

ANNEX B

Florasulam

B.1 Identity

B.1.1 Identity of the active substance (Annex IIA 1)

B.1.1.1 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

B.1.1.2 Manufacturer of the active substance (Annex IIA 1.2)

Manufacturer : 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

B.1.1.3 ISO common name and synonyms (Annex IIA 1.3)

Common name : Florasulam (ISO-proposed)

B.1.1.4 Chemical name (Annex IIA 1.4)

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

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

B.1.1.5 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.

B.1.1.6 CAS, EEC and CIPAC numbers (Annex IIA 1.6)

CAS number : 145701-23-1

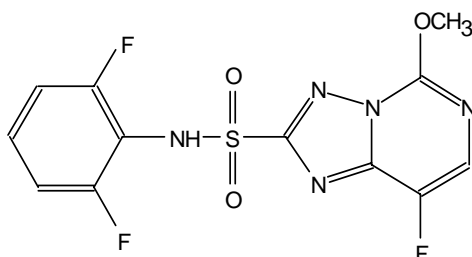
EEC number : not available

CIPAC number : not available

B.1.1.7 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

B.1.1.8 Method or methods of manufacture (Annex IIA 1.8)

Confidential information, see Annex C

B.1.1.9 Specification of the purity of the active substance (Annex IIA 1.9)

Minimum purity of florasulam technical : 970 g/kg

B.1.1.10 Identity of inactive isomers, impurities and additives (Annex IIA 1.10)

Confidential information, see Annex C

B.1.1.11 Analytical profile of batches (Annex IIA 1.11)

Confidential information, see Annex C

B.1.2 Identity of the plant protection product EF-1343 (Annex IIA 3.1; Annex IIIA 1)

B.1.2.1 Current, former and proposed trade names and development code numbers (Annex IIIA 1.3)

Trade name : PRIMUS

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.

B.1.2.2 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

B.1.2.3 Type of the preparation and code (Annex IIIA 1.5)

Suspension concentrate (SC)

B.1.2.4 Function (Annex IIIA 1.6)

Herbicide

B.1.2.5 Composition of the preparation (Annex IIIA 1.4)

Table 1.2.5-1 : 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	

B.1.3 References relied on

Annex point(s) 91/414/EEC	Author, Title, Test institute, Report number/Study ID, Date of report For publications: reference	Dow AgroScience s Report No.	GLP GEP	Published Protected
IIA 1.11	Boothroyd, S, Characterisation of XDE-570 Technical Batch Number TSN 100298 Interim Report: Assay, Differential Scanning Calorimetry and Initial Mass Spectrometry DowElanco Europe, Letcombe Regis, Oxon, UK 93030/DA, February 1994	GHE-P-3395	Yes	Unpublished protected
IIA 1.11	Boothroyd, S, Characterisation of XDE-570 Pure Batch Number DECO-293-021 Interim Report: Assay, Differential Scanning Calorimetry and Initial Mass Spectrometry DowElanco Europe, Letcombe Regis, Oxon, UK 93030/DB, March 1994	GHE-P-3517 R	Yes	Unpublished protected
IIA 1.11	Boothroyd, S, Knowles, S Reassay of XDE-570 (Tech), TSN 100298 DowElanco Europe, Letcombe Regis, Oxon, UK 93030/DD, August 1994	GHE-P-3718	Yes	Unpublished protected
IIA 1.11	Boothroyd, S, Ghosh, D, Knowles, S, Characterisation of XDE-570 Pure Batch Number DECO-293-021: Summary Report DowElanco Europe, Letcombe Regis, Oxon, UK 93030/DB, February 1996a	GHE-P-4703	Yes	Unpublished protected
IIA 1.11	Boothroyd, S, Ghosh, D, Knowles, S, Characterisation of XDE-570 Technical Batch Number TSN 100298: Summary Report DowElanco Europe, Letcombe Regis, Oxon, UK 93030/DA, February 1996b	GHE-P-4702	Yes	Unpublished protected
IIA 1.11	Boothroyd, S, Knowles, S, Characterisation of XDE-570 5-Hydroxy, Batch A1151-3 DowElanco Europe, Letcombe Regis, Oxon, UK 93030/DH, February 1996	GHE-P-4759	Yes	Unpublished protected
IIA 1.11	Boothroyd, S, Knowles, S, Re-analysis of XDE-570 Analytical Standard, DECO-293-021 DowElanco Europe, Letcombe Regis, Oxon, UK 93030/DJ, March 1996a	GHE-P-4761	Yes	Unpublished protected
IIA 1.11	Boothroyd, S, Knowles, S, Re-analysis of XDE-570 Analytical Standard, TSN100298 DowElanco Europe, Letcombe Regis, Oxon, UK 93030/DI, March 1996b	GHE-P-4760	Yes	Unpublished protected
IIA 1.11	Knowles, S, Re-analysis of XDE-570 Technical, TSN 100511 DowElanco Europe, Letcombe Regis, Oxon, UK P97-034, July 1997	GHE-P-6448	Yes	Unpublished protected
IIA 1.11	Knowles, S, Droussopoulos, C, Characterisation of XDE-570 Technical, TSN 100298 DowElanco Europe, Letcombe Regis, Oxon, UK P98-066, August 1998	GHE-P-7307	Yes	Unpublished protected
IIA 1.11	Knowles, S, Ghosh, D, Five Batch Characterisation of XDE-570 Technical	GHE-P-6447	Yes	Unpublished protected

