LEVEL 1

Florasulam

Statement of subject matter and purpose for which the monograph was prepared

1.1 Purpose for which the monograph was prepared (Document A)

1.2 Summary and assessment of information relating to the collective assessment of dossier (Document B)

This monograph is submitted to support the application for the first inclusion of the new active substance florasulam in Annex I to Directive 91/414/EEC.

1.3 Identiy of the active substance (Annex IIA 1)

1.3.1 Name and address of applicant(s) for inclusion of the active substance in Annex I (Annex IIA 1.1)

Applicant : Dow AgroSciences
Letcombe Laboratories
Letcombe Regis
Wantage
Oxon OX12 9JT
United Kingdom

Tel. No. : (44) 1235-772900
Tfx. No. : (44) 1235-774749

Contact person : Alison McReath

Member State address : Dow AgroSciences BV
Laarstraat 16
B-2610 Wilrijk
Belgium

Tel. No. : (32) 3 821 02 39
Tfx. No. : (32) 3 821 02 20

Contact person : Thierry Schoonejans

1.3.2 Manufacturer of the active substance (Annex IIA 1.2)

Manufacturer and contact point: The Dow Chemical Company
969 Building
Midland
MI 48667
USA

Tel. No. : (517) 638-7646
Tfx. No. : (517) 638-7805

Location of plant: same address as above
Contact person : Chess Mizell

1.3.3 ISO common name and synonyms (Annex IIA 1.3)

Common name : Florasulam (ISO-proposed)

1.3.4 Chemical name (Annex IIA 1.4)

IUPAC nomenclature : 2', 6', 8-Trifluoro-5-methoxy-s-triazolo [1,5-c]pyrimidine-2-sulfonanilide

CA nomenclature : N-(2,6-diflurophenyl)-8-fluoro-5-methoxy(1,2,4)triazolo(1,5-c)pyrimidine-2-sulphonamide

1.3.5 Manufacturer's development code number (Annex IIA 1.5)

	Code number	Used between
Active substance	XR-570	1990 - January 1994
	XDE-570	January 1994 - January 1997
	DE-570	February 1997 - present
Formulation	XRM 5230 (120 g DE-570/L SC)	April 1990 - December 1994
	EF-1289 (50 g DE-570/L SC)	January 1994 - December 1994
	EF-1343 (50 g DE-570/L SC)	February 1995 - present

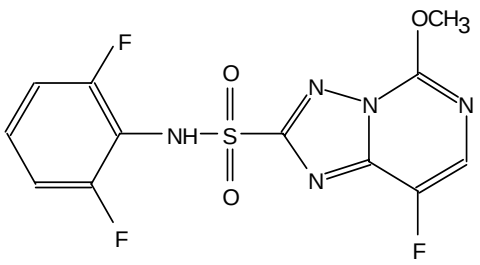
Use of these codes has been consistent with time throughout EU Member States.

1.3.6 CAS, EEC and CIPAC numbers (Annex IIA 1.6)

CAS number : 145701-23-1
EEC number : not available
CIPAC number : not available

1.3.7 Molecular formula, molecular mass and structural formula (Annex IIA 1.7)

Molecular formula: $C_{12}H_8O_3N_5F_3S$
Structural formula:



Molecular mass: 359.3

1.3.8 Method or methods of manufacture (Annex IIA 1.8)

Confidential information, see Annex C

1.3.9 Specification of the purity of the active substance (Annex IIA 1.9)

Minimum purity of florasulam technical : 970 g/kg

1.3.10 Identity of inactive isomers, impurities and additives (Annex IIA 1.10)

Confidential information, see Annex C

1.3.11 Analytical profile of batches (Annex IIA 1.11)

Confidential information, see Annex C

1.4 Identity of the plant protection product EF-1343 (Annex IIA 3.1; Annex IIIA 1)

1.4.1 Current, former and proposed trade names and development code numbers (Annex IIIA 1.3)

Trade name : PRIMUS SC
Code numbers :

Code number	Assigned on	Formulation	Use
XRM 5230	April 1990	120 g DE-570/L (SC)	Used until end 1994 in biology trials
EF-1289	11 January 1994	50 g DE-570/L (SC)	Used during 1994 for biology and probe crop residue trials
EF-1343	23 February 1995	50 g DE-570/L (SC)	Used in biology and regulatory trials from 1995 onwards

EF-1343 is the formulation intended for commercialisation.

1.4.2 Manufacturer or manufacturers of the plant protection product (Annex IIIA 1.2)

Applicant :

Dow AgroSciences
Letcombe Laboratories
Letcombe Regis
Wantage
Oxon OX12 9JT
United Kingdom

Tel. No. :(44) 1235-772900
Tfx. No. :(44) 1235-774749

Contact person :Alison McReath

Member State address :Dow AgroSciences BV
Laarstraat 16
B-2610 Wilrijk
Belgium

Tel. No. :(32) 3 821 02 39
Tfx. No. :(32) 3 821 02 20

Contact person :Thierry Schoonejans

Manufacturer of the preparation :

Kwizda
Division Landwirtschaft, Plant Leobendorf
F. Joh. Kwizda Gesellschaft mbH
A-2100 Leobendorf, Laaer Strasse
Austria

Tel. No. : (43) 2262-735-40-37
Tfx. No. : (43) 2262-735-40-49

Contact person : Willy Zsifkovits

Location of plant : same address as above

and/or

Rhone Poulenc Agriculture Limited
Sedagri UK
Sweet Briar Road
Norwich NR6 5AP
United Kingdom

Tel. No. : (44) 1603-242-306
Tfx. No. : (44) 1603-242-297

Contact person : Richard Stephenson

Location of plant : same address as above

Manufacturer of the active substance : The Dow Chemical Company
969 Building
Midland
MI 48667
USA

Tel. No. :(517) 638-7646
Tfx. No. :(517) 638-7805

Contact person : Chess Mizell

Location of plant :same address as above

1.4.3 Type of the preparation and code (Annex IIIA 1.5)

Suspension concentrate (SC)

1.4.4 Function (Annex IIIA 1.6)

Herbicide

1.4.5 Composition of the preparation (Annex IIIA 1.4)

Table 1.4.5-1 : Composition of EF-1343

Component	Content (g/L)	Function
Florasulam - pure a.s. - TC (min. purity 97%)	 (50) 50 - 51.5	Active substance
Other components	Confidential information, see Annex C	

1.5 Uses of the plant protection product EF-1343

1.5.1 Fields of use (Annex IIA 3.3; Annex IIIA 3.1)

Agriculture

1.5.2 Effects on harmful organisms (Annex IIA 3.2; Annex IIIA 3.2)

Florasulam is a post-emergence herbicide which kills broadleef weeds.
'Florasulam is a member of the 1,5c triazolopyrimidine sulfonanilides, a class of herbicides known to inhibit the plant enzyme acetolactate synthase enzyme (ALS). The inhibition of ALS results in a number of distinctive whole plant symptoms. Growth of sensitive species is retarded within a matter of hours of application although visible effects may not be observed for several days. Symptoms appear first in the upper meristematic region of the plants as chlorosis and necrosis. The upper new leaves often take on a wilted appearance. The effects then spread to the remaining parts of the plant. In some species there is a reddening of the midrib and veins. Complete desiccation of the plant may occur in 7-10 days in ideal growing conditions but may take up to 6-8 weeks under less ideal conditions. '

1.5.3 Summary of intended uses (Annex IIA 3.4; Annex IIIA 3.3 to 3.7, 3.9)

Depending on the EU countries, minor differences in the GAP are observed for the cereal growth stage and the application rate. The detailed GAP for each EU country were presented in the Document E-1 of the notifier.

Table 1.5.3-1 Summary of intended uses of EF-1343

Crop **Weeds** **Formulation type**	**Country : Europe**	**Rate per application (g a.s./ha)**	**Maximum rate per season (g a.s./ha)**	**Spray concentration (g a.s./hl)**	**Maximum number of applications per season** **Timing**	**Pre-harvest interval in days**	**Spray interval**
Winter cereals Broadleaf weeds (mainly *Galium aparine, Stellaria media, Matricaria spp.*) SC 50 g/l	N/S	0.5-7.5	75	-	1 (2) : split treatment with a total rate of 7.5 g a.s./ha./season BBCH 12 to 49 (2-3 leaves to stem elongation)	NA	6-8 weeks

Waiting periods between last application and sowing or planting succeeding crops are as follows : In the event of crop failure, spring wheat, spring barley, spring oat, maize or ryegrass may be sown immediately.

1.5.4 Information on authorizations in EU Member States (Annex IIIA 12.1)

Table 1.5.4-1 : Authorizations and Registrations in the EU

Country	**Type of authorization**	**Crops/uses**	**Authorization details**
Belgium	Commercial	winter wheat, winter barley, winter oat	PRIMUS SC 50 g/l Reg. N°. 9074/B Exp. Date : 18-01-2001

LEVEL 2

Florasulam

Reasoned statement of the overall conclusions drawn by the Rapporteur Member State

2.1.1 Identity

Florasulam (DE-570) is a member of the 1,5c triazolopyrimidine sulfonanilides, a class of post-emergence herbicides known to inhibit the plant enzyme acetolactate synthase enzyme (ALS) which is a key enzyme in the biosynthesis of the branched chained amino acids isoleucine, leucine and valine.

Minimum purity of florasulam technical : 970 g/kg

This information is based on material produced by a pilot plant production system. The notifier states that if any change in the specified purity is made, once industrial scale procedures and methods have stabilized, it will be notified to the Commission and Member States.

Florasulam technical does not contain any inactive isomers or diastereo-isomers, or additives.

The notifier states that none of the impurities is considered to be of particular toxicological or environmental concern on the basis of their low levels.

