ANNEX B

Pyraflufen-ethyl

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 : Nihon Nohyaku Co., Ltd.
2-5, 1-Chome, Nihonbashi, Chuo-ku
Tokyo 103, Japan

Tel. No. : (81) 3-3274-3383
Tfx. No. : (81) 3-3281-2443

Community address : Nihon Nohyaku London Office
3rd Floor, 8 Cork Street
Mayfair
London W1X 1PB, UK

Contact persons :

Nihon Nohyaku Co., Ltd.	Rhône-Poulenc Agro
Nihon Nohyaku London Office 3rd Floor, 8 Cork Street Mayfair London W1X 1PB, UK	Rhône-Poulenc Agro 14-20, rue Pierre Baizet 69009 Lyon, France
Hiroshi Suzuki Assistant Manager	P.E.Th. van der Kouwe Registration Manager
Tel. No. : (44) 171-434-0033 Tfx. No. : (44) 171-287-1335	Tel. No. : (33) 4 72 85 28 39 Tfx. No. : (33) 4 72 85 29 64

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

Manufacturer : Ihara Chemical Industry Co., Ltd.
1-4-26, Ikenohara, Taito-ku
Tokyo 110, Japan

Tel. No. : (81) 3-3822-5241

Location of plant : Ihara Chemical Industry Co., Ltd.
Shizuoka Plant
1800, Nakanogo, Fujikawa-cho, Ihara-gun
Shizuoka 421-33, Japan

Contact persons :

Nihon Nohyaku Co., Ltd.	Rhône-Poulenc Agro
Nihon Nohyaku London Office 3rd Floor, 8 Cork Street Mayfair London W1X 1PB, UK	Rhône-Poulenc Agro 14-20, rue Pierre Baizet 69009 Lyon, France
Hiroshi Suzuki Assistant Manager	P.E.Th. van der Kouwe Registration Manager
Tel. No. : (44) 171-434-0033 Tfx. No. : (44) 171-287-1335	Tel. No. : (33) 4 72 85 28 39 Tfx. No. : (33) 4 72 85 29 64

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

Common name : Pyraflufen-ethyl (ISO-proposed), no synonyms

B.1.1.4 Chemical name (Annex IIA 1.4)

IUPAC nomenclature : ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetate

CA nomenclature : ethyl 2-chloro-5-[4-chloro-(5-difluoromethoxy)-1-methyl-1*H*-pyrazol-3-yl]-4-fluorophenoxyacetate

B.1.1.5 Manufacturer's development code number (Annex IIA 1.5)

Code number : ET-751

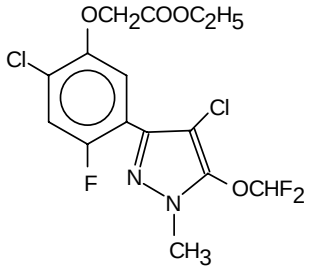
B.1.1.6 CAS, EEC and CIPAC numbers (Annex IIA 1.6)

CAS number : 129630-19-9
EEC number : not allocated
CIPAC number : not allocated

B.1.1.7 Molecular formula, molecular mass and structural formula (Annex IIA 1.7)

Molecular formula : $C_{15}H_{13}Cl_2F_3N_2O_4$

Structural formula :



Molecular mass : 413.18

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 pyraflufen-ethyl technical : 956 g/kg (certified limit)

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 MILAN™ (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 : MILAN™
Code number : EXP 31279A

B.1.2.2 Manufacturer or manufacturers of the plant protection product (Annex IIIA 1.2)

Applicant : Nihon Nohyaku Co., Ltd.
2-5, 1-Chome, Nihonbashi, Chuo-ku
Tokyo 103, Japan

Tel. No. : (81) 3-3274-3383
Tfx. No. : (81) 3-3281-2443

Community address : Nihon Nohyaku London Office
3rd Floor, 8 Cork Street
Mayfair
London W1X 1PB, UK

Contact person : Hiroshi Suzuki
Assistant Manager
Tel. No. : (44) 171-434-0033
Tfx. No. : (44) 171-287-1335

Manufacturer of the preparation : Rhône-Poulenc Agro
14-20, rue Pierre Baizet
69009 Lyon Cedex 09, France

Tel. No. : (33) 4 72 29 25 25 (general)
Tfx. No. : (33) 4 72 29 27 99 (general)

Location of plant : Rhône-Poulenc Agrochimie
1, Avenue Edouard-Herriot
B.P. 442, Limas
69656 Villefranche s/Saone, France

Tel. No. : (33) 4 74 62 76 76 (general)

Contact person : P.E.Th. van der Kouwe
Registration Manager
Tel. No. : (33) 4 72 85 28 39
Tfx. No. : (33) 4 72 85 29 64

Manufacturers of the active substances :