Annex point(s) 91/414/EEC	Author, Title, Test institute, Report number/Study ID, Date of report For publications: reference	Dow AgroScience s Report No.	GLP GEP	Published Protected
	DowElanco Europe, Letcombe Regis, Oxon, UK P97-007, November 1997			
IIA 1.11	Knowles, S, Olive, C, Characterisation of XDE-570 Technical , TSN 100529 DowElanco Europe, Letcombe Regis, Oxon, UK P98-054, July 1998	GHE-P-7286	Yes	Unpublished protected
IIA 1.11	Knowles, S, Olive, C, Characterisation of XDE-570 Technical , TSN 100318 DowElanco Europe, Letcombe Regis, Oxon, UK 93030/DK April 1999	GHE-P-7813	Yes	Unpublished protected
IIA 1.11	Knowles, S, Richardson, N, Portwood, D, Olive,C, Five Batch Characterisation of XDE-570 Technical DowElanco Europe, Letcombe Regis, Oxon, UK P98-066, August 1998	GHE-P-7307	Yes	Unpublished protected
IIA 1.11	Richardson, N, Boothroyd, S, Knowles, S, Characterisation and Purity Determination of XDE-570 Technical Batch Number TSN 100511 DowElanco Europe, Letcombe Regis, Oxon, UK 93030/DC, February 1995	GHE-P-3814	Yes	Unpublished protected
IIA 1.11	Richardson, N, Knowles, S, Ghosh, D, Characterisation of XDE-570 5-Hydroxy (DECO-393-053) as a Secondary Standard DowElanco Europe, Letcombe Regis, Oxon, UK 93030/DE, July 1995a	GHE-P-4050	Yes	Unpublished protected
IIA 1.11	Richardson, N, Knowles, S, Ghosh, D, Characterisation of XDE-570 5-Hydroxy (DK1-B550-16) as a Secondary Standard DowElanco Europe, Letcombe Regis, Oxon, UK 93030/DF, July 1995b	GHE-P-4049	Yes	Unpublished protected

ANNEX B

Florasulam

B.2 Physical and chemical properties

B.2.1 Physical and chemical properties of the active substance (Annex IIA 2)

With respect to the test substances used for the determination of the physical and chemical properties, the following purity values should be taken into account :

- for the purified a.s. : 99.7% (batch No. DECO-293-021 - certificate of analysis) (Boothroyd et al., 1996)
- for the a.s. as manufactured (TC) : 99.3% (batch No. TSN 100511 - certificate of analysis) (Boothroyd et al., 1995)
- for the a.s. as manufactured (TC)* : 99.6% (batch No. TSN 100529 - certificate of analysis)

Table B.2.1-1 : Physical and chemical properties of florasulam

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.1 Melting point, freezing point or solidification point (IIA 2.1.1)	- EEC-method A1 (capillary method) - GLP-compliance stated	purified a.s. : melting point range = 193.5 to 230.5°C with decomposition (from stage C onwards, sample was observed to darken in appearance)	- Acceptable	Cowlyn, 1995
B.2.1.2 Boiling Point (IIA 2.1.2)			- Not applicable : a.s. decomposes upon melting	
B.2.1.3 Temperature of decomposition or sublimation (IIA 2.1.3)	- EEC-method A1 (capillary method) - GLP-compliance stated	purified a.s. : decomposition begins at approx. 202.5 °C (stage C of melting)	- Acceptable	Cowlyn, 1995
B.2.1.4 Relative density (IIA 2.2)	- EEC-method A3 (pycnometer) - GLP-compliance stated	purified a.s. : relative density at 22°C = 1.53	- Acceptable (test temperature 22°C instead of 20°C)	Niemtus, 1996a

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.5 Vapour pressure (IIA 2.3.1)	- EEC-method A4 (vapour pressure balance) - GLP-compliance stated	purified a.s. : vapour pressure at 25°C = 1×10^{-5} Pa (max. value estimated by imposing a shallow slope of -2000 for the vapour pressure/temp. relationship)	- Acceptable	Taylor, 1994 in : Cowlyn, 1995
B.2.1.6 Volatility, Henry's law constant (IIA 2.3.2)	- Calculation only - GLP not relevant	purified a.s. : vapour pressure at 20°C = 0.77×10^{-5} Pa water solubility at 20°C - pH 5 = 0.084 g/L water solubility at 20°C - pH 7 = 6.36 g/L water solubility at 20°C - pH 9 = 94.2 g/L \Rightarrow H at 20°C, pH 5 = 3.29×10^{-5} Pa.m ³ /mol \Rightarrow H at 20°C, pH 5 = 4.35×10^{-7} Pa.m ³ /mol \Rightarrow H at 20°C, pH 5 = 2.94×10^{-8} Pa.m ³ /mol	Acceptable	Madsen, 1999 Ghosh, 1997a
B.2.1.7 Physical state (IIA 2.4.1)	- GLP-compliance stated	purified a.s. : solid at 25°C technical material : also solid	- Acceptable	Sydney, 1996a Findings regarding technical material were mentioned in Tier II (no report)
B.2.1.8 Colour (IIA 2.4.1)	- Munsell Color system (under natural daylight) - GLP-compliance stated	purified a.s. : off-white (N9.5/90.0% R) technical material : also off-white	- Acceptable	Sydney, 1996a Findings regarding technical material were mentioned in Tier II (no report)