2.1.2 Physical and chemical properties

Active substance :

The physico-chemical properties of the active substance can be summarized as follows :

Melting point :	193.5 to 230.5°C with decomposition
Boiling point :	Not required
Temperature of decomposition :	approx. 202.5 °C
Relative density (22°C) :	1.53
Vapour pressure (25°C) :	1.10^{-5} Pa
Henry's law constant (20°C) :	2.29×10^{-5} Pa.m^3/mol
Physical state :	purified a.s. : solid at 25°C Technical material : also solid.
Colour :	purified a.s. : off-white Technical material : off-white
Odour	purified a.s. : non discernible odour Technical material : non discernible odour
UV/VIS absorption (λ_{max}) :	*UV/VIS absorption characteristics :* λ (nm) ε (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 2.74×10^4 DE-570 does not absorb wavelengths above 290 nm.
Solubility in water (20°C) :	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 (20°C) in g/L :	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 coefficient (log P_{ow}) (20°C) :	at pH 4.0 : log P_{ow} = 1.00 at pH 7.0 : log P_{ow} = -1.22 at pH 10.0 : log P_{ow} = -2.06
Hydrolysis :	*Tests at 50°C at pH 4, 7 and 9* : pH 4 and 7 : hydrolytic stability (= less than 5% degradation after 7 d) pH 9 : k = 0.378 d^{-1};$t_{1/2}$ = 2 d (triazole-label) *Tests at 25°C at pH 5, 7 and 9* : pH 5 : no degradation observed after 30 d pH 7 : no degradation observed after 30 d 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) *Further test at 20°C at pH 9* : k = 0.00316 d^{-1}; $t_{1/2}$ = 219 d (phenyl-label) k = 0.00306 d^{-1}; $t_{1/2}$ = 226 d (triazole-label)
Direct phototransformation :	Further tests are required
Quantum yield :	Φ = 0.074
Dissociation constant :	pK_a = 4.54 (determined at 22-23°C)
Stability in air :	estimated half-life of DE-570 in the atmosphere (by hydroxyl radical oxidation) : 1.82 h
Flammability/auto-flammability :	not highly flammable/ not self-heating substance
Flash point :	Not applicable (melting point > 40 °C)
Explosive properties :	not explosive
Oxidizing properties :	no oxidizing properties
Surface tension :	σ = 71.5 mN/m at 21 °C (not surface active)

The dossier also contained studies determining physico-chemical properties of the metabolite 5-hydroxy DE-570, relevant to its behaviour in the environment (Summary table of the physico-chemical properties is given in Annex B, point 2.1).

Formulation :

Summary table of the physico-chemical properties of the product EF-1343 (Suspension concentrate : 50 g/L florasulam) is given in Annex B, point 2.2.

2.1.3 Details of uses and further information

Uses of the formulation containing florasulam :

Protected crops are winter and spring cereals including winter wheat, winter barley, winter oats, winter rye, spring wheat, spring barley, spring oats, spring rye, and triticale.

Florasulam is a post-emergence herbicide which is effective against broadleaf weeds. The primary targets are *Galium aparine (main target) , Stellaria media, Matricaria* spp*, Papaver rhoeas,* volunteer oil seed rape. In addition, there are many other weeds which are listed by country in the individual biology dossiers.

Packaging :

After 8 weeks storage at ambient temperature and at 40°C, the PET containers were found to be satisfactory with respect to container shape. There was no evidence of deterioration of the containers under either test condition. The observed levels of base distension after 8 weeks at 40°C, were not considered detrimental to the stability of the containers and thus to safety during normal storage, transit or use.
Average mass changes after 8 weeks storage were - 0.62% (40°C) and - 0.04% (ambient) respectively. The losses are primarily due to permeation of water from EF-1343 and are not considered significant.
'The packagings are resistant to EF-1343.'

Procedure for cleaning application equipment and protective clothing :

The following label statement is proposed with respect to cleaning application equipment.

'To avoid subsequent injury to crops other than cereals, all spraying equipment must be thoroughly cleaned both inside and out, using All Clear Extra spray cleaner as follows :

1. Immediately after spraying, drain tank completely. Any contamination on the outside of the spraying equipment should be removed by washing with clean water.
2. Rinse inside of tank with clean water and flush through booms and hoses using at least one tenth of the spray tank volume. Drain tank completely.
3. Half fill tank with clean water and add All Clear Extra at the recommended rate. Agitate and then briefly flush the boom and hoses with the cleaning solution. Top up with water making sure the tank is completely full and allow to stand for 15 minutes with agitation. Flush the boom and hoses and drain tank completely.
   If it is not possible to drain the tank completely, step 3 must be repeated before going onto step 4.
4. Nozzles and filters should be removed and cleaned separately with All Clear Extra solution containing 50 mL of All Clear Extra per 10 L of water.
5. Rinse the tank with clean water and flush through the boom and hoses using at least one tenth of the spray tank volume. Drain tank completely.
6. For disposal of washings, follow Code of Practice for the Safe Use of Pesticides on Farms and Holdings. Do not spray onto sensitive crop or land intended for cropping with sensitive crop.'

These proposals are based on the results of a commercial-scale tank cleaning study (Ref. GHE-P-6791 and Ref. Q14), in which a spray solution of EF-1343 was prepared in a commercial sprayer and washed out using various washing methods (All Clear Extra, water alone, water alone using a mechanical in tank rinsing aid or no rinse). The same procedure was repeated for a tank mix of EF-1343 with Alto 100SL (100 g a.s./L cyproconazole), to test whether this affected the removal of EF-1343 from the spray tank. After completion of the washing techniques the spray tank was filled with a spray solution of Betanal E (114 g a.s./L phenmedipham), a product known to have the ability to remove any remaining deposits of active substances such as DE-570 from the spray tank. The amount of florasulam in this Betanal E spray solution was determined by immunoassay and compared with the no observable effect levels (NOEL) established for various crops.
The results indicate that the 'water only' washing procedure does not provide sufficient safety margin for the most sensitive crops (chicory and carrots), although on other crops this technique would be acceptable.

Cleaning procedures for protective clothing were not addressed as such.

Re-entry intervals, waiting periods and other precautions to protect man, livestock and the environment :

Pre-harvest and re-entry periods of EF-1343

Pre-harvest interval (in days) for each relevant crop :	'No PHI between application and harvest at maturity is proposed for cereals'
Re-entry period (in days) for livestock to areas to be grazed :	'In cases where livestock may be fed immature cereal crops following crop failure, a re-entry period of 7 d is proposed'
Re-entry period (in hours or days) for man to crops, buildings or spaces treated :	'No re-entry period for man to treated crops is required'
Withholding period (in days) for animal feedingstuffs :	'In cases where livestock may be fed immature cereal crops following crop failure, a re-entry period of 7 d is proposed. No other withholding period is required.'
Waiting period (in days) between application and handling treated products :	'No waiting period is required.'
Waiting period (in days) between last application and sowing or planting succeeding crops :	'In the event of crop failure, spring wheat, spring barley, spring oats, maize or ryegrass may be sown immediately. All other crops may be sown safely at the normal rotational interval specific for the crop. In both cases, no specific cultivation is required.' See point B.6.9.

Recommended methods, precautions and handling procedures to minimize the risks relating to warehouse storage, user level storage, transport, fire - Detailed procedures for use in the event of an accident during transport, storage or use :

This information is presented under the form of a provisional Safety Data Sheet pursuant to Article 27 of Council Directive 67/548/EEC.

Hazards identification : Very toxic to algae

Handling :Use good personal hygiene. Do not consume or store food in the work area. Wash hands and exposed skin before eating, drinking or smoking and after work.
*Respiratory protection :*For most conditions, no respiratory protection should be needed.
For emergency conditions : use an approved positive-pressure self-contained breathing apparatus.
*Hand/skin protection :*Wear clean, long-sleeved, body-covering clothing. Use gloves, impervious to this material, when prolonged or frequently repeated contact could occur.
For emergency conditions : use protective clothing impervious to this material. Selection of specific items will depend on operation.
*Eye/face protection :*Use safety glasses

Storage : Product should be stored in compliance with local regulations. Store in a cool, dry, well-ventilated place in the original container. Protect from excessive heat and cold. Do not store near food, drink,

animal feeding stuffs, pharmaceuticals, cosmetics or fertilisers. Keep out of reach of children.

Transport :

· Road/rail/inland waterway :
Proper shipping name : 3082, Environmentally hazardous substance, liquid, N.O.S. (contains DE 570 5%)
UN 3082
Kemmler code : 90
Class 9
Item number 11°c
Label 9

· Sea :
not classified for sea

· Air :
Proper shipping name : 3082, Environmentally hazardous substance, liquid, N.O.S. (contains DE 570 5%)
UN 3082
Class 9
Label 9
Passenger instructions 914
Cargo instructions 911

Fire : *Extinguishing media* : Water fog or fine spray; carbon dioxide; dry chemical; foam

Combustion gases : During a fire, smoke may contain the original material in addition to unidentified toxic and/or irritating compounds.

Specific methods of fire-fighting :Keep containers cool by spraying with water. Contain run-off to prevent entry into water or drainage systems.

Protective equipment : Firefighters should wear protective clothing and use self-contained breathing apparatus.

Emergency measures in case of an accident : EF-1343 is very toxic to algae. Do not contaminate ponds, waterways or ditches with chemical or used container.

Spillages : Do not wash into sewers or into any body of water. Advise water authority if spillage has entered water course or drainage system.
Soak up with sand or other non-combustible absorbent material and place into containers for disposal. Contain runoff to prevent entry into water or drainage systems.

Decontamination : Thorough cleaning of contaminated areas (e.g. buildings, vehicles, etc.) is recommended with water and detergent. Contain washings to ensure no further contamination of the environment. Heavily contaminated soil should be removed for disposal.

Disposal : Damaged packaging, adsorbents and other materials should be incinerated at an appropriate facility.