Pyraflufen-ethyl : Ihara Chemical Industry Co., Ltd.
1-4-26, Ikenohara, Taito-ku
Tokyo 110, Japan

Bifenox :Rhône-Poulenc
B.P. 17
38800 Le Pont de Claix, France

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

Preparation type and code : 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 MILAN™

Component	Content (g/L)	Function
Pyraflufen-ethyl - pure a.s. - TC (average purity 97.9%)	 (9) 9.2	Active substance
Bifenox - pure a.s. - TC (average purity 98%)	 (500) 510	Active substance
Other components	Confidential information, see Annex C	

B.1.3 References relied on

Identity of the active substance (Annex IIA 1; Annex IIIA 1, 3.1 to 3.4)

Author(s)	Year	Annex IIA Point Title Company, Report No.	GLP GEP Y/N	Published or not Y/N	Owner
		Annex IIA, 1.8, 1.9, 1.10, 1.11 See Document J	Y	N	NN

Identity of the formulation MILAN (Annex IIIA 1, 3.1 to 3.7, 3.9 and 12.1)

Author(s)	Year	Annex IIA Point Title Company, Report No.	GLP GEP Y/N	Published or not Y/N	Owner
	1997	Annex IIIA, 1.4 See Document J	Y	N	NN & RPA

ANNEX B

Pyraflufen-ethyl

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 of the active substance, the following purity values should be taken into account :

- for the purified a.s. : 99.4% (batch No. 5AM0027P - certificate of purity)
- for the a.s. as manufactured (TC) : 97.7% (batch No. 5AM0026D - certificate of purity)

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

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 with hot block heating) - GLP-compliance stated	purified a.s. : melting point range = 126.4 to 127.2 □C	- Acceptable	Russell, 1996a
B.2.1.2 Boiling Point (IIA 2.1.2)	- EEC-method A2 (Siwoloboff-method with oil bath heating) - GLP-compliance stated	purified a.s. : boiling point could not be determined; decomposition above its melting point	- Acceptable	Russell, 1996a
B.2.1.3 Temperature of decomposition or sublimation (IIA 2.1.3)	- EEC-method A2 (Siwoloboff-method with oil bath heating) - GLP-compliance stated	purified a.s. : thermal decomposition begins at approx. 240 □C	- Acceptable	Russell, 1996a
B.2.1.4 Relative density (IIA 2.2)	- EEC-method A3 (gas comparison pyknometer)	purified a.s. : relative density at 24 □C = 1.565 ± 0.002	- Acceptable (test temperature 24 □C instead of 20 □C)	Russell, 1996a

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	- GLP-compliance stated			
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 = 1.6 10^{-8} Pa (extrapolated)	- Acceptable - Pyraflufen-ethyl is very slightly volatile	Russell, 1996a
B.2.1.6 Volatility, Henry's law constant (IIA 2.3.2)	- Calculation only - GLP not relevant	purified a.s. : vapour pressure = 1.6 10^{-8} Pa water solubility = 0.082 mg/L □ H = 8.1 10^{-5} Pa.m³/mol	- In the report, Henry's law constant is calculated using the vapour pressure at 25 □C and the water solubility at 20 □C. Using the vapour pressure at 20 □C (= 4.3 10^{-9} Pa, extrapolated), H equals 2.2 10^{-5} Pa.m³/mol. Neither value is however of environmental significance (a.s. is very slightly volatile) - Acceptable	Russell, 1996a
	- BBA-guideline IV, 6-1	^{14}C-labelled a.s. (formulated as EXP31279A),	- Acceptable as	Kubiak, 1996

Study	Guidelines and GLP	Findings	Evaluation and conclusions supplementary information	References
B.2.1.6 (cont'd)	- GLP-compliance stated	radiochemical purity > 99% : tests performed in closed chamber under constant conditions of air temperature (19.8-19.9 □C), air humidity (44.7-46.3%) and wind speed (1.20-1.26 m/s) : · no volatilization of ^{14}C-ET-751 from plant or soil surfaces was observed in the course of a 24 h period · except for very small amounts of $^{14}CO_2$ (0-0.5%), no volatile metabolites were determined		
B.2.1.7 Physical state (IIA 2.4.1)	- Visual inspection - GLP-compliance stated	purified a.s. : at ambient temperature :fine powder a.s. as manufactured (TC) : at ambient temperature :fine powder with some claying present	- Acceptable	Russell, 1996a Russell, 1996b
B.2.1.8 Colour (IIA 2.4.1)	- Visual test (comparison with reference colour card) - GLP-compliance stated	purified a.s. : white a.s. as manufactured (TC) : cream coloured	- Acceptable	Russell, 1996a Russell, 1996b
B.2.1.9 Odour (IIA 2.4.2)	- Assessment at arms length - GLP-compliance stated	purified a.s. : no significant odour a.s. as manufactured (TC) : no significant odour	- Acceptable	Russell, 1996a Russell, 1996b
			- Acceptable, although	Russell, 1996a