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References																
B.2.1.9 Odour (IIA 2.4.2)	- GLP-compliance stated	purified a.s. : no discernible odour technical material : also no discernible odour	- Acceptable	Sydney, 1996a Findings regarding technical material were mentioned in Tier II (no report)																
B.2.1.10 Spectra of the active substance (IIA 2.5.1)	- GLP-compliance stated	purified a.s. and a.s. as manufactured (TC) : <i>Following spectra were provided :</i> IR (KBr; spectrum measured between 4000 and 400, resp. 600 cm ⁻¹) UV/VIS (methanol; spectra measured between 1) 190-900 nm and 2) 190-400 nm) MS (EI at 70 eV) ¹ H-NMR (250 MHz; DMSO-d ₆) ¹³ C-NMR (63 MHz; DMSO-d ₆) The different spectra were found to be consistent with the structure of DE-570 <i>UV/VIS absorption characteristics :</i> <table><thead><tr><th></th><th><u>λ (nm)</u></th><th><u>ε (L.mol⁻¹.cm⁻¹)</u></th></tr></thead><tbody><tr><td rowspan="2">acidic (pH 0.75) :</td><td>259.8</td><td>1.22x10⁴</td></tr><tr><td>203.8</td><td>2.99x10⁴</td></tr><tr><td rowspan="2">basic (pH 13.21) :</td><td>262.4</td><td>2.36x10⁴</td></tr><tr><td>209.7</td><td>1.84x10⁴</td></tr><tr><td>methanolic (pH 12.60) :</td><td>204.1</td><td>2.74x10⁴</td></tr></tbody></table> DE-570 does not absorb wavelengths above 290 nm <i>Optical purity :</i> not relevant (DE-570 is not a resolved optical isomer)		<u>λ (nm)</u>	<u>ε (L.mol⁻¹.cm⁻¹)</u>	acidic (pH 0.75) :	259.8	1.22x10 ⁴	203.8	2.99x10 ⁴	basic (pH 13.21) :	262.4	2.36x10 ⁴	209.7	1.84x10 ⁴	methanolic (pH 12.60) :	204.1	2.74x10 ⁴	- Acceptable	<u>purified a.s.:</u> Boothroyd et al., 1996 (UV, IR, NMR) Comb, 1994 (MS) <u>a.s. as manufactured (TC) :</u> Boothroyd et al., 1995
	<u>λ (nm)</u>	<u>ε (L.mol⁻¹.cm⁻¹)</u>																		
acidic (pH 0.75) :	259.8	1.22x10 ⁴																		
	203.8	2.99x10 ⁴																		
basic (pH 13.21) :	262.4	2.36x10 ⁴																		
	209.7	1.84x10 ⁴																		
methanolic (pH 12.60) :	204.1	2.74x10 ⁴																		

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.11 Spectra for impurities (IIA 2.5.2)	- Applicant's statement	"No impurities are considered to be of toxicological, ecotoxicological or environmental significance"	- Acceptable	
B.2.1.12 Solubility in water (IIA 2.6)	- EEC-method A6 (flask method with HPLC analysis) - GLP-compliance stated	purified a.s. : solubility at 20°C 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	- Acceptable.	Cowlyn, 1995
B.2.1.13 Solubility in organic solvents (IIA 2.7)	- CIPAC MT 157 (flask method with HPLC analysis) - GLP-compliance stated	purified a.s. : solubility at 20°C in n-heptane* : 0.019x10 ⁻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)	- Acceptable (solubility determined with purified a.s. instead of technical material)	Cowlyn, 1995
B.2.1.14 Partition coefficient n-octanol/water	- EEC-method A8 (shake flask method with HPLC analysis and UV spectrophotometry)	purified a.s. : at 20°C at pH 4.0 : log P _{ow} = 1.00 at pH 7.0 : log P _{ow} = -1.22	- Acceptable.	Cowlyn, 1995

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
(IIA 2.8)	- GLP-compliance stated	at pH 10.0 : $\log P_{ow} = -2.06$		
B.2.1.15	- No guideline specified	[triazolopyrimidine- ¹⁴ C]- labelled a.s., radiochemical	- Method does not	Jackson and Portwood,

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	<p>- No GLP-compliance stated (but claimed to be performed to the spirit of GLP)</p>			

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	- US EPA N 161-1	[phenyl-UL- ¹⁴ C]- and [9-triazolopyrimidine- ¹⁴ C]-	- Method does not	Phillips, 1996

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	<p data-bbox="510 379 725 435">- GLP-compliance stated</p>			

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.16 Direct phototransformation of purified a.s. in water using artificial light under sterile conditions	- US EPA N 161-2 (natural sunlight at 40°N latitude, resp. in May (AN) and June (TP))	[aniline-UL- ¹⁴ C]- and [9-triazolopyrimidine- ¹⁴ C]-labelled a.s. (AN and TP resp.), radiochemical purity resp. 97.7 and 99.0% : at 25°C, buffered at pH 5 (sterile conditions, acetonitrile as cosolvent) : <i>Mass balance</i> :	- Method concurs with SETAC-procedures, except for use of natural sunlight instead of artificial light source. Results are	Yoder, 1996

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	<p data-bbox="510 376 712 432">- GLP-compliance stated</p>			

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.16 (Cont'd)	<p>- No guideline specified (xenon lamp and natural sunlight (summer at 40°N latitude))</p> <p>- No GLP-compliance stated</p>	<p>[phenyl-UL-¹⁴C]- labelled a.s. (xenon) and [9-triazolopyrimidine-¹⁴C]- labelled a.s. (natural), radiochemical purity not stated : at 25°C, buffered at pH 5 :</p> <p><i>Photolysis rate :</i> $k = 0.08 \text{ d}^{-1}$; $t_{1/2} = 9 \text{ d}$ (xenon) $k = 0.005 \text{ d}^{-1}$; $t_{1/2} = 139 \text{ d}$ (natural sunlight)</p> <p>No material balance, no identification of photodegradation products</p>	<p>- Method does not concur with SETAC-procedures (apparently no sterile conditions, not clear if xenon lamp is equipped with appropriate filter to exclude $\lambda < 290 \text{ nm}$) and photodegradation products were not identified.</p>	Yoder, 1998
B.2.1.17 Quantum yield of direct phototransformation (IIA 2.9.3)	<p>- US EPA N 161-2 (natural sunlight at 40°N latitude, resp. in May (AN) and June (TP))</p> <p>- GLP-compliance stated</p>	<p>[aniline-UL-¹⁴C]- and [9-triazolopyrimidine-¹⁴C]- labelled a.s. (AN and TP resp.), radiochemical purity resp. 97.7 and 99.0% :</p> <p><u>quantum yield :</u> $\Phi = 0.074$ (determined using PNAP/pyr actinometer)</p> <p><u>environmental photolytic lifetime :</u></p> <ul style="list-style-type: none"> · in water at 40°N latitude : expected $t_{1/2}$ ranges from 46 d in summer to 585 d in winter · in water at 20°N latitude : expected $t_{1/2}$ ranges from 32 d in summer to 77 d in winter · in water at 60°N latitude : expected $t_{1/2}$ ranges from 95 d in summer to 38240 d in winter <p>(calculated using the solar irradiance values reported in Leifer (1988))</p>	<p>- Acceptable</p>	Yoder, 1996

