity	970
Molecular formula	$C_{12}H_8O_3N_5F_3S$
Molecular mass	359.3
Structural formula	
Melting point	193.5 to 230.5□C with decomposition
Boiling point	Not required
Appearance	Purified a.s. : solid at 25°C. Technical material : also solid.
Relative density	1.53
Vapour pressure	1 x 10^{-5} Pa at 25°C
Henry's law constant	3.29 x 10^{-5} Pa.m^3/mol (pH 5) at 20°C 4.35 x 10^{-7} Pa.m^3/mol (pH 7) at 20°C 2.94 x 10^{-8} Pa.m^3/mol (pH 9) at 20°C

Solubility in water	solubility in : purified water (pH 5.6-5.8) : 0.121 g/L pH 5.0 buffer : 0.084 g/L pH 7.0 buffer : 6.36 g/L pH 9.0 buffer : 94.2 g/L
Solubility in organic solvents	solubility in : n-heptane* : 0.019×10^{-3} g/L xylene* : 0.227 g/L dichloroethane : 3.75 g/L methanol : 9.81 g/L n-octanol* : 0.184 g/L acetone : 123 g/L ethyl acetate : 15.9 g/L acetonitrile : 72.1 g/L * g/L solution (rest : g/L solvent)
Partition co-efficient (log P_{ow})	pH 4.0: log P_{ow} = 1.00
	pH 7.0: log P_{ow} = -1.22
	pH 10.0: log P_{ow} = -2.06
Hydrolytic stability (DT_{50})	50°C: pH 4 and 7: less than 5% degradation after 7d
	50°C: pH 9: k = 0.378 d^{-1};$t_{1/2}$ = 2 d (triazole-label)
	25°C:pH 5: no degradation observed after 30 d
	25°C:pH 7: no degradation observed after 30 d
	25°C:pH 9: k = 0.00692 d^{-1}; $t_{1/2}$ = 100 d (phenyl-label) k = 0.00706 d^{-1}; $t_{1/2}$ = 98 d (triazole-label)
Dissociation constant	pK_a = 4.54 (determined at 22-23°C)
Quantum yield of direct photo-transformation in water at ε >290 nm	Φ= 0.074
Flammability	not highly flammable/ not self-heating substance
Explosive properties	not explosive
UV/VIS absorption (max.)	□□□□□□□□□□□□□□□□□□□□□□□□□□ □ (nm) □ (L.mol^{-1}.cm^{-1}) acidic (pH 0.75) : 259.8 1.22×10^4 basic (pH 13.21) : 262.4 2.36×10^4 methanolic (pH 12.60) : 204.1 2.74x104 florasulam has no absorption max. above 290 nm, but □ > 10 L.mol^{-1}.cm^{-1}.
Photostability in water (DT_{50})	pH 5, 25 °C, natural sunlight 40°N, June and May; t1/2 = 88-223 d

APPENDIX II

END POINTS AND RELATED INFORMATION

FLORASULAM

1 Toxicology and metabolism

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	High bioavailability (91%) within 24 h
Distribution:	Uniformly distributed ; highest residues in skin and carcass at 168 h
Potential for accumulation:	No evidence for accumulation
Rate and extent of excretion:	rapid and extensive (approx 91%) within 24 h, mainly via urine (85%) within 24 h
Toxicologically significant compounds:	Parent compound and metabolites
Metabolism in animals:	limited; > 70% of dose excreted as parent compound ; hydroxylation of phenyl moiety and subsequent conjugation to a limited extent

Acute toxicity

Rat LD_{50} oral:	> 6000 mg/kg bw
Rat LD_{50} dermal:	> 2000 mg/kg bw
Rat LC_{50} inhalation:	> 5 mg/l(4 hr; nose only)
Skin irritation:	non irritant
Eye irritation:	non irritant
Skin sensitization (test method used and result):	non sensitizer (Buehler and M&K tests)

Short term toxicity

Target / critical effect:	Anemia,hepatotoxicity , renal hypertrophy epithelial cells, collecting ducts, adrenal vacuolation(dog)
Lowest relevant oral NOAEL / NOEL:	1 y & 90 d dog (oral feed) ; 5 mg/kg bw/d;
Lowest relevant dermal NOAEL / NOEL:	28-d rat, systemic toxicity > 1000 mg/kg bw/d
Lowest relevant inhalation NOAEL / NOEL:	no data- not required