Protection : EF-1343 does not present any acute or irritation (eyes and skin) hazard, however exposure should be kept to a minimum. Bystanders must be kept out of contaminated areas and upwind of spills.
Emergency personnel should wear eye protection and whole body impervious clothing (e.g. butyl rubber, nitrile styrene butadiene rubber viton and PVC are all suitable materials).

First aid measures :

Ingestion :Do not induce vomiting. Call a physician. The decision of whether to induce vomiting or not should be made by an attending physician.
Eye contact :Irrigate immediately with water for at least 5 minutes.
Skin contact :Wash off in flowing water or shower, use soap if available.
Inhalation :Remove to fresh air. Consult a physician.

Note to physician :No specific antidote. Supportive care. Treatment based on judgement of physician in response to symptoms of patient.

Procedures for destruction or decontamination of the formulation and its packaging :

** Neutralization procedures for use in the event of accidental spillages :*

'EF-1343 does not require specific neutralization. Any spilt material should be absorbed onto dry, inert material (e.g. sand) and swept up into labelled containers for disposal.'

** Controlled incineration - Pyrolytic behaviour of the active substance under controlled conditions at 800°C :*

'If destruction is necessary, then incineration is recommended, however contact with the supplier should be made to evaluate the return of excess material before destruction is undertaken. Incineration (min. 1220°C for 2 seconds) must take place in a facility approved to handle chemical waste.'

The halogen content of florasulam is less than 60%; information on the pyrolytic behaviour of the active substance is thus not required.

** Methods other than controlled incineration for disposal of the plant protection product, contaminated packaging and contaminated materials :*

'Container and washings must be disposed of safely and in accordance with applicable regulations. The preferred options are to send to a licensed reclaimer or to permitted incinerators. Do not re-use the container for any purpose.'

2.1.4 Classification and labelling

Active-substance : Florasulam

Classification :	N, R50/53	
Labelling :		
Hazard symbol :	N	
Indication of danger :	dangerous for the environment.	
Risk phrases :	R50/53	very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Safety phrases :	S 60	This material and its container must be disposed of as hazardous waste.
	S 61	Avoid release to the environment. Refer to special instructions/safety data sheets.

Justification of the proposals for the classification and labelling of Florasulam

Proposed classification	**Justification**
N, R50/53	EC_{50} (*Selenastrum capricornutum*-72 h)= 8.94 µg a.s./L Poorly biodegradable : CO_2 production equivalent to 2% of TCO_2 after 29 days.

Formulation EF-1343

Classification : N, R50/53

Labelling :

Hazard symbol : N

Indication of danger : dangerous for the environment.

Risk phrases :	R50/53	very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Safety phrases :	S 2	keep out of reach of the children
	S 13	keep away from food, drink and animal feeding stuffs
	S 20/21	when using, do not eat, drink or smoke
	S 36/37	wear suitable protective clothing and gloves
	S 60	This material and its container must be disposed of as hazardous waste waste.
	S 61	Avoid release to the environment. Refer to special instructions/safety data sheets.

Justification for the proposal for the classification and labelling of EF-1343

Proposed classification	**Justification**
N, R50/53	EC_{50} (*Selenastrum capricornutum*-72 h)= 61.1 µg./L

2.2 Methods of analysis

2.2.1 Analytical methods for analysis of the active substance as manufactured

The HPLC-method (UV detection at 260 nm) is suitable for the determination of DE-570 in DE-570 technical. No CIPAC method exists for this active substance.

The HPLC-method (UV detection at 260 nm) is suitable for determination of the structurally related impurities 1-5 and 8 in DE-570 technical. Validation data demonstrating the applicability of the method for the determination of impurity 7 (= unknown E) and impurity 11 (= unknown A), which are present in the pilot plant scale technical material at levels > 0.1%, still remain to be provided.
The GC-method (FID system) is suitable for determination of the process solvents in DE-570 technical.

2.2.2 Analytical methods for formulation analysis

The HPLC-method (UV detection at 260 nm) appears suitable for determination of the DE-570 content in SC-formulations (50 g/L), but specificity/interferences could have been demonstrated in a more conclusive manner. No CIPAC method is available for the a.s. in the preparation.

2.2.3 Analytical methods for residue analysis

Feed and food of plant origin :
The HPLC-method ERC 95.6 (with UV detection at 260 nm after derivatization) allows determination of DE-570 residues in food matrices of plant origin (wheat and barley fractions) with a LOQ of 0.01 mg/kg for grain and 0.05 mg/kg for straw and whole plant. Being fully validated, it can be recommended for enforcement.
Multi residue method DFG S19 was found to be not suitable for routine analysis of DE-570 residues.

Feed and food of animal origin :
Methods for the determination of DE-570 residues in food matrices of animal origin were not submitted since livestock feeding studies are not required.
However, the validation of the analytical method for the determination of DE-570 and its metabolites in animal metabolism studies should be submitted.

Water :
The HPLC-UV methods provided for *water analysis* allow determination of parent DE-570 in drinking water and surface water with a LOQ of resp. 0.05 µg/L and 0.10 µg/L. Methods ERC 96.14 and ERC 96.15 also allow determination of major metabolite 5-OH DE-570 with a LOQ of 0.10 µg/L in drinking water and 0.20 µg/L in surface water. All methods were fully validated and can thus be recommended for monitoring of the drinking water limit.

The ELISA-method submitted (RaPID test-kit) is equally suitable for determination of DE-570 residues in drinking water, surface water and ground water with a LOQ of 0.1 µg/L. Showing good correlation with abovementioned HPLC-methods, it can even be put forward as the primary monitoring method, using the HPLC methods for confirmatory analysis.

Soil :
All methods submitted for *soil analysis* allow determination of parent DE-570 (and in most cases also of its main metabolite 5-hydroxy DE-570) in different soil types with a LOQ of 0.05 µg/kg; they are all fully validated.
The methods in which DE-570 and 5-OH DE-570 are extracted by organic solvent determine the extractable residue, while the methods in which the initial extraction is achieved by shaking with distilled water allow to assess the bioavailability of the residues in soil.

Methods ERC 95.1, ERC 95.2 and ERC 96.21 involve the use of ESP LC-MS/MS, which is not considered to be commonly available. Method ERC 97.07 on the other hand uses a more readily available technique (GC with MSD) and thus appears suitable for monitoring purposes as far as extractable residue is concerned.
The ELISA-method submitted (RaPID test-kit), showing good correlation with ERC 95.2, can be put forward as monitoring method for bioavailable residue.

Air :
The HPLC-UV method submitted for *air analysis* allows to determine parent DE-570 in ambient and warm, humid air with a LOQ of 1.5 µg/m³. The method was fully validated and thus appears suitable for monitoring of exposure.

Body fluids and tissues :
The HPLC method submitted allows determination of parent DE-570 in human plasma and urine with a LOQ of ≈ 100 µg/L.
Further methodology for the determination of DE-570 residues in animal tissues is not required as the a.s. is not classified as toxic or highly toxic.

2.3 Impact on human and animal health

2.3.1 Effects having relevance to human and animal health arising from exposure to the active substance or to their transformation products

Absorption, distribution, metabolism, excretion :
After oral administration in rats, absorption of florasulam was rapid and extensive reaching 85-91% of the dose. Increasing the dose by a factor of 50 reduced somewhat the absorption to 77%.
After dermal application, a potentially absorbed dose of 12% was calculated.
30 minutes post-dosing, distribution was large and the amount of radioactivity was highest in gastrointestinal tract, carcass, skin and organs involved in metabolism and excretion e.g.liver and kidney. The average amount of radioactivity remaining in rats 168 h post-dosing was low and <0.01% of the dose. At that time, the greatest amount remained in the skin (0.18-0.52%).
Metabolism of florasulam was minor and limited to hydroxylation of the phenyl ring without affecting the sulfonamide bond.
Excretion reached 96-99% of the dose within 7 day mainly as unchanged florasulam. Urinary excretion was the major route and represented 77-89% of the dose within 24 h after administration while fecal excretion represented 6.5% of the dose. Increasing the dose reduced urinary excretion to 77% with a concomitant increase in fecal excretion to 16%.
In plants , laying hens and lactating goats, florasulam is rapidly and extensively excreted . Metabolism does not occur at a high rate and does not differ from rat.

Acute toxicity :
In rat and mice, acute oral toxicity of florasulam was low, however, some death occurred in rats, at 6000 mg/kg bw and at 5000 mg/kg bw in mice, females being more sensitive than males. Transient clinical signs such as salivation, urine and fecal soiling in the perineal area suggest toxic effects towards the autonomic (parasympathomimetic) system .
Florasulam caused a minor, transient depression of activity and depression of reactivity to noise stimulus on the day of dosing in male rats at 2000 mg/kg bw. These effects, as well as perineal soiling disappeared after day 3.
Local signs such as erythema and edema which completely resolved on day 10 were observed after dermal application. Female rabbits were also more sensitive than males.
Florasulam is not a skin and eye irritant, it is not a sensitizer and is not classified.

Summary of acute toxicity

Type of test	Batch n°, purity	Results	Classification	References
Acute oral, rat	B.n°.TSN100298 ; 99.2%	LD_{50} combined > 5000 mg/kg bw	-	Gilbert and Yano, 1995
Acute oral, mice	b.n° XDE-570 ; 99.3%	LD_{50} combined > 5000 mg/kg bw	-	Brooks, 1997
Rabbit, dermal, semi-occluded	B.n°XDE-570; 99.2%	LD_{50} > 2000 mg/kg bw	-	Gilbert, 1995a
Rat, aerosol, nose only inhalation, 4 hours	B.n°. TSN100511, lot 940714; 99.3%	LC_{50} > 5 mg/l (= 420 mg/kg bw)	-	Clements and Cieszlak, 1995
Rabbit, skin irritation	B.n°.XDE570, TSN100298 ; 99.2%	Not irritant	-	Gilbert, 1995b
Rabbit, eye irritation	B.n°.XDE570, TSN100298 ; 99.2%	Not irritant	-	Gilbert, 1995c
Maximisation test	B.n°.XDE570, TSN100298 ; 99.2%	Not sensitizer	-	Johnson, 1996
Buehler test	B.n°.XDE570, TSN100298 ; 99.2%	Not sensitizer	-	Gilbert, 1995d

Short-term toxicity:

In rat and mice, oral administration of florasulam induced a decreased food intake, probably related to food unpalatibility, and a reduced body weight. Target organs were kidneys in which a minor functional impact was observed. Kidney proximal tubules presented nuclear pleomorphism and multifocal necrosis. These effects were noted, after 2-3 week exposure, at 500 mg/kg bw/d onwards.
In dogs, hepatocellular injury and cholestasis were reported at 150 mg/kg bw/d onwards. Some kidney tubule vacuolation was seen.