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.17 (cont'd)	<ul style="list-style-type: none"> - No guideline specified (xenon lamp and natural sunlight (summer at 40°N latitude)) - No GLP-compliance stated 	<p>[phenyl-UL-¹⁴C]- labelled a.s. (xenon) and [9-triazolopyrimidine-¹⁴C]- labelled a.s. (natural), radiochemical purity not stated : <u>quantum yield</u> : $\Phi = 0.32$ (xenon) $\Phi = 0.066$ (natural sunlight) (determined using PNAP/pyr actinometer)</p>	<ul style="list-style-type: none"> - Not acceptable : Φ is unequivocal parameter, independent of the type of light source used for its determination. - Scientific basis of study is questionable : in xenon lamp experiment, Φ was calculated using light absorption rate constants or irradiance values taken from literature, referring to average natural summer sunlight at 40°N latitude. Instead, the actual irradiance received by the photolysis samples (from xenon lamp) 	Yoder, 1998
B.2.1.18 Dissociation in water of purified active substance (IIA 2.9.4)	<ul style="list-style-type: none"> - OECD-guideline 112 (spectrophotometric method) - GLP-compliance stated 	<p>purified a.s. : $pK_a = 4.54$ (determination at 22-23°C)</p>	- Acceptable	Niemtus, 1996a

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.19 Estimated photo chemical oxidative degradation (IIA 2.10)	- Atmospheric Oxidation Program Version 1.55a (1994) (based on Atkinson-method) - GLP not applicable	overall rate constant = 70.4×10^{-12} cm ³ /molecule.s ⇒ estimated half-life of DE-570 in the atmosphere (by hydroxyl radical oxidation) : 1.82 h (calculated with 1.5×10^6 OH-radicals/cm ³ and 12 h day)	- Acceptable	Ghosh, 1997b
B.2.1.20 Flammability (IIA 2.11.1)	- EEC-method A10 - GLP-compliance stated	a.s. as manufactured (TC) : no ignition, only melting ⇒ a.s. is not classified as highly flammable	- Acceptable	Niemtus, 1996b
B.2.1.21 Auto-flammability (IIA 2.11.2)	- EEC-method A16 - GLP-compliance stated	a.s. as manufactured (TC)* : no self-ignition before the onset of melting at 194°C ⇒ a.s. is not classified as a self-heating substance	- Acceptable	Comb, 1997
B.2.1.22 Flash point (IIA 2.12)			- Not applicable (melting point > 40 °C)	
B.2.1.23 Explosive properties (IIA 2.13)	- EEC-method A14 - GLP-compliance stated	a.s. as manufactured (TC) : · no thermal sensitivity · no mechanical sensitivity with respect to shock · no mechanical sensitivity with respect to friction ⇒ a.s. is not classified as an explosive	- Acceptable	Niemtus, 1996b

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.24 Surface tension (IIA 2.14)	- EEC-method A5 (Ring method : surface tension torsion balance) - GLP-compliance stated	purified a.s. : $\sigma = 71.5 \text{ mN/m}$ at 21 °C (99 mg/L solution) \Rightarrow a.s. is not surface active	- Surface tension was measured using a 82% saturated solution in water instead of a 90% solution, as prescribed in EEC A5.	Sydney, 1996a
B.2.1.25 Oxidizing properties (IIA 2.15)	- EEC-method A17 - GLP-compliance stated	a.s. as manufactured (TC) : <u>main test</u> : · burning rate of reference mixture = 0.76 mm/s (barium nitrate/cellulose 60/40 (w/w)) · max. burning rate of test mixtures = 0.66 mm/s (test substance/cellulose 10/90 (w/w)) \Rightarrow a.s. is not oxidizing	- Main test was not repeated 5 times with the 3 test mixtures exhibiting the highest burning rates, as prescribed in EEC A17. No comment was made regarding the eventual pretreatment of the test substance (sieving/grinding).	Niemtus, 1996b

The dossier also contained studies determining physico-chemical properties of the metabolite 5-hydroxy DE-570, relevant to its behaviour in the environment..

Table B.2.1-2 : Physical and chemical properties of metabolite 5-hydroxy DE-570 of florasulam

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.5-2 Vapour pressure (IIA 2.3.1)	- EEC-method A4 (vapour pressure balance) - GLP-compliance stated	technical material, 97% pure : vapour pressure at 25°C = 2.7×10^{-6} Pa (max. value estimated by imposing a shallow slope of -2000 for the vapour pressure/temp. relationship)	- Acceptable as supplementary information,	Niemtus, 1996c
B.2.1.12-2 Solubility in water (IIA 2.6)	- EEC-method A6 (flask method with HPLC-analysis)	technical material, 97% pure : solubility at 20°C in	- Acceptable as supplementary information	Niemtus, 1996c

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	<p>- GLP-compliance stated</p>	<p> purified water (pH 4.73-4.88) : 0.354 g/L pH 5.0 buffer : 0.633 g/L pH 7.0 buffer* : > 450 g/L pH 9.0 buffer* : > 800 g/L solubility at 10°C in purified water (pH 4.90-4.96) : 0.313 g/L solubility at 30°C in purified water (pH 4.55-4.72) : 0.420 g/L * modified test (performance of flask method was not possible due to acidic nature of test substance) </p>		