Genotoxicity

Non genotoxic potential

Long term toxicity and carcinogenicity

Target / critical effect:	kidney collecting duct hypertrophy, papillary mineralisation, necrosis and inflammation (rat and/or mice)
Lowest relevant NOAEL:	2 yr rat (oral feed): 10 mg/kg bw/d
Carcinogenicity:	no carcinogenic potential

Reproductive toxicity

Target / critical effect - Reproduction:	No reproductive toxicity at parental toxic doses
Lowest relevant reproductive NOAEL / NOEL:	NOAEL > 500 mg/kg bw/d
Target / critical effect - Developmental toxicity:	No developmental toxicity or teratogenicity
Lowest relevant developmental NOAEL / NOEL:	NOAEL rabbit : 500 mg/kg bw/d

Delayed neurotoxicity

no evidence of neurotoxicity from acute and long-term neurotoxicity studies

Other toxicological studies

Renal cells affected are probably Type A intercalated cells, involved in acid-base regulation

Medical data

Limited; new active substance, No detrimental effects on health in manufacturing personnel

Summary

	Value	Study	Safety factor
ADI:	0.05 mg/kg/bw/d	1 year dog study	100
AOEL systemic:	0.05 mg/kg/bw/d	90 day dog study	100
AOEL inhalation:	Not allocated, not necessary		
AOEL dermal:	Not allocated, not necessary		
ARfD (acute reference dose): (if ARfD is required, please provide also information on dietary intake for children, e.g. NESTI)	Not necessary		

Dermal absorption

12% within 24 h, *in vivo* rat study

2 Fate and behaviour in the environment

2.1 Fate and behaviour in soil

Route of degradation

Aerobic:

Mineralization after 100 days:	4.8-13.5% after 100 d
Non-extractable residues after 100 days:	29.6-57.1% after 100 d
Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	5-OH (max 71.6 %) , DFP-ASTCA (max 17.8%) , ASTCA (max 40.0%), TSA (max 15.9%)

Supplemental studies

Anaerobic:	Degradation to metabolite 5-OH (max 87%) Low mineralization (1.3% max) Bound residue (max 11.2% after 365 d)
Soil photolysis:	DT50 of 44 and 158 d , respectively under light and in the dark 5-OH and unknown 1 at maximum level of 2.1 and 2.8%; 27.7% bound residue
Remarks:	**-**

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):	DT_{50lab} (20°C, aerobic, a.s.): 0.7-4.5 days (median : 1.6 d; 4 soils) DT_{50lab} (20°C, aerobic, field cap, a.s.): 7.4-10 days (2 soils) DT_{50lab} (20°C, aerobic, 5-OH): 10-31 days (median : 27 d 4 soils) DT_{50lab} (20°C, aerobic, DFP-ASTCA): 8-25 days (2 soils) DT_{50lab} (20°C, aerobic, ASTCA): 158-502 days (2 soils) DT_{50lab} (5°C, aerobic, a.s.): 19-45 days (2 soils) DT_{50lab} (20°C, anaerobic, a.s.): 11-14 days (2 labellings)
DT_{90}lab (20 °C, aerobic):	DT_{90lab} (20°C, aerobic, a.s.): 2.2-15 days (median : 5.3 d; 4 soils) DT_{90lab} (20°C, aerobic, 5-OH): 34-102 days (median: 89 d 4 soils)
DT_{50}lab (10 °C, aerobic):	DT_{50lab} (5°C, aerobic, a.s.): 19-45 days (2 soils)

DT_{50}lab (20 °C, anaerobic):	DT_{50lab} (20°C, anaerobic, a.s.): 11-14 days (2 labellings)

Field studies (country or region)

DT_{50f} from soil dissipation studies:	DT_{50f}: a.s. = 2-18 days, (median : 8.5d ; 6 locations in France, UK, Germany, Greece)
	DT_{50f}: 5-OH = 9-95 days, (median : 15.5 d; 6 locations in France, UK, Germany, Greece)
DT_{90f} from soil dissipation studies:	DT_{90f}: a.s. = 23-61 days, (median : 40.5 d; 6 locations in France, UK, Germany, Greece)
	DT_{90f}: 5-OH = 41-209 days, (median : 60 d; 6 locations in France, UK, Germany, Greece)
Soil accumulation studies:	Not required
Soil residue studies:	Not required