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.10 Spectra of the active substance (IIA 2.5.1)	- GLP-compliance stated (except for NMR-spectrum)	purified a.s. : All the required spectra were provided and the major peaks of the different spectra were consistent with the accepted structure of ET-751: IR (KBr; spectrum measured between 4000 and 500 cm^{-1}) UV/VIS (methanol; spectra measured between 200 and 750 nm) MS (EI+ at 70 eV) ^{1}H-NMR (270.16MHz, $CDCl_3$) *UV/VIS absorption characteristics (neutral conditions) :* λ = 203 nm :ε = 28700 $L.mol^{-1}.cm^{-1}$ λ = 243 nm :ε = 12800 $L.mol^{-1}.cm^{-1}$ λ = 291 nm :ε = 5900 $L.mol^{-1}.cm^{-1}$ acidic and alkaline spectra : not significantly different from neutral spectrum	NMR-spectrum was apparently not generated by a GLP-lab.	
B.2.1.11 Spectra for impurities (IIA 2.5.2)	- GLP-compliance stated	impurities 1 to 9 (= structurally related impurities), resp. purity between 96.6 and 99.8% : Following spectra were provided : IR (KBr; spectra recorded between 4000 and 400 cm^{-1}) UV/VIS (methanol; spectra recorded between 200 and 400 nm) MS (EI at 70 eV) ^{1}H-NMR and ^{13}C-NMR ($CDCl_3$ or DMSO-d_6) The major peaks of the different spectra were consistent with the structure of each resp. impurity.	- Acceptable	Sakamoto and Kudo, 1996a Sakamoto and Kudo, 1996b Sakamoto and Kudo, 1996c

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.12 Solubility in water (IIA 2.6)	- EEC-method A6 (column elution method with HPLC analysis) - GLP-compliance stated	purified a.s. : solubility in water at 20 °C = 0.082 ± 0.009 mg/L (pH 6.48-6.97) Since pyraflufen-ethyl is not capable of forming ions, its water solubility was determined only in the neutral range (see also B.2.1.18).	- Acceptable.	Russell, 1996a
B.2.1.13 Solubility in organic solvents (IIA 2.7)	- direct addition method, resp. flask method (with HPLC analysis)* - GLP-compliance stated	a.s. as manufactured (TC) : solubility at 20 °C in n-heptane* : 234 mg/L p-xylene : 41.7 to 43.5 g/L 1,2-dichloromethane : 100 to 111 g/L methanol* : 7.39 g/L acetone : 167 to 182 g/L ethyl acetate : 105 to 111 g/L	- Acceptable.	Russell, 1996b
B.2.1.14 Partition coefficient n-octanol/water (IIA 2.8)	- EEC-method A8 OECD-guideline 117 (HPLC) - GLP-compliance stated	purified a.s. : at ambient temp. : log P_{ow} = 3.49 (aqueous part of mobile phase = water) Since pyraflufen-ethyl does not have acid or alkaline properties, log P_{ow} was determined only in the neutral range (see also B.2.1.18)	- Acceptable.	Russell, 1996a
	- EEC-method C7	[pyrazole-5-^{14}C]-labelled a.s., radiochemical purity		Ikemoto, 1996a

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	- GLP-compliance stated			

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 (IIA 2.9.2)	- FAO Revised guidelines on environmental criteria for the registration of pesticides (Heraeus Suntest CPS apparatus : Xenon arc lamp, λ<290 nm filtered out)	[pyrazole-5-^{14}C]-labelled a.s., radiochemical purity > 99% : at 20 ± 3 □C, buffered at pH 5 (sterile conditions, acetonitrile as cosolvent) : *Mass balance :* · recovery ranged from 94.5 to 99.8% of applied radioactivity · material balance after 48 h incubation : % of applied radioactivity	- Acceptable (method concurs with the SETAC-procedures)	Ikemoto, 1997

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	- GLP-compliance stated (except for MS and NMR analyses of ET-751 and PD-1)			

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
		PD-1 was easily photodegraded to many minor polar products (estimated half-life : □ 15.3 h)		
B.2.1.17 Quantum yield of direct phototransformation (IIA 2.9.3)	- UBA-guideline : "Phototransformation of Chemicals in Water, Part A : Direct Phototransformation" (1990) - ECETOC Technical report No. 12 (1984)	[pyrazole-5-^{14}C]-labelled a.s., radiochemical purity > 99% : <u>quantum yield :</u> Φ = 10.7% <u>environmental photolytic lifetime :</u> in the top mm of a natural aquatic system	- The RMS has some reservations with regard to the equation that was used for the calculation of Φ, more specifically with regard to the constant 1.505 x 10^{-11} in that	Ikemoto, 1997 Corgier, 1997a