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.13-2 Solubility in organic solvents (IIA 2.7)	- CIPAC MT 157 (flask method with HPLC-analysis) - GLP-compliance stated	technical material, 97% pure : solubility at 20°C in n-heptane : $< 2.5 \times 10^{-6}$ g/L xylene : 428×10^{-6} g/L dichloroethane : 0.0313 g/L methanol* : 28.0 g/L n-octanol : 0.359 g/L acetone* : 91.8 g/L ethyl acetate : 4.25 g/L acetonitrile* : 31.9 g/L * g/L solvent (rest : g/L solution) mag weg	- Acceptable as supplementary information	Niemtus, 1996c
B.2.1.14-2 Partition coefficient n-octanol/water (IIA 2.8)	- EEC-method A8 (shake flask method with HPLC analysis) - GLP-compliance stated	technical material, 97% pure : at 20°C at pH 4.0 : $\log P_{ow} = 0.32$ at pH 7.0 : $\log P_{ow} = -1.85$ at pH 9.0 : $\log P_{ow} = -2.32$	- Acceptable as supplementary information	Niemtus, 1996c
B.2.1.18-2 Dissociation in water of purified active substance (IIA 2.9.4)	- OECD-guideline 112 (spectrophotometric method) - GLP-compliance stated	technical material, 97% pure : $pK_a^1 = 4.53$ $pK_a^2 = 7.22$	- Acceptable as supplementary information	Niemtus, 1996c

B.2.2 Physical and chemical properties of the plant protection product (Annex IIIA 2)

Table B.2.2-1 : Physical and chemical properties of EF-1343 (Suspension concentrate : 50 g/L florasulam)

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.1 Physical state (IIIA 2.1)	- Visual observation - GLP-compliance stated	opaque liquid	- Acceptable	Banks, 1996
B.2.2.2 Colour (IIIA 2.1)	- Visual observation - GLP-compliance stated	white	- Acceptable	Banks, 1996
B.2.2.3 Odour (IIIA 2.1)	- GLP-compliance stated	no discernible odour	- Acceptable	Sydney, 1996b
B.2.2.4 Explosive properties (IIIA 2.2.1)	- EEC-method A14 - GLP-compliance stated	· no thermal sensitivity · no mechanical sensitivity with respect to shock ⇒ EF-1343 is not explosive	- Acceptable	Sydney, 1996b
B.2.2.5 Oxidizing properties (IIIA 2.2.2)	- EPA/OPPTS No. 830.6314 - GLP-compliance stated	· reacted with potassium permanganate solution (as indicated by colour change) · non-reactive toward monoammonium phosphate zinc dust water ⇒ EF-1343 shows no oxidizing properties	- Acceptable (method EEC A17 is not applicable to liquids)	Comb, 1998
B.2.2.5 (cont'd)	- DSC	air atmosphere :	- Acceptable as	McGrath and Foster,

Study	Guidelines and GLP	Findings	Evaluation and conclusion supplementary information	References
	- Study carried out in GLP-compliant facility	no exothermic decomposition events before 450°C nitrogen atmosphere : no exothermic decomposition events before 335°C		1997
B.2.2.6 Flash point (IIIA 2.3)	- EEC-method A9 (Pensky-Martens closed cup) - GLP-compliance stated	no flash point below boiling temperature (approx. 96°C) (barometric pressure : 1035 mbar)	- Acceptable	Comb, 1998
B.2.2.7 Flammability (IIIA 2.3)			- Not applicable (liquid preparation)	
B.2.2.8 Auto- flammability (IIIA 2.3)	- EEC-method A15 (BS 4056) - GLP-compliance stated	no auto-ignition temperature below 400 °C	- Acceptable	Comb, 1998
B.2.2.9 Acidity or alkalinity and pH value (IIIA 2.4.1)	- CIPAC MT 75.1 - GLP-compliance stated	neat product at 20 °C : pH = 6.19 As the pH of the undiluted material is between 4 and 10, determination of acidity/alkalinity is not required	- Acceptable	Banks, 1996
B.2.2.10 pH of a 1 % aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	- CIPAC MT 75.2 - GLP-compliance stated	1% aqueous dispersion at 20°C : pH = 4.36	- Acceptable	Banks, 1996

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References										
B.2.2.11 Kinematic viscosity (IIIA 2.5.1)			- Not applicable (preparation not intended for ULV-use)											
B.2.2.12 Viscosity (III 2.5.2)	- In-house method EU-AM-93-2 (Carri-med Controlled Stress Rheometer) - GLP-compliance stated	at 20°C : <table><tr><td><u>shear rate (s⁻¹)</u></td><td><u>η (mPa.s)</u></td></tr><tr><td>424</td><td>19.5</td></tr><tr><td>212</td><td>26.3</td></tr><tr><td>106</td><td>35.8</td></tr><tr><td>53</td><td>49.2</td></tr></table>	<u>shear rate (s⁻¹)</u>	<u>η (mPa.s)</u>	424	19.5	212	26.3	106	35.8	53	49.2	- Method concurs with OECD 114 - Acceptable, although report is somewhat concise.	Banks, 1996
<u>shear rate (s⁻¹)</u>	<u>η (mPa.s)</u>													
424	19.5													
212	26.3													
106	35.8													
53	49.2													
B.2.2.13 Surface tension (IIIA 2.5.3)	- EEC-method A5 (Ring method : surface tension torsion balance) - GLP-compliance stated	0.15% v/v suspension : σ = 41.5 mN/m (at 24°C) 0.0083% v/v suspension : σ = 57.5 mN/m (at 25°C) ⇒ EF-1343 is surface active	- Acceptable	Sydney, 1996b										
B.2.2.14 Relative density (IIIA 2.6.1)	- In-house-method EU-AM-91-33 (oscillating densitometer) - GLP-compliance stated	at 20°C : density = 1.0318 g/mL	- Method concurs with EEC A3 - Acceptable	Banks, 1996										
B.2.2.15 Bulk or tap density (IIIA 2.6.2)			- Not applicable (liquid preparation)											