After 13 week oral exposure of rats, at 500 mg/kg bw/d onwards, different parts of the nefron were target of florasulam:
- renal collecting ducts (probably Type A intercalated cells) were hypertrophied , in male and females F344 and CD rats, severity was higher in CD rats.
- descending proximal tubules necrosis with degeneration/regeneration of a higher portion of the nephron, in females CD and F344 rats. This effect is typical of acute necrosis with regeneration rather than a 13 week old rat lesion.
- In the tubules of papilla, small foci of mineralized debris were reported in females F344 rats, while in CD rats, papillary necrosis with secondary hyperplasia was observed..

While intercalated cell hypertrophy and urine acidification were reversible, mineralization in papillae and degeneration/regeneration in cortical tubules did not recover in female F344 high dose group.

Bilateral multifocal hypertrophy of epithelial cells of collecting ducts was also observed in mice kidneys at a very slight degree suggesting probably an adaptative response. This lesion was morphologically the same as that reported in Fisher 344 rats. Anemia and decreased extramedullary hematopoiesis in the spleen was also evidenced.
For these studies, a NOAEL = 100 mg/kg bw/d is acceptable.

Dogs were the most sensitive species. Anemia was reported and increased serum enzymes suggested hepatotoxicity at 50 mg/kg bw/d. Renal hypertrophy and adrenal vacuolation were also evident. The hypertrophic intercalated cells, seen in dogs, seems to represent a slight exacerbation of a spontaneous lesion, as this effect was not associated with any cellular degeneration or necrosis. In dogs, the lowest NOAEL was 5 mg/kg bw/d.
From these repeated dose, subchronic experiments, a reference NOAEL of 5 mg/kg bw/d can be derived for short-term repetitive exposures.

Summary of short term-toxicity

Type of test	Compound and test substance purity	Results			References
		NOAEL (mg/kg bw /day)	LOAEL (mg/kg bw/day)	Critical endpoints	
Rat, oral, 14 day	B.n°.AGR - 291939, 92.2 %	100	500	renal tubules alterations : nuclear pleomorphism	Szabo and Davis, 1993
Mice, oral, 14 day	B.n°.AGR 291939, 92.2	1000	-	small body weight reduction	Svabo and Davis, 1992
Dog, oral, 28 day	TSN 100511, lot n° 940714; 99.3 %	<50	50	↗AP,↘ body weight	Sullivan and Cronin Singleton, 1995a
Rat, F344 oral, 90 day	lot n° 930910; 99.2 %	100	500	renal collecting duct hypertrophy ↘ body weight, altered urinary parametes, anemia	Redmond and Johnson, 1996
Rat, CD oral,	lot n° 940714;	100	500	renal collecting duct hypertrophy	Liberacki, et

Type of test	Compound and test substance purity	Results			References
		NOAEL (mg/kg bw /day)	LOAEL (mg/kg bw/day)	Critical endpoints	
90 day	99.3 %				al., 1996
Mice, oral, 90 day	lot 930910 ; 99.2%	100	500	renal collecting duct hypertrophy	Redmond and Johnson, 1996
Dog, oral, 90 day	lot n°. 940714 ; 99.3%	5	50	kidney : slight hypertrophy of collecting duct cells, slight liver vacuolation ; ↗AP	Sullivan and Singleton, 1995b
Dog, oral, 1 year	TSN 100511; lot n°. 940714, 99.3%	5	50	↗AP ; kidney : slight hypertrophy of collecting duct cells ; adrenal vacuolation ; anemia	Stebbins and Haut, 1997
Rabbit, dermal , 28 day	TSN 100511; lot n°. 940714, 99.3%	1000	-	-	Scorrichini and Kociba, 1997

Genotoxicity:
Florasulam was tested for its mutagenic potential *in vitro* and negative results were observed in the bacterial point mutation assay as well as in the mammalian cell assay. Negative results were also reported in its ability to induce *in vitro* chromosomal damage in rat lymphocytes. Florasulam did not induce micronuclei in mouse bone-marrow after *in vivo* administration.
In conclusion, florasulam is devoid of genotoxic effects *in vitro* and *in vivo*.

Summary of genotoxicity

Type of test	Result	Purity, batch n°	References
In vitro genotoxicity tests:			
S. typhimurium (TA100, TA1535, TA 98, TA1537) and *E.coli* (WP2uvrA) ± S9, DMSO	negative	99.2% TSN100298	Lawlor, 1995
HPRT, CHO-K1-BH4, DMSO	negative	99.2% TSN100298	Linscombe, 1995a
Chromosome aberration assay, rat lymphocytes, DMSO	negative	99.2% TSN100298	Linscombe, 1995b
In vivo genotoxicity tests:			
mouse, micronucleus bone marrow assay 1250, 2500, 5000 mg/kg bw, in corn oil	negative	99.2% TSN100298	Lick, 1995

Long-term toxicity :
Florasulam identified in rats body weight, body weight gain, and the kidney as target organs. Urine analysis revealed a treatment-related decrease of urinary pH for males receiving 250 or 500 mg/kg bw/d and for females receiving 125 or 250 mg/kg bw/d; urine specific gravity was decreased in high dose males, with lower levels of urinary protein and ketones. Kidney weight were increased in high dose males at 1 and 2 year and in high dose females at 2 year. At and above dose levels of 125 mg/kg bw/d, hypertrophy of cells within the collecting duct of the kidney were observed upon histopathological examination after 1 year, and more prominent after 2 year. In males given 250 or 500 mg/kg bw/d, mineralization of sloughed epithelial cells within loops of Henle was also reported. Unilateral papillary necrosis was reported in males. These effects were not associated with a deterioration of the renal function.

Florasulam was not carcinogenic in rats. The NOAEL in this study is 10 mg/kg bw/d.

In mice, at 500 and 1000 mg/kg bw/d, florasulam produced consistent microscopic effects, with the kidney being the only target organ identified. Hypertrophy of collecting duct cells was observed in the inner and outer stripe of the renal medulla, affecting sometimes cells in the proximal portion of the papilla. There was also an increased incidence of decreased cytoplasmic vacuolation of the cortical epithelial cells which may have contributed to the lower kidney weights. Clinical chemistry was not indicative of altered renal function. Treated mice were found to have less spontaneous occurring geriatric renal disease compared to their respective control.
In mice, florasulam was not carcinogenic and the NOAEL is 50 mg/kg bw/d.

The underlying mechanism for collecting duct cell hypertrophy is not fully understood. It is however suggested that α-intercalated cells are involved.

Summary of long-term toxicity and carcinogenicity

Type of test Test species	**Test substance purity**	**Results**			**References**
		NOAEL (mg/kg bw/ day)	**LOAEL (mg/kg bw/day)**	**Critical endpoints**	
Rat, 104 week	99.3% ; lot n°. 940714	10	125	↗ clinical signs, urinary pH↘, cell hypertrophy collecting duct	Johnson, Haut and Stebbins, 1997
Mice, diet, 78 week	lot n°.940714, 99.3%	50	500	↘ kidney weight; ↗ hypertrophy collecting duct individual cells; renal tubule, cortex ↘ vacuolation	Quast, Haut, and Kociba, 1997

Reproduction toxicity:
In the two generation study, parental animals receiving florasulam at the highest dose (500 mg/kg bw/d) had decreased food consumption and body weight during most of the pre-mating, gestation and lactation periods. An increased relative kidney weight was observed in P1 and P2 adults. Necrosis and/or inflammation of the renal papilla with the resultant hemorrhagic cast in the lumen of the urinary bladder occurred in some top dose P1 and P2 rats. There were no abnormalities in the reproductive performance of parental animals and the reproductive index of offspring.
In develommental studies in rats, maternal toxicity was observed at 750 mg/kg bw/d as suggested by the decreased body weight, food consumption and increased kidney weights. No adverse embryonal/fetal effects were observed at any dose level tested.
In rabbits, no maternal toxicity was observed and there was no evidence of teratogenicity at dose levels up to and including 500 mg/kg bw/d.

Summary of reproductive toxicity and teratogenicity

Type of test Test species	**Test substance purity**	**Results**			**References**
		NOAEL (mg/kg b w/ day)	**LOAEL (mg/kg b w /day)**	**Critical endpoints**	
Rat, 2 generation study	lot n°. 940714, 99.3%	reprotox > 500 syst.toxicity =100	- 500	↗Kidney weight, necrosis and/or inflammation renal papilla, hemorrhagic cast in urinary	Liberacki, Carney and Kociba, 1997

Type of test Test species	Test substance purity	Results			References
		NOAEL (mg/kg b w/ day)	**LOAEL (mg/kg b w /day)**	**Critical endpoints**	
				bladder	
rat, developmental	lot.n°940714; 99.3%	maternal tox = 250 developmental tox > 750	750 -	↘food consumption, body weight, ↗kidney weight	Liberacki and Carney, 1997
Rabbit, developmental	lot.n°940714; 99.3%	maternal tox > 500 developmental tox > 500	600 -	range finding study: mortality, ↘ transient food consumption	Zablotny andCarney, 1997

Neurotoxicity:

Florasulam caused a minor, transient depression of activity and depression of reactivity to noise stimulus on the day of dosing in male rats at 2000 mg/kg bw. Perineal soiling occurred in some high and mid dose female rats. These effects disappeared after day 3.
After 1 year feeding, there were no effects of florasulam on any parameters measured in rats, that would suggest a neurotoxic effect.