Remarks: e.g. effect of soil pH on degradation rate	**-**

Adsorption/desorption

K_f / K_{oc}: K_d:	Koc (a.s.) = 4-54 (mean = 22; 1/n = 0.86-1.00; n = 6); Kd (a.s.) = 0.14-0.94 (mean = 0.46; n = 6) Koc (5-OH) = 7-32 (mean = 18; 1/n = 0.88-1.10; n= 6); Kd (5-OH) = 0.07-1.73 (mean = 0.375; n = 6) Koc (DFP-ASTCA) = 24-110 (mean = 53.1; n = 10); Kd (DFP-ASTCA) = 0.26-1.10 (mean = 0.71; n = 10) Koc (ASTCA) = 27-159 (mean = 83; n = 10); Kd (ASTCA) = 0.30-1.87 (mean = 1.17; n = 10)
pH dependence:	no

Mobility

Laboratory studies:

Column leaching:	15 g a.s./ha, 2 days, 200 mm rainfall : 67.7-92.1% applied radioactivity in the leachate
Aged residue leaching:	Not required

Field studies:

Lysimeter/Field leaching studies:	1 appl at 5 g a.s./ha on sand : total residue of 1 year = 0.03-0.05 µg /l 1 appl at 5 g a.s./ha on loam : total residue of 1 year < 0.01 to 0.01 µg /l 1 appl at 25 g a.s./ha on sand (exaggerated rate) : total residue of 1 year = 0.27µg /l = metabolites 5-OH, ASTCA, DFP-TSA, polar compounds, a.s. is absent

Remarks:	**-**

2.2 Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	pH 5, 25 °C: no hydrolysis after 30 d
	pH 7, 25°C: no hydrolysis after 30 d
	pH 9, 25°C: t1/2 = 98-100 d
Major metabolites:	major metabolite : 5-OH
Photolytic degradation:	pH 5, 25 °C, natural sunlight 40°N, June and May; t1/2 = 88-223 d
Major metabolites:	Triazolosulfonic acid (TPSA)

Biological degradation

Readily biodegradable:	No
Water/sediment study:	
	DT50 (a.s., water) ≈ DT50 whole system
DT_{50} water:	DT90 (a.s., water) ≈ DT90 whole system
DT_{90} water:	
DT_{50} whole system:	DT50 (a.s., whole system) = 8.7-18.0 d
DT_{90} whole system:	DT90 (a.s., whole system) = 28.7-59.7 d
	DT50 (5-OH, whole system) = 68.59-243.96 d
Distribution in water / sediment systems (active substance)	Mainly present in water phase
Distribution in water / sediment systems (metabolites)	5-0H distributed in water and sediment phases
	mineralisation : max 3.7% after 100 days
	bound residue : maximum 11% after 100 days
Accumulation in water and/or sediment:	no

Degradation in the saturated zone

-

Remarks:

-

2.3 Fate and behaviour in air

Volatility

Vapour pressure:	1 x 10^{-5} Pa at 25°C
Henry's law constant:	3.29 x 10^{-5} Pa.m^3/mol (pH 5) at 20°C 4.35 x 10^{-7} Pa.m^3/mol (pH 7) at 20°C 2.94 x 10^{-8} Pa.m^3/mol (pH 9) at 20°C

Photolytic degradation

Direct photolysis in air:	-
Photochemical oxidative degradation in air DT_{50}:	DT_{50} = 1.82 h, Atkinson method
Volatilisation:	from plant surfaces: -0.8% volatilisation within 24 h
	from soil: 1.3% volatilisation within 24 h

Remarks:	**-**

3 Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 = 5000 mg a.s./kg bw (mice)
Acute toxicity to birds:	LD50 = 1046 mg a.s./kg bw
Dietary toxicity to birds:	LC50 > 5000 mg a.s./kg food
Reproductive toxicity to birds:	NOEC = 1500 mg a.s./kg food
Reproductive toxicity to mammals:	NOAEL = 100 mg a.s./kg bw or 2000 mg a.s./kg food

Aquatic Organisms

Active substance

	Time-scale	*Endpoint*	*Toxicity*
Acute toxicity fish:	96 h	LC50	> 100 mg a.s./l
Long term toxicity fish:	28 d	NOEC	119 mg a.s./l
Bioaccumulation fish:			BCF = 0.8-2.2
Acute toxicity invertebrate:	Daphnia: 48 h	LC50	> 292 mg a.s./l
Chronic toxicity invertebrate:	Daphnia: 21 d	NOEC	38.9 mg a.s./l
Acute toxicity algae:	72 h	ErC50	0.00894 mg a.s./l
Chronic toxicity sediment dwelling organism:	Chironomus: 28 d	NOEC	10 mg a.s./l
Acute toxicity aquatic plants:	Lemna: 14 d	EC50	0.00118 mg a.s./l