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.16 Stability after storage for 14 days at 54 °C (IIIA 2.7.1)	- CIPAC MT 46.1.3 - GLP-compliance stated	after storage for <u>14 d at 54 °C</u> : · <i>chemical stability of a.s.</i> : DE-570 content : 50.97 g/L (initial : 51.90 g/L) · <i>physical stability</i> : suspensibility : 100% (initial : 101%) 75 µm sieve residue: 0.0120% (initial : 0.0165%) pH (1% dispersion) : 4.91 (initial : 4.36) pH (neat) : 6.19 (initial : 6.19) no significant change in appearance, density, viscosity and particle size distribution ⇒ EF-1343 will be chemically and physically stable under field use conditions	- Acceptable, although not all relevant physical properties were tested after storage (no pourability and spontaneity of dispersion)	Banks, 1996
	- CIPAC MT 46.1.2 - GLP-compliance stated	after storage for <u>14 d at 54±2°C</u> : · <i>chemical stability of a.s.</i> : DE-570 content : 48.83 g/L (initial : 49.18 g/L) · <i>physical stability</i> : suspensibility : 0.017% v/v : 100.1% (initial : 100.1%) 0.067% v/v : 100.2% (initial : 100.3%) spontaneity of dispersion : 98.7% (initial : 99.7%) 75 µm sieve residue: 0.0269% (initial : 0.0257) pH (1% dispersion) : 4.87 (initial : 4.80) rinsability : 0.0020% (initial : 0.0022%) appearance : clear liquid (oil) on top, no sediment (cake) on bottom, easy rehomogenisation	- Acceptable	de Ryckel, 1998
B.2.2.17			- Not applicable	

Study	Guidelines and GLP	Findings	Evaluation and conclusion (preparation is not heat sensitive)	References
Stability after storage for other periods and temperatures (IIIA 2.7.1)				
B.2.2.18 Minimum content after heat stability testing (IIIA 2.7.1)		see B.2.2.16		
B.2.2.19 Effect of low temperature on stability (IIIA 2.7.2)	<ul style="list-style-type: none"> - CIPAC MT 39.1 - GLP-compliance stated 	after storage for <u>7 d</u> at $0\pm 1^{\circ}\text{C}$: <ul style="list-style-type: none"> · no modification of appearance · 75 μm sieve residue : 0.0210% (initial : 0.0257%) · suspensibility : <ul style="list-style-type: none"> 0.017% v/v : 100.2% (initial : 100.1%) 0.067% v/v : 100.2% (initial : 100.3%) · spontaneity of dispersion : 99.3% (initial : 99.7%) 	- Acceptable	de Ryckel, 1998
B.2.2.20 Shelf life (IIIA 2.7.3)	<ul style="list-style-type: none"> - Guidelines for formulation and storage stability requirements for UK registration (PSD, MAFF) 	after storage for <u>8 weeks</u> at $40\pm 5^{\circ}\text{C}$ in PET packaging, resp. HDPE packaging : <p><i>product :</i></p> <ul style="list-style-type: none"> · stable with regard to a.s. content 	<ul style="list-style-type: none"> - Method concurs with GIFAP No. 17 - Acceptable; since no significant chemical or physical changes 	Turri and Olive, 1997

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
	- GLP-compliance stated	<ul style="list-style-type: none"> · stable with regard to physical properties (no significant variation in active suspensibility, spontaneity of dispersion, wet sieve residue, pourability, persistent foam and pH) · no claying <i>containers :</i> <ul style="list-style-type: none"> · satisfactory with respect to change of shape (trace to slight base distension observed is not considered to be detrimental to safety) · satisfactory with respect to mass change (average mass loss observed, primarily due to permeation of water, is not considered to be significant) <p>⇒ shelf-life of 2 years is expected</p>	occurred in the accelerated test, the product will most likely comply with a shelf-life specification of 2 years. - Real-time study demonstrating stability for at least 2 years at ambient temperature in the commercial packaging is currently ongoing (report ready for submission by 10/99)	
B.2.2.21 Wettability (IIIA 2.8.1)			- Not applicable (liquid preparation)	
B.2.2.22 Persistent foaming (IIIA 2.8.2)	- CIPAC MT 47.2 - GLP-compliance stated	dilution of the formulation with CIPAC water D to a concentration of 0.15% v/v at 23°C : after 10 s : 39 mL foam 1 min : 33 mL 3 min : 32 mL 12 min : 23 mL	- Water D was used instead of water C - Acceptable, on condition that 0.15% is really the max. conc. recommended in directions for use.	Sydney, 1996b
B.2.2.23 Suspensibility (IIIA 2.8.3)	- CIPAC MT 161 (with a.s. content analysis by GC)	0.05% v/v suspension in 342 ppm standard hard water at 30°C :	- Tested suspension is not representative for all concentrations	Banks, 1996

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
	- GLP-compliance stated	suspensibility = 101% w/w	recommended in the directions for use. According to CIPAC MT 161, when a range of concentrations is recommended, the test should be performed with the highest and lowest concentration (i.e. 0.5 % v/v and 0.01% v/v).	
B.2.2.24 Spontaneity of dispersion (IIIA 2.8.3)	- CIPAC MT 160 (with a.s. content analysis by HPLC) - GLP-compliance stated	in standard water C at 30°C : spontaneity of dispersion = 107.4%	- Acceptable	Sydney, 1996b
B.2.2.25 Dilution stability (IIIA 2.8.4)			- Not applicable (preparation is not a water soluble product)	
B.2.2.26 Dry sieve test and wet sieve test (IIIA 2.8.5)	- CIPAC MT 59.3 - GLP-compliance stated	wet sieve residue on 75 µm sieve = 0.0165%	- Acceptable	Banks, 1996
B.2.2.27			- Not applicable	