Summary of neurotoxicity

Type of test Test species	Test substance purity	Results			References
		NOAEL (mg/kg bw/day)	LOEAEL (mg/kg bw/day	Critical endpoints	
Rat, acute	lot n°. TSN 100511; 99.3%	200	1000	Perineal soiling	Mattsson, Guirk and Yano, 1997
Rat, chronic	lot n°. TSN 100511; 99.3%	systemic toxicity = 10 neurotoxicity = 250/500	125/250	Perineal soiling	Shankar and Johnson, 1996

2.3.2 Acceptable daily intake (ADI)

An ADI can be calculated from the lowest NOAEL of 5 mg/kg bw/d, identified in the 1 year dog study. The effects at the next highest dosage of 50 mg/kg bw/d were an increase in serum AP activity, of hepatic origin, hypertrophy of renal collecting duct cells and adrenal gland vacuolation.
Applying an assessment factor of 100 (10 for interspecies variation x 10 for intraspecies variation), the acceptable daily intake becomes :

ADI = 0.05 mg/kg bw/day

The applicant proposes to use the next higher dose of 50 mg/kg bw/d as being a NOAEL, because the increased PA activity was without any histopathological correlate, the renal hypertrophy was only slightly more pronounced than the spontaneous form of the lesion seen in this species and the adrenal vacuolation also represents a slight exacerbation of a spontaneous lesion.

2.3.3 Acute reference dose (ARfD)

Florasulam has been assessed in acute toxicity studies in rats and mice, in an acute neurotoxicity study in rats and in developmental studies in rats and rabbits. In all of these studies, florasulam showed a very low acute toxicity. It can be concluded from the submitted data, that there is no concern with regard to acute intake by consumers. Therefore, there is no need for derivating an ARfD.

2.3.4 Acceptable operator exposure level (AOEL)

The AOEL short-term for man is calculated on the basis of an internal NOAEL from a sub-chronic animal experiment, taking into account the apparent degree of absorption, and applying an assessment factor, chosen in function of the critical effect observed in the animal experiments.
There is no evidence that florasulam is mutagenic, carcinogenic, neurotoxic, teratogenic or a reproduction toxin.

It appears from the animal experiment that a subchronic exposure to 5 mg/kg bw/d (lowest NOAEL, taken from the 90 day, dog study) of florasulam will not result in any toxic effect. At the next highest dosage, AP was increased, hepatic vacuolation as well as a slight hypertrophy of epithetial cells lining renal collecting ducts were observed. The oral absorption seems to be near 100%. Applying an assessment factor of 100 for extrapolation to man. The acceptable operator exposure level, expressed as an internal, systemic dose becomes:

AOEL systemic = 0.05 mg/kg bw/d

The notifier proposed to use the same study but taking an assessment factor of 25, this gives an AOEL =0.2 mg/kg bw/d.

Although a 28-day dermal study with rats is available, it was not considered appropriate to derive a dermal AOEL, since no tratment-related effects were observed up to the highest dose level.

2.3.5 Drinking water limit

-

2.3.6 Impact on human or animal health arising from exposure to the active substance or to impurities contained in it

Health risk for humans:
There have been no reports of cases of exposure of humans to florasulam The use of florasulam has, so far, been confined to company internal trials. Thus ther has been no exposure of the general population. In animals, symptoms of acute intoxication were rather unspecific and transient. There was no evidence of bioaccumulation.
The risk for humans that genotoxicity, reproductive or developmental toxicity, long-term oral toxicity, will develop from the repetitive, adequate use of florasulam seems to be low. The compound is not carcinogenic.

Health risk for animals :
The acute toxicity of florasulam by oral, inhalation and dermal routes is low and florasulam does not need to be classified. In repetitive exposures in mammals, the kidney and the liver are the main target organs. Florasulam is not genotoxic, has no reproductive or developmental toxicity and is not carcinogenic.

Exposure resulting from the application of formulations containing florasulam :

- Operator exposure :
Primus SC is intended for use on winter and spring cereals and will have one or two applications per season. Potentially, Primus SC could be applied during a five-month period each year. Applicators could experience frequent exposure for more than three months in any 12-month period. However, evidence suggest that this scenario is unlikely to occur in practice. Operator exposure to florasulam was calculated using the UK-POEM and German model for the application on field crop, tractor mounted boom with air assisted sprayers. The operator exposure (% AOEL, degree of exposure E) without protective equipment is acceptable.

- Exposure of bystanders:
It can be assumed that bystanders may be present during the field application of Primus SC and can therefore be considered to be exposed mainly by the airborne route and dermal route. Using data from the UK-POEM model, calculation of operator exposure during application of the spray (for a 0.25 mg/l solution of florasulam application) will lead to an exposure of 1.262 mg/person/day corresponding to 42% of the AOEL. Exposure of bystanders is acceptable.

***- Exposure of workers*:**
Primus SC is applied on cereals crops from the stage 2-3 leaves to stem elongation. Worker reentry is therefore not expected.

Human exposure resulting from ingestion of residues :
The calculation of the TMDI according to the WHO guidelines resulted in an intake of residues representing about 0.1% of the ADI for a mean consumer.
Florasulam should therefore not pose any risk to the consumer.

2.4 Residues

2.4.1 Definition of the residues relevant to MRLs

Plant products :
Residues in wheat grain at maturity are exceptionally low and as a result, no further investigation of the nature of the residues is conducted.
In straw at maturity, no parent compound is observed in early application plants with only small amounts of glucose onjugate moiety.
The metabolism study indicates a rapid metabolization of Florasulam with a cleavage across the sulphonamide bridge.
In late application plants, the parent molecule, the glucose conjugate moiety and the tentatively identified metabolites are present accounting for very low levels.

In view of these low levels of residue and considering exaggerated application rate in the study, the residue definition for monitoring is proposed as parent compound only.
Two metabolites are not present in rat metabolism but their concentration is found to be very low. Therefore, their toxicological significance is considered as negligible.

A method of analysis is available for the parent compound in plant products.

No conversion factor for assessment of consumer safety (calculation based on the ratio extractable residues/residue to be monitored) can be established as the identification of the metabolites in mature wheat grain is not possible.

Animal products :
The metabolism studies in goat and hens indicate a slight metabolization of Florasulam.
The major constituant of the total residues is the parent molecule in excreta, milk, eggs and edible tissues.
Unknown metabolites are also observed in goats and hens but their amounts are too low for further characterization.
The residue definition for monitoring is proposed as the parent compound although residue levels in edible tissues are predicted to be very low.

There is no metabolite of particular toxicological concern formed in livestock.

No method of analysis is submitted for feedstuffs of animal origin. The notifier states that the residue levels in edible tissues are predicted to be very low and not present at levels which would be appropriate for monitoring.

Florasulam can be considered as non fat soluble.

The conversion factor for assessment of consumer safety (calculation based on the ratio extractable residues/residue to be monitored) is :
-For milk, liver, kidney and eggs : 1.

2.4.2 Residues relevant to consumer safety

The intended uses provided by the notifier are summarized in annex B, section B.6.4.
These uses concern cereals. The intake of residues resulting from these agricultural practices by the consumer represents about 0.07% of the ADI for a mean consumer, 0.16% of the ADI for a German 4-6 years old girl, 0.17% and 0.20% of the ADI respectively for a child and an infant from United Kingdom.

2.4.3 Residues relevant to worker safety

See point 2.3.6.

2.4.4 Proposed EU MRLs and compliance with existing MRLs

Florasulam is a new herbicide. There is currently no community MRL.

Supervised crop residue trials in winter cereals (winter wheat, winter barley, durum wheat) indicate that there are no quantifiable residues in grain.

MRL proposal for cereal grains : 0.01* mg/kg.

2.4.5 Proposed EU import tolerances and compliance with existing import tolerances

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2.4.6 Basis for differences, if any, in conclusions reached having regard to established or proposed CAC MRLs

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2.5 Fate and behaviour in the environment

2.5.1 Definition of the residues relevant to the environment

Definition of the residue in soil : florasulam and metabolite 5-OH
Definition of the residue in water : florasulam and metabolite 5-OH

2.5.2 Fate and behaviour in soil

Route of degradation :

Under aerobic conditions the active substance is degraded into to the major metabolite 5-hydroxy and then into the metabolite DFP-ASTCA (M3). The degradation of DFP-ASTCA occurred via the cleavage of the sulphonamide bridge to form ASTCA (M4). The decarboxylation of DFP-ASTCA to DFP-TSA (M1) and ASTCA (M4) to TSA (M6) should be considered as artefacts due to the extraction procedure.
- The metabolites 5 hydroxy, DFP-ASTCA, ASTCA and TSA were found, at least in one soil, at level > 10%.
- The DT_{50} of florasulam in four soils under aerobic conditions at 20°C were in the range 0.7 - 4.5 days. The metabolite 5-hydroxy was degraded with an estimated DT_{50} of 7 to 31 days.
- The mineralization reached 4.8 - 13.5 % after 100 days. Bound residues reached 29.6 - 57.1 % after 100 days.

Under anaerobic conditions, florasulam is degraded into 5-OH metabolite with a DT_{50} of 11-14 days. The metabolite 5-OH underwent almost no degradation during the whole study duration. 5-OH metabolite levels remain constant from day 30 to day 368 : 69.4 to 85.1% RR and 63.4 to 87% RR respectively for the phenyl and the triazolopyrimidine labeled a.s.
A secondary metabolite recovered at maximum level of 8.2 and 6.4% after 368 days was tentatively identified as triazolo-methyl/carboxylic acid.
The mineralization was low (maximum level of 0.1 and 1.3% RR). Maximum bound residue levels were 11.2 and 7.2% after 368 days. The average mass balances in the 2 sets of samples were 95.2 and 96.5%.