Metabolite 5-OH

	Time-scale	*Endpoint*	*Toxicity*
Acute toxicity fish:	96 h	LC50	> 91 mg/l
Acute toxicity invertebrate:	Daphnia: 48 h	LC50	> 96.7 mg/l
Acute toxicity algae:	72 h	EbC50	21.32 mg /l

Honeybees

Acute oral toxicity:	LD50 > 100 µg a.s./bee
Acute contact toxicity:	LD50 > 100 µg a.s./bee

Other arthropod species

Test species	Effect
Typhlodromus pyri	Stage protonymphs (lab), dose 0.0075 kg a.s/ha Beneficial capacity E :12.3%
	Stage protonymphs (lab), dose 0.015 kg a.s/ha Beneficial capacity E :43.6 %
Aphidius rhopalosiphi	Stage adults (lab), dose 0.0075 kg a.s/ha Beneficial capacity E :25.2%
	Stage adults (lab), dose 0.015 kg a.s/ha Beneficial capacity E :49.7 %
Poecilus cupreus	Stage adults (lab), dose 0.0075 kg a.s/ha Beneficial capacity E : 0%
	Stage adults (lab), dose 0.015 kg a.s/ha Beneficial capacity E :0 %
Chrysoperla carnea	Stage first instar larvae (lab), dose 0.0075 kg a.s/ha Beneficial capacity E :77.55%
	Stage first instar larvae (lab), dose 0.015 kg a.s/ha Beneficial capacity E :100 %
Chrysoperla carnea	Stage first instar larvae (extended lab), dose 0.0075 kg a.s/ha Beneficial capacity E :0%

Earthworms

Acute toxicity:	LC50 > 1320 mg a.s./kg soil
Reproductive toxicity:	-

Soil micro-organisms

Nitrogen mineralization:	Negligible effects at application rate equivalent to 0.01 and 0.05 mg a.s./kg soil
Carbon mineralization:	Negligible effects at application rate equivalent to 0.01 and 0.05 mg a.s./kg soil

APPENDIX III

FLORASULAM

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

B.6 Toxicology and metabolism

Annex point/ reference number	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or not**
IIA 5.8.1	Brookes, KJ	2000	5-Hydroxy-Florasulam: Acute Oral Toxicity in Fischer 344 Rats, The Dow Chemical Company, DR-0348-6279-001,GLP, not published
IIA 5.8.1	Linscombe, VA, Jackson, KM, Engle, KE	2000	Evaluation of 5-Hydroxy-Florasulam in an *in vitro* Chromosomal Aberration Study Utilising Rat Lymphocytes The Dow Chemical Company ,001109,GLP, not published
IIA 5.8.1	Linscombe, VA, Schisler, MR, Beuthin, AS	2000	Evaluation of 5-Hydroxy-Florasulam in the Chinese Hamster Ovary Cell/Hypoxanthine-Guanine-Phosphoribosyl Transferase (CHO/HGPRT) Forward Mutation Assay The Dow Chemical Company ,001105, GLP, not published
IIA 5.8.1	Bowles, A.J.	2000	5-Hydroxy Florasulam: Reverse mutation assay “Ames Test” Using *Salmonella Typhimurium* and *Escherichia Coli*. The Dow Chemical Company , GHE T-1075, GLP, not published

B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 7.2.1.3.2	Jackson, R	1998	The identification and characterisation of DE-570 metabolites from a sediment/water study Dow AgroSciences, GLP, unpublished report, GHE-P-7366
IIA 7.1.2	Jackson, R and Massart, J.	1999	The Soil Sorption of DFP-ASTCA and ASTCA (Two Metabolites of DE-570), Dow AgroSciences, GLP, unpublished report, GHE-P-7622
IIA 7.1.1.2	Jackson, R and Massart, J.,	1998	The Degradation of DFP-ASTCA and ASTCA (Two Metabolites of DE-570) in Soil, Dow AgroSciences, GLP, unpublished report, GHE-P-7522

B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not
IIA 8.4.1	Ward, TJ, Magazu, JP, Boeri, RL	1998	Toxicity of Metabolites of XDE-570 to the Earthworm, *Eisinia foetida* Dow AgroSciences, GLP, unpublished report, DECO HET DR-0312-6565-074