Study	Guidelines and GLP	Findings	Evaluation and conclusion (preparation is not a powder nor a granule)	References
Size distribution of particles - Nominal size range of particles (IIIA 2.8.6.1)				
B.2.2.28 Dust content and particle size of dust (IIIA 2.8.6.2)			- Not applicable (preparation is not a granule).	
B.2.2.29 Friability and attrition characteristics of granules (IIIA 2.8.6.3)			- Not applicable (preparation is not a granule).	
B.2.2.30 Emulsifiability, emulsion stability, re-emulsifiability (IIIA 2.8.7.1)			- Not applicable (preparation does not form emulsions)	
B.2.2.31 Stability of dilute emulsions (IIIA 2.8.7.2)			- Not applicable (preparation does not form (is not an) emulsion(s))	
B.2.2.32 Flowability (IIIA 2.8.8.1)			- Not applicable (preparation is not a granule)	
B.2.2.33	- CIPAC MT 148	residue R = 1.3% w/w	- Acceptable	Sydney, 1996b

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
Pourability (including rinsed residue) (IIIA 2.8.8.2)	- GLP-compliance stated	rinsed residue R' = 0.2% w/w		
B.2.2.34 Dustability following accelerated storage (IIIA 2.8.8.3)			- Not applicable (preparation is not a dustable powder).	
B.2.2.35 Physical compatibility of tank mixes (IIIA 2.9.1)	<p>- In-house-method (SOP/FMN/06) : <i>static test</i> : visual assessment + rating the degree of homogeneity, dispersion, flocculation, creaming, oiling and sedimentation <i>dynamic test</i> : agitating for 15 min + sieving (45 µm)</p> <p>- GLP-compliance stated</p>	<p>EF-1343 was found to be <u>compatible</u> with (according to static test) : Allegro, Ally, Amistar, Azur, Boscor, Brio, Capture, Celio, Compete 80EW, Corbel, Cycocel 5C New, Deloxil, Etheverse, First, Fortress, Foxtril Super, Iloxan CE, Iso Stef 500, KWG 4168, Maestro II, Moddus, Opus, Opus Team, Orkan, Pointer, Puma S, Quartz, Sponsor, Sportak Delta, Terpal, Tilt Turbo, Tolkan Fox, Unix</p> <p><u>compatible with agitation</u> with (according to dynamic test) : Folicur, Foxpro D+</p> <p>None of the commercially available potential tank mix partners tested were found to be incompatible. No indication of chemical reactivity was apparent in any mixture.</p>	- Acceptable	Fowles, 1997

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.35 (cont'd)	<p>- In-house-method : <i>static test</i> : visual assessment + rating the degree of homogeneity, dispersion, flocculation, creaming, oiling and sedimentation/determination of redispersibility/ sieving (150 and 45 µm) <i>dynamic test</i> : visual assessment during agitation for 15 min + sieving (45 µm)</p> <p>- No GLP-compliance stated</p>	<p>EF-1343 was found to be <u>compatible</u> with (according to static test) : Mowdown SC, Brodal SC, Quartz SC <u>compatible with agitation</u> with (according to dynamic test) : Compete 5WP, Compete 20WP</p> <p>None of the commercially available potential tank mix partners tested were found to be incompatible.</p>	- Acceptable	Smith, 1995
B.2.2.36 Chemical compatibility of tank mixes (IIIA 2.9.2)	<p>- In-house-method</p> <p>- No GLP-compliance stated</p>	<p>EF-1343 showed no significant chemical losses (<5% relative) over a 24 h period at 30°C when mixed with potential mixing partners :</p> <p>2,4-D DMA 2,4-D K+ Lontrel K+ ENSOL liquid fertilizer at field dilution rates</p>	- Acceptable	Knowles, 1995
B.2.2.37 Distribution and adhesion (IIIA 2.10)			- Not applicable (preparation is not intended for seed treatment)	

B.2.3 References relied on

Physical and chemical properties of the active substance (Annex IIA 2)

Annex point(s) 91/414/EEC	Author, Title, Test institute, Report number/Study ID, Date of report For publications: reference	Dow AgroScience s Report No.	GLP GEP	Published Protected
IIA 2.5.1	Boothroyd, S., Ghosh, D., Knowles, S., Characterisation of XDE-570 Pure Batch Number DECO-293-021: Summary Report DowElanco Europe, Letcombe Regis, Oxon, UK 93030/DB, February 1996	GHE-P-4703	Yes	Unpublished Protected
IIA 2.11.2	Comb, AL, XDE-570 (Technical): Relative Self-Ignition Temperature for Solids Huntingdon Life Sciences, Eye, Suffolk, UK DWC902/970482, September 1997	GHE-P-6452	Yes	Unpublished Protected
IIA 2.1.1 IIA 2.3.1 IIA 2.6 IIA 2.7 IIA 2.8	Cowlyn, TC, XDE-570 (Pure) : Determination of Physico-chemical Properties Pharmaco::LSR, Eye, Suffolk, UK 94/DES179/0560, February 1995	GHE-P-3668	Yes	Unpublished Protected
IIA 2.3.2	Ghosh, D, Determination of Henry's Law Constant for DE-570 DowElanco Europe, Letcombe Regis, Oxon, UK P97-073, December 1997a	GHE-P-6788	Yes	Unpublished Protected
IIA 2.10	Ghosh, D, Estimation of Photochemical Oxidation of DE-570 DowElanco Europe, Letcombe Regis, Oxon, UK P97-072, December 1997b	GHE-P-6787	Yes	Unpublished Protected
IIA 2.9.1	Jackson, R, Portwood, D, The Aqueous Hydrolysis of XR-570 DowElanco Europe, Letcombe Regis, Oxon, UK None stated, December 1993	GHE-P-3326	No	Unpublished Protected
IIA 2.3.2	Madsen S. Calculation of the Henry's Law Constant for DE-570 from pH 5, 7, and 9 Buffered Water Dow AgroSciences LLC, Formulation, Sciences & Technology, Indianapolis, Indiana June 1999	NAFST087	No	Unpublished Protected
IIA 2.2 IIA 2.9.4	Niemtus, K, XDE-570 (Pure) : Determination of Physico-Chemical Properties Huntingdon Life Sciences Ltd, Eye, Suffolk, UK 93030/CJ; 95/DES282/0813, February 1996b	GHE-P-4909	Yes	Unpublished Protected
IIA 2.11.1 IIA 2.13 IIA 2.15	Niemtus, K, XDE-570 Technical : Determination of Physico-Chemical Properties Huntingdon Life Sciences Ltd, Eye, Suffolk, UK 93030/CI; 95/DES283/0827, February 1996a	GHE-P-4910	Yes	Unpublished Protected
IIA 2.9.1	Phillips, M, The Determination of the Hydrolytic Stability of Radiolabelled XDE-570 Inveresk Research International Ltd, Tranent, Scotland, UK 386209, September 1996	GHE-P-4986	Yes	Unpublished Protected