Florasulam is degraded in air-dried soil with DT_{50} of 44 and 158 days, respectively under light, and in the dark. The photolytic DT_{50} of florasulam is 62 days.
Metabolite 5-hydroxy and Unknown 1were detected at maximum level of 2.1 and 2.8%. High level of radioactivity was recovered as bound residue (27.7% after 22 days)

Rate of degradation :
The rate of degradation of the a.s. and metabolite 5-OH was evaluated in several soils under different temperatures (5, 15, 20, 25°C) and moisture conditions (saturation, field capacity, wilt point).
The rate of degradation was found to be a strong function of temperature : approximate 3-fold and 4-fold decrease in DT_{50} with every 10°C rise in Marcham soil and Cuckney soil, respectively.
Moisture conditions, on the contrary, do not play a significant role in the rate of degradation of the a.s. and metabolite 5-OH.

The rate of degradation of the metabolites ASTCA (158-502 d) and DFP-ASTCA (8-25 d) evaluated in 2 soils at 20°C

Dissipation in the field :
Florasulam is degraded in soil under field conditions following spring application with DT_{50} values in the range 2-18 days. Its major metabolite 5-OH is degraded with DT_{50} values of 9-95 days. Florasulam and its major metabolite were recovered in deeper horizons at following concentrations :
Maximum concentrations of florasulam at 10-20 cm : <0.05-0.75 µg/kg; 20-30 cm : < 0.05-0.96 µg/kg; 30-40 cm : <0.05-0.29; 40-50 cm : <0.05-0.29 µg/kg
Maximum concentrations of metabolite 5-OH at 10-20 cm : <0.10-0.35 µg/kg; 20-30 cm : < 0.05-0.19 µg/kg; 30-40 cm : <0.05-0.22; 40-50 cm : <0.05-0.11 µg/kg

Adsorption, desorption :
Koc of 4-54 indicate that florasulam has 'very high mobility' according to Mc Call classification.
Koc of 7-32 indicate that the metabolite 5-hydroxy has 'very high mobility' according to Mc Call classification.
Koc of 24-110 indicate that DFP-ASTCA has 'very high to high mobility' according to Mc Call classification.
Koc of 27-159 indicate that ASTCA has 'very high to high mobility' according to Mc Call classification.

Column leaching :
The column leaching study confirms the high leaching potential of florasulam and metabolite 5-hydroxy. Significant degradation of the a.s. occurred during the 2-day leaching period.

Lysimeters :
Several lysimeters were installed in order to investigate the leaching of florasulam under different soil/ application rate/ application date conditions. (sand and loam soils, 5 and 25 g a.s./ha, applications in February or April, single application or applications during two succeeding years) The effect of single application or applications during 2 successive years was also assessed.

- The total radioactivity recovered in the combined leachates of one year (normal application rate of 5 g a.s./ha) was detected at level < 0.1 µg/l. The radioactivity was identified as metabolites 5-hydroxy, ASTCA, DFP-TSA and polar compounds.
- Florasulam was not detected in the leachates.

PEC soil :
The PEC were calculated assuming that
- Florasulam has a DT_{50} of 18 days (maximum field DT_{50}; very conservative assumption); metabolite 5-OH has a DT_{50} of 95 days (maximum field DT_{50}; very conservative assumption)
- The active substance is applied once/season, at the maximum rate of 7.5 g a.s./ha, in cereals (2-3 leaves to stem elongation)
- 100% of the spray reaches the soil surface.
- The active substance is distributed in a 5 cm soil layer with a soil density of 1.5 g/cm^3

PEC soil of the active substance and metabolite 5-OH

Time after applications (days)	Cereals 7.5 g a.s./ha 1 application 100% of applied dose reaching the soil			
	Florasulam		metabolite 5-OH	
	Actual concentration (mg/kg soil)	TWA concentration (mg/kg soil)	Actual concentration (mg/kg soil)	TWA concentration (mg/kg soil)
0	0.0100	0.0100	0.0100	0.0100
1	0.0096	0.0098	0.0099	0.0100
2	0.0093	0.0096	0.0099	0.0099
4	0.0086	0.0093	0.0097	0.0099
7	0.0076	0.0088	0.0095	0.0097
14	0.0058	0.0077	0.0090	0.0095
21	0.0044	0.0069	0.0086	0.0093
28	0.0034	0.0061	0.0081	0.0090
50	0.0015	0.0044	0.0069	0.0084
100	0.0002	0.0025	0.0048	0.0071

2.5.3 Fate and behaviour in water

Hydrolysis :
Hydrolysis rate (t½) of florasulam is = 219-226 d at pH 9, 20°C. No hydrolysis occurs at pH 5, 7. The main hydrolysis product is the 5-OH.

Photodegradation :
Photolysis rate (t½) of florasulam under natural sunlight conditions is 88 and 223 d, respectively for the aniline and triazolpyrimidine labeled a.s. The main photodegradation product of florasulam is the triazolosulfonic acid of florasulam (TPSA)

Ready biodegradability :
Florasulam and the metabolite 5-OH are not ready biodegradable.

Water sediment study :
The a.s. is degraded with DT_{50} values of 8.7-18 days (whole system) . The metabolite 5-hydroxy is degraded slowly with DT_{50} up to 244 days (whole system).
Unknown 1 accounted for a maximum of 39 % (phenyl label) and 14% (triazolpyrimidine label) of applied radioactivity in the sandy loam system at 182 days and 10% (phenyl label) or 11% (triazolpyrimidine label) in the clay loam system at 182 or 100 days. Unknown 3 reached at maximumof 15% at 100 days in the sandy loam system with phenyl label, but was less than 5% in the other 3 treatment groups.

The active substance and metabolites were recovered in both water and sediment phases.
The mineralization reached levels of 0-3.7 % after 100 days depending of test system. Bound residue reached a maximum of 4.5-11.2% applied radioactivity after 100 days.

PEC surface water :
The PECsw were calculated assuming that :

- The a.s. is degraded with DT_{50} of 18 d (maximum value in water/sediment study); the metabolite 5-OH is degraded with DT_{50} of 244 d (maximum value in water/sediment study);
- Drift scenarios according to Ganzelmeier (1992) is applied.
- The waterbody is 30 cm deep
- The application rate is 7.5 g a.s./ha
- Calculations according to a first order kinetics

PEC sw of the active substance and metabolite 5-OH

Time after applications (days)	**Cereals** **7.5 g a.s./ha** **1 application, 1m drift** **4% of applied dose reaching the water body**			
	florasulam		**metabolite 5-OH**	
	Actual concentration (µg/l)	**TWA concentration (µg/l)**	**Actual concentration (µg/l)**	**TWA concentration (µg/l)**
0	0.1	0.1	0.1	0.1
1	0.096	0.098	0.1	0.1
2	0.093	0.0 96	0.099	0.1
4	0.086	0.093	0.099	0.099
7	0.076	0.088	0.098	0.099
14	0.058	0.077	0.096	0.098
21	0.045	0.069	0.094	0.097
28	0.034	0.061	0.092	0.096
42	0.020	0.050	0.089	0.094

PEC groundwater :

Calculation of PEC (groundwater) for DE-750 Metabolites Using PELMO 3.0 (Mc Reath A., 1999)
To assess potential concentrations in ground water, simulations were performed with the computer model PELMO (version 3.0) using the following scenarios : Borstel and Parabraunerde soils; Hamburg average climate; 1 application of florasulam to winter wheat at the maximum rate of 3.75 g a.s./ha (7.5 g a.s./ha, 50% crop interception) on 15th April; Oilseed rape was taken as following crop.

No parent florasulam was predicted to leach over five years .The 5-hydroxy metabolite showed a maximum average annual concentration of 0.038 µg/L during year 1 in Borstel soil and 0.060 µg/L during year 2 in the Parabraunerde. No 5-hydroxy metabolite was predicted to leach in year 3. Predicted annual concentrations of DFD-ASTCA were very low with a maximum of 0.019 µg/L during year 2 in the Parabraunerde. The highest predicted concentrations in leachate were seen for the ASTCA metabolite : maximum average annual concentrations were 0.224 µg/L during year 3 Borstel soil and 0.273 µg/L during year 3 in Parabraunerde. Average annual concentrations of ASTCA were less than 0.1 µg/L during all other years.

2.5.4 Fate and behaviour in air

- The Henry constant reveals that the a.s. is moderatly volatile.

  vapour pressure at 20°C = 0.77×10^{-5} Pa
  water solubility at 20°C = 0.121 g/L

  $\Rightarrow$ H at 20°C = 2.29×10^{-5} Pa.m³/mol

- No volatilization from plant or from soil occurs.

2.6 Effects on non-target species

2.6.1 Effects on terrestrial vertebrates

TER birds :
The risk assessment for birds is based on the following assumptions :
- LD_{50} (*Coturnix coturnix japonica*, a.s.) = 1046 mg a.s./kg bw
- LC_{50} (*Coturnix coturnix japonica*, a.s., 5 d) > 5000 mg a.s./kg food
- NOEC (*Colinus virginianus*, a.s., 21 weeks) = 1500 mg a.s./kg food
- Food consumption of 30% bw for small birds
- The initial residue is estimated according to Hoerger and Kenaga (1972)
- the maximum application rate is g a.s./ha

The TER reveal that the acute (5669-16031), short-term (8130-22989) and long-term (2439-6897) risk to birds is negligible.

TER mammals :
The risk assessment for mammals is based on the following assumptions :
- LD_{50} (rat, oral) = 5000 mg a.s./kg bw
- NOAEL (rat, reproduction) = 2000 mg a.s./kg food
- Food consumption of 30% bw for small mammals
- The initial residue is estimated according to Hoerger and Kenaga (1972)
- the maximum application rate is 7.5 g a.s./ha

The TER reveal that the acute (27100-76628) and long-term (3252-9195) risk to mammals is negligible.