Annex point(s) 91/414/EEC	Author, Title, Test institute, Report number/Study ID, Date of report For publications: reference	Dow AgroScience s Report No.	GLP GEP	Published Protected
IIA 2.4.1 IIA 2.4.2 IIA 2.14	Sydney, P, XDE-570: Determination of Physico-Chemical Properties Huntingdon Life Sciences Ltd, Eye, Suffolk, UK 93030/CL; 96/DES396/0863, August 1996	GHE-P-5530	Yes	Unpublished Protected
IIA 2.9.2 IIA 2.9.3	Yoder, RN, Aqueous Photolysis of XDE-570 in Natural Sunlight DowElanco, Indianapolis, Indiana 46268, USA ENV95023, March 1996	GH-C 3951	Yes	Unpublished Protected
IIA 2.9.2 IIA 2.9.3	Yoder R. N. Comparative Photolysis of DE-750 Under Xenon Light and Natural Sunlight Global Environmental Chemistry Laboratory - Indianapolis Lab Dow Agro Sciences LLC, Indianapolis, Indiana July 1998	GH-C 4751	No	Unpublished Protected

Physical and chemical properties of the metabolites (Annex IIA 2)

Annex point(s) 91/414/EEC	Author, Title, Test institute, Report number/Study ID, Date of report For publications: reference	Dow AgroScience es Report No.	GLP GEP	Published Protected
IIA 2.3.1 IIA 2.6 IIA 2.7 IIA 2.8 IIA 2.9.4	Niemtus, K, XDE-570 5-Hydroxy Metabolite : Determination of Physico-Chemical Properties Huntingdon Life Sciences Ltd, Eye, Suffolk, UK 93030/CH; 95/DES279/0812, February 1996c	GHE-P-4908	Yes	Unpublished Protected

Physical and chemical properties of the formulation EF 1343 (Annex IIIA 2)

Annex point(s) 91/414/EEC	Author, Title, Test institute, Report number/Study ID, Date of report For publications: reference	Dow AgroSciences Report No.	GLP GEP	Published Protected
IIIA 2.1.1 IIIA 2.4.1 IIIA 2.4.2 IIIA 2.5.2 IIIA 2.6.1 IIIA 2.7.1 IIIA 2.8.3.1 IIIA 2.8.5	Banks, G, Accelerated Storage Stability Test (CIPAC MT 46.1.3) for XDE-570 50 g/l SC Herbicide, EF-1343 DowElanco Europe, Letcombe Regis, Oxon, UK GHE-P-4714, January 1996	GHE-P-4714	Yes	Unpublished Protected
IIIA 2.2.2 IIA 2.3	Comb, A, Determination of physico-chemical properties for DE-570 50G/L SC herbicide, EF-1343 DowAgrosciences Europe, Letcombe Regis, Oxon, UK	GHE-P-7221	Yes	Unpublished Protected
IIIA 2.9.1	Fowles, AM, Dilution Compatibility of EF-1343, (DE-570 50 g/l SC), with Commercially Available Agrochemical Products DowElanco Europe, Letcombe Regis, Oxon, UK 93023/DC, October 1997	GHE-P-6472	Yes	Unpublished Protected
IIIA 2.9.2	Knowles, S, XDE-570 g/l Formulation Tank Test to Determine the Effect of Potential Mixing Partners on Chemical Stability DowElanco Europe, Letcombe Regis, Oxon, UK 95017, September 1995	GHE-P-4547	No	Unpublished Protected
IIIA 2.2.2	McGrath, G, Foster, N, Differential Scanning Calorimetry of DE-570 50 g/l SC Herbicide, EF-1343 DowElanco Europe, Letcombe Regis, Oxon, UK 93023, December 1997	GHE-P-6499	Yes	Unpublished Protected
IIIA 2.8.4	McGrath, G, Dilution Stability of DE-570 50 g/l SC Herbicide, EF-1343 DowElanco Europe, Letcombe Regis, Oxon, UK 93023, December 1997	GHE-P-6883	No	Unpublished Protected
IIIA 2.9.1	Smith, G, Dilution Compatability of EF-1343 with Commercially Available Agrochemical Products DowElanco Europe, Letcombe Regis, Oxon, UK FST:93023, July 1995	GHE-P-4467	No	Unpublished Protected
IIIA 2.1.2 IIIA 2.2.1 IIIA 2.5.3 IIIA 2.8.2 IIIA 2.8.3.2 IIIA 2.8.8.2	Sydney, P, Determination of Physico-Chemical Data Properties of DE-57050 g/l SC Herbicide, EF-1343 Huntingdon Life Sciences Ltd, Eye, Suffolk, IP23 7PX, England 95023/CA, October 1996	GHE-P-6232	Yes	Unpublished Protected
IIIA 2.7.3	Turri, E, Olive, C, Packaging stability trial for DE-570 50 g/l Herbicide, EF-1343. Interim Results DowElanco Europe, Kings Lynn, UK KLP-97-005, October 1997	GHE-P-6402	Yes	Unpublished Protected