2.6.2 Effects on aquatic species

TER active substance :
The following assumptions were made to assess the risk to water organisms :

- The toxicity figures which were taken into account were :
LC_{50} fish > 100 mg a.s./l
LC_{50} daphnia > 292 mg a.s./l
ErC_{50} alga = 8.94 µg a.s./l
EC_{50} *Lemna gibba* = 1.18 µg a.s./l
NOEC fish =119 mg a.s./l
NOEC daphnia = 38.9 mg a.s./l

- 30 cm water depth,
- spray drift according to Ganzelmeir (1992),

The results of the studies with the a.s. and with the formulation were used to calculate the acute TER.
The TER calculations with both types of data reveal that the aquatic organisms (fish, aquatic invertebrates, algae, aquatic plants) are not at acute risk (TERac fish = 1000000; TERac daphnia =2920000). Algae (*Selenastrum capricornutum, Anabaena flos-aquae*; TER algae = 89) and aquatic plants (*Lemna minor*; TER lemna = 12) are the most sensitive aquatic organisms.

Chronic TER are based on a conservative assumption : NOEC of the chronic trout and daphnid studies were compared to the initial PEC (1 m, 4% drift) . The TER calculations reveal the absence of chronic risk to aquatic organisms (TERchr fish = 1190000 ; TERchr daphnia = 389000).

Impact of the metabolites :
The main metabolite 5-hydroxy DE-570 presents a low toxicity to fish and aquatic invertebrates. It presents a low toxicity to the most sensitive alga *Selenastrum capricornutum*.
The herbicidal activity of the metabolites (metabolite 5-hydroxy-DE-570, ASTCA, DFP-ASTCA, DFP-TSA) is negligible in comparison with the activity of the a.s.

2.6.3 Effects on bees and other arthropods

Bees :
The LD_{50} (*Apis mellifera*, oral and contact) > 100 µg a.s./bee
Hazard quotients (< 0.075) reveal that the bees are not at risk.

Other non-target arthropods :
Florasulam is a post emergence broadleef weed herbicide used in cereals at the maximum rate of 7.5 g a.s./ha. Florasulam can be applied from stage BBCH 12 (2 leaves) to stage BBCH 49 (stem elongation).
At the application rate of 7.5 g a.s./ha florasulam is is harmless to *Typhlodromus pyri, Aphidius rhopalosiphi* and *Poecilus cupreus*.
Florasulam is slightly harmful to *Chrysoperla carnea* in laboratory test. Florasulam is harmless to *Chrysoperla* in an extended laboratory test performed at the application of 7.5 g a.s./ha

2.6.4 Effects on earthworms and other soil macro-organisms

Earthworms :
The LC_{50} (*Eisenia foetida*, 14 d, a.s.) > 1320 mg a.s./kg soil.

The following assumptions were made to assess the acute risk for earthworms :
- 100% of the spray reaches the soil surface.
- The substance (or formulation) is distributed in a 5 cm soil layer with a soil density of 1.5 g/cm^3

Due to the very high margin of safety observed with the acute TER (TERac > 132000) for the a.s. and the formulation EF-1343, The risk to earthworms is negligible and further testing of the sublethal effects is not required.

Other soil macro-organisms :
As the absence of risk has been demonstrated for soil non-target arthropods (*Poecilus cupreus*), earthworms and soil non-target micro-organisms, no specific studies are necessary to evaluate the effects to these organisms.

2.6.5 Effects on soil micro-organisms

The impact of florasulam on the nitrogen turnover and the soil respiration was evaluated in 2 soils. Florasulam was applied at at the concentration of 0.01 and 0.05 mg/kg soil, equivalent to the application rates of 7.5 g a.s. /ha and 37.5 g a.s./ha, at a penetration of 5 cm and soil gravity of 1.5 g/cm^3.
Effects on the nitrogen turnover (<15% after 28 days) and on the soil respiration (< 15% after 60 days) are below the trigger values established in the Annex of Directive 91/414 (<25% after 100 days) and indicate a low risk of the a.s. to soil microorganisms.

2.6.6 Effects on other non-target organisms (flora and fauna)

'Florasulam demonstrates very high levels of activity on broadleaf weeds and low activity against grasses. Pre-emergence activity is appreciably less than post-emergence activity and the rapid degradation of Florasulam to metabolites of low phytotoxicity will ensure that the risk to non-target plants is minimal once the active substance is degraded in the soil. Florasulam shows no appreciable activity against insects and only weak fungicidal activity at rates considerably higher than those exhibiting herbicidal properties.'

2.6.7 Effects on biological methods of sewage treatment

Under the normal conditions of practical use (herbicide in cereals) it is not expected that florasulam will contaminate sewage treatment plant.

LEVEL 2

Florasulam

Appendix 1 : Standard Terms and Abbreviations

Part 1 Technical Terms

A	ampere
ACH	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADP	adenosine diphosphate
AFID	alkali flame-ionization detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD_{50}	approximate median lethal dose, 50%
AOEL	acceptable operator exposure level
AMD	automatic multiple development
approx.	approximate
as	active substance
at. wt.	atomic weight
ATP	adenosine triphosphate
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
b.p.	boiling point
BSP	bromosulfophthalein
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10^{-2})
°C	degree celsius (centigrade)
CAD	computer aided design
cd	candela
CDA	controlled drop(let) application
CEC	cation exchange capacity
cf	confer, compare to
ChE	cholinesterase
cm	centimetre
CNS	central nervous system
CoC	code of conduct
COD	chemical oxygen demand
cu	cubic

cv	coefficient of variation
Cv	ceiling value
cyt	cytogenetic analysis
d	day
DL	racemic (optical configuration, a mixture of dextro- and laevo-; preceding a
dlt	dominant lethal test
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic Acid
dnd	DNA-damage
dni	DNA-inhibition
dnr	DNA-repair
dns	unscheduled DNA-synthesis
DO	dissolved oxygen
DOC	dissolved organic carbon
DT	disappearance time
DTH	delayed-type hypersensitivity
EC	effective concentration
ECD	electron capture detector
ELISA	enzyme linked immunosorbent assay
EMDI	estimated maximum daily intake
EP	end-use product
ERL	extraneous residue limit
F_0	parental generation
F_1	filial generation, first
F_2	filial generation, second
FID	flame ionization detector
f.p.	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram
GAP	good agricultural practice
GC-EC	gas chromatography with electron capture detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice

GFP	good field practice
G.I.	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GPC	gel-permeation chromatography
GPPP	good plant protection practice
h	hour(s)
ha	hectare
Hb	haemoglobin
HCG	human chorionic gonadotropin
hl	hectolitre
hma	host-mediated assay
HPLC	high pressure liquid chromatography or high performance liquid
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
Ht	haematocrit
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilization concentration
i.d.	internal diameter
ID	ionization detector
i.m.	intramuscular
inh	inhalation
i.p.	intraperitoneal
IPM	integrated pest management
IR	infrared
i.v.	intravenous
k	kilo
K	Kelvin
kg	kilogram
l	litre
LBC	loosely bound capacity
LC	lethal concentration

LC	liquid chromatography
LC_{50}	lethal concentration, median
LCA	life cycle analysis
LC_{Lo}	lethal concentration low
LD_{50}	lethal dose, median; dosis letalis media
LD_{Lo}	lethal dose low
LOAEL	lowest observable adverse effect level
LOD	limit of determination
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LT	lethal threshold
m	metre
M	molar
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
µg	microgram
mg	milligram
min	minute(s)
ml	millilitre
MLD	minimum lethal dose
mm	millimetre
mma	microsomal mutagenicity test
mmo	mutation in microorganisms
mnt	micronucleus test
mo	month(s)
mol	Mol
m.p.	melting point
MP	manufacturing-use product
mrc	gene conversion and mitotic recombination
MRE	maximum residue expected
MRL	maximum residue level
msc	mutation in mammalian somatic cells
MSDS	material safety data sheet
MTD	maximum tolerated dose

n	normal (defining isomeric configuration)
NAEL	no adverse effect level
n.d.r.	not dose-related
NEDI	no effect daily intake (mg/kg body wt/day)
NEL	no effect level
NERL	no effect residue level
NMR	nuclear magnetic resonance
no.	number
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
nse	non standard exposure
o	ortho (indicating position in a chemical name)
ODP	ozone-depleting potential
OP	organophosphorous pesticide
otr	oncogenic transformation
p	para (indicating position in a chemical name)
Pa	pascal
2-PAM	2-pralidoxime
PC	paper chromatography
PCV	haematocrit (packed corpuscular volume)
PD	position document
PEC	predicted environmental concentration
PED	plasma-emissions-detector
pH	pH-value
PHI	pre-harvest interval
pic	phage inhibition capacity
PNEC	predicted no effect concentration
p.o.	by mouth
P_{ow}	partition coefficient between n-octanol and water
ppb	parts per billion
ppm	parts per million
ppq	parts per quadrillion
ppt	parts per trillion

PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	prothrombin time
PTT	partial thromboplastin time
RAC	raw agriculture commodity
RBC	red blood cell
Rf	ratio of fronts
RL_{50}	residual lifetime
RNA	ribonucleic acid
rns	rinsed
RPM	reversed phase material
RRT	relative retention time
s.c.	subcutaneous
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SBLC	shallow bed liquid chromatography
sce	sister chromatid exchange
SD	standard deviation
SE	standard error
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
sin	sex chromosome loss and nondisjunction
slt	specific locus test
sp/spp.	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
sp gr	specific gravity
spm	sperm morphology
sq	square
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
SVAT	soil-vegetation-atmosphere transfer

t	tonne (metric ton)
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TC_{Lo}	toxic concentration, low
TD	thermionic detector, alkali flame detector
TD_{Lo}	toxic dose low
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGAI	technical grade of the active ingredient
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TOC	total organic carbon
trn	heritable translocation test
TWA	time weighted average
UDS	unscheduled DNA synthesis
ULV	ultra low volume
UV	ultraviolet
v/v	volume ratio (volume per volume)
WBC	white blood cell
wk	week
wt	weight
wt/vol	weight per volume
w/w	weight per weight
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

Part 2 Organisations and Publications

BA	Biological Abstracts (Philadelphia)
CA	Chemical Abstracts
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCPR	Codex Committee on Pesticide Residues
CIPAC	Collaborative International Pesticides Analytical Council Ltd
COREPER	Comite des Representants Permanents
EC	European Commission
ECCA	European Crop Care Association
ECPA	European Crop Protection Association
EHCD	Environmental Health Criteria Document
EINECS	European Inventory of Existing Commercial Chemical Substances
EPPO	European and Mediterranean Plant Protection Organization
EU	European Union
FAO	Food and Agriculture Organization of the UN
FJCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
GATT	General Agreement on Tariffs and Trade
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques
IARC	International Agency for Research on Cancer
IBT	Industrial Bio-Test Laboratories
IMO	International Maritime Organisation
IOBC	International Organization for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IR-4	Interregional Research Project No 4
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JECFA	FAO/WHO Joint Expert Committee on Food Additives
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)

NATO	North Atlantic Treaty Organisation
NCI	National Cancer Institute (USA)
NCTR	National Center for Toxicological Research (USA)
NGO	non-governmental organization
OECD	Organization for Economic Cooperation and Development
PAN	Pesticide Action Network
RNN	Re-registration Notification Network
SCPH	Standing Committee on Plant Health
SI	Systeme International d'Unites
SITC	Standard International Trade Classification
UN	United Nations
UNEP	United Nations Environment Programme
WHO	World Health Organization
WTO	World Trade Organization
WWF	World Wildlife Fund

LEVEL 2

Florasulam

Appendix 2 : Preparation (Formulation) Types and Codes

Preparation (Formulation) Types and Codes*

Code	Description	Definition
AB	Grain bait	Special forms of bait.
AE	Aerosol dispenser	A container-held preparation which is dispersed generally by a propellant as fine droplets/particles upon actuation of a valve.
AL	Other liquids to be applied undiluted	Self defining.
BB	Block baits	Special forms of bait.
BR	Briquette	Solid block designed for controlled release of active substance into water.
CB	Bait concentrate	A solid or liquid intended for dilution before use as a bait.
CG	Encapsulated granule	A granule with a protective or release controlling coating.
CS	Capsule suspension	A stable suspension of capsules in a fluid normally intended for dilution with water before use.
DC	Dispersible concentrate	A liquid homogeneous preparation to be applied as a solid dispersion after dilution in water.
DP	Dustable powder	A free-flowing powder suitable for dusting.
DS	Powder for dry seed treatment	A powder for application in the dry state directly to seed.
EC	Emulsifiable concentrate	A liquid, homogeneous preparation to be applied as an emulsion after dilution in water.
ED	Electrochargeable liquid	Special liquid preparation for electrostatic (electrodynamic) spraying.
EO	Emulsion, water in oil	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of pesticide in water in a continuous organic liquid phase.
ES	Emulsion for seed treatment	A stable emulsion for application to the seed either directly or after dilution.
EW	Emulsion, oil in water	A fluid, heterogeneous preparation consisting of a dispersion of fine globules of pesticide in an organic liquid in a continuous water phase.
FD	Smoke tin	Special form of smoke generator.
FG	Fine granule	A granule in the particle size range from 300 to 2500 µ.
FK	Smoke candle	A smoke generator in the form of a candle.
FP	Smoke cartridge	Special form of smoke generator.
FR	Smoke rodlet	Special form of smoke generator.
FS	Flowable concentrate for seed treatment	A stable suspension for application to the seed either directly or after dilution.
FT	Smoke tablet	Special form of smoke generator.
FU	Smoke generator	A combustible preparation generally solid, which upon ignition releases the active substances in the form of a smoke.

Code	Description	Definition
FW	Smoke pellet	Special form of smoke generator.
GA	Gas	A gas packed in pressure bottle or pressure tank.
GB	Granular bait	Special forms of bait.
GE	Gas generating product	A preparation which generates a gas by chemical reaction.
GG	Macrogranule	A granule in the particle size range from 2000 to 6000 µ.
GP	Flo-dust	Very fine dustable powder for pneumatic application in glass-houses.
GR	Granule	A free-flowing solid preparation of a defined granule size range ready for use.
GS	Grease	Very viscous preparation based on oil or fat.
HN	Hot fogging concentrate	A preparation suitable for application by fogging equipment either directly or after dilution.
KN	Cold fogging concentrate	A preparation suitable for application by cold fogging equipment, either directly or after dilution.
LA	Lacquer	A solvent based film-forming preparation.
LS	Solution for seed treatment	A solution for application to the seed either directly or after dilution.
MG	Microgranule	A granule in the particle size range from 100 to 600 µ.
OF	Oil miscible flowable (=oil active substances in a miscible suspension)	A stable suspension of concentrate fluid intended for dilution in an organic liquid before use.
OL	Oil miscible liquid	A liquid, homogenous preparation to be applied as a homogenous liquid after dilution in an organic liquid.
OP	Oil dispersible powder	A powder preparation to be applied as a suspension after dispersion in an organic liquid.
PA	Paste	A water based film forming preparation.
PB	Plate bait	Special forms of bait.
PC	Gel or paste concentrate	A solid preparation to be applied as a gel or a paste after dilution with water.
PR	Plant rodlet	A small rodlet, usually a few centimetres in length and a few millimetres in diameter containing active substance.
PS	Seed coated with a pesticide	Self defining.
RB	Bait (ready for use)	A preparation designed to attract and be eaten by the target species.
SB	Scrap bait	Special forms of bait.
SC	Suspension concentrate	A stable suspension of active substance(s) in a fluid (= flowable concentrate) intended for dilution with water before use.
SE	Suspo-emulsion	A fluid, heterogeneous preparation consisting of a stable dispersion of active substance(s) in the form of solid particles and of fine globules in a

Code	Description	Definition
		continuous water phase.
SG	Water soluble granules	A preparation consisting of granules to be applied as a true solution of active substance after dissolution in water but may contain insoluble inert ingredients.
SL	Soluble concentrate	A liquid homogenous preparation to be applied as a true solution of the active substance after dilution with water.
SO	Spreading oil	A preparation designed to form a surface layer on application to water.
SP	Water soluble powder	A powder preparation to be applied as a true solution of the active substance after solution in water but which may contain insoluble inert ingredients.
SS	Water soluble powder for seed treatment	A powder to be dissolved in water before application to the seed.
SU	Ultra low volume (ULV) suspension	A suspension ready for use through ULV equipment.
TB	Tablet	Solid preparation in the form of small, flat plates for dissolution in water.
TP	Tracking powder	A rodenticidal contact preparation in powder form.
UL	Ultra low volume (ULV) liquid	A homogenous liquid ready for use through ULV equipment.
VP	Vapour releasing product	A preparation containing one or more volatile ingredients, the vapours of which are released into the air. Evaporation rate normally is controlled by using suitable preparations and/or dispensers.
WG	Water dispersible granule	A preparation granule consisting of granules to be applied after disintegration and dispersion in water.
WP	Wettable powder	A powder preparation to be applied as a suspension after dispersion in water.
WS	Water dispersible powder for slurry seed treatment	A powder to be dispersed at high concentration in water before application as a slurry to the seed.
XX	Others	

*based upon the catalogue of Pesticide Formulation types and International Coding Systems, developed by GIFAP in co-operation with the German working group on documentation questions. (Arbeitsgruppe EDV Pflanzenschutz Versuchswesen). GIFAP Technical Monograph No 2. 1989.

LEVEL 2

Florasulam

Appendix 3 : Listing of endpoints

LEVEL 3

Florasulam

Proposed decision with respect to the application for inclusion of the active substance in Annex I

3.1 Background to the proposed decision

The information provided by the notifier was sufficient to evaluate the a.s. according Directive 91/414/EEC. The evaluation of the data and the risk assessment which were performed showed that the use of the a.s. according to GAP do not cause unacceptable risk to human beings and to the environment.

3.2 Proposed decision concerning inclusion in Annex I

The RMS proposes to include the active substance florasulam in the Annex I of the Directive 91/414/EEC.

3.3 Rational for the postponement of the decision to include the active substance in Annex I, or for the conditions and restrictions to be associated with a proposed inclusion in Annex I, as appropriate

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LEVEL 4

Florasulam

Further information to permit a decision to be made, or to support a review of the conditions and restrictions associated with the proposed inclusion in the Annex I

4.1 Identity of the active substance

-

4.2 Physical and chemical properties

4.2.1 Physical and chemical properties of the active substance

Point addressed	Information or study required	Deadline
IIA 2.9.2	Further tests on direct phototransformation of purified a.s. in water according to SETAC-procedures (using xenon light source)	

4.2.2 Physical and chemical properties of the plant protection product (EF-1343 : SC : 50 g/L Florasulam)

Point addressed	Information or study required	Deadline
IIIA 2.5.3, IIIA 2.8.2	Surface tension and persistent foaming should be determined at concentrations which are relevant to the GAP proposed in each MS.	
IIIA 2.8.3	Full report on suspensibility according to CIPAC MT 161	

4.3 Data on application and further information

Point addressed	Information or study required	Deadline
IIIA 4.2	Cleaning procedures for protective clothing must be addressed	

4.4 Classification, packaging and labelling

-

4.5 Methods of analysis

Point addressed	Information or study required	Deadline
IIA 4.2.1, IIIA 5.2.1	Validation of the analysis method for tissues of animal origin (analysis method submitted under point IIA 6.2 - metabolism in animal)	

4.6 Toxicology and metabolism

-

4.7 Residue data

-

4.8 Environmental fate and behaviour

-

4.9 Ecotoxicology

-