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	- GLP-compliance stated (except for calculation of environmental lifetime)	situated in Europe at 52□ Northern Latitude : $t_{1/2}$ ranges from3.3 h in June to 55.3 h in December (calculated using the solar light intensity determined by Frank & Klöpffer (1988))	equation. Taking the equation in ECETOC No. 12 as a basis, the RMS believes that the constant should equal 1.505×10^{-10}, resulting in a quantum yield of 1.07% instead of 10.7%. Consequently, the environmental half-life values stated by the notifier need to be multiplied by a factor 10, resulting in a range from 33 h in June to 553 h in December. Considering the half-life for artificial light (29.7 h), these values seem more realistic.	
B.2.1.18 Dissociation in water of purified active substance (IIA 2.9.4)	- Applicant's statement	"Not applicable as pyraflufen-ethyl does not have acid or alkaline properties"	- Acceptable	

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.19 Estimated photo chemical oxidative degradation (IIA 2.10)	- OECD Environment Monograph No. 61 (1992), using PCGEMS software (based on Atkinson-method) - GLP-compliance stated	estimated half-life of ET-751 in the troposphere at 298K (by reaction with OH-radicals) = 11.3 h	- Acceptable	Corgier, 1997b Corgier and Plewa, 1997
B.2.1.20 Flammability (IIA 2.11.1)	- EEC-method A10 - GLP-compliance stated	a.s. as manufactured (TC) : no propagated ignition was observed □ a.s. is not classified as highly flammable	- Acceptable	Russell, 1996b
B.2.1.21 Auto-flammability (IIA 2.11.2)	- EEC-method A16 - GLP-compliance stated	a.s. as manufactured (TC) : no ignition detected below the melting point □ a.s. is not classified as a self-heating substance	- Acceptable	Russell, 1996b
B.2.1.22 Flash point (IIA 2.12)			- Not applicable (melting point > 40 □C)	
	- EEC-method A14		- Acceptable	Russell, 1996b

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.23 Explosive properties (IIA 2.13)	- GLP-compliance stated	a.s. as manufactured (TC) : · no thermal sensitivity (limiting diameter < 2 mm) · no mechanical sensitivity with respect to shock (limiting impact energy > 40 Joules) · no mechanical sensitivity with respect to friction (limiting load > 360 Newton) □ a.s is not classified as an explosive		
B.2.1.24 Surface tension (IIA 2.14)	- EEC-method A5 (Surface Tension (torsion) Balance) - GLP-compliance stated	purified a.s. : σ = 74.16 mN/m at 20 □C (90% saturated solution) a.s. as manufactured (TC) : σ = 72.70 mN/m at 20 □C (90% saturated solution)	- Acceptable, although not really required (water solubility of pyraflufen-ethyl is less than 1 mg/L).	Russell, 1996a Russell, 1996b
	- EEC-method A17		- Not acceptable : test	Russell, 1996b

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.25 Oxidizing properties (IIA 2.15)	- GLP-compliance stated	a.s. as manufactured (TC) : *<u>main test</u> :* · max. burning rate of reference mixtures = 0.606 mm/s (barium nitrate/cellulose 60/40 (w/w)) · max. burning rate of test mixtures = 0.625 mm/s (test substance/cellulose 10/90 (w/w)) The latter value is however regarded as unrepresentative. Taking into account that the mean burning rate of the 6 test mixtures (test substance/cellulose 10/90 (w/w)) equals 0.539 mm/s □ a.s. is considered not to be oxidizing	is inconclusive. For safety reasons, the max. burning rate - and not the mean value - should be considered when evaluating oxidizing properties (cfr. EEC A17). Moreover, it is not clear why the max. value of 0.625 mm/s is regarded as unrepresentative; even when omitting this value, the results of the 10/90 mixtures still don't all fall within 10% of their arithmetic mean. This is most likely due to the in-homogeneity of the sample (test sample was neither sieved nor ground). - New test will be reported by the end of January 1999.	
	- EEC-method A17	-	In absence of	Tran Thanh Phong,

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.25 Oxidizing properties (IIA 2.15)	- GLP-compliance stated		information of the maximum burning rate of the barium nitrate/cellulose reference, the burning rate of the test compound cannot be determined.	1999

The dossier also contained some studies determining physico-chemical properties of the metabolites of pyraflufen ethyl.

Table B.2.1-2 : Physical and chemical properties of metabolites of pyraflufen-ethyl

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	metabolite E-1, purity not specified : vapour pressure at 25 °C = < 4.2 10^{-4} Pa (max. value estimated by imposing a regression slope on a chosen data point; normal regression analysis being not meaningfull) test material darkened slightly under the conditions used	- Acceptable as supplementary information	Bates, 1996a
B.2.1.12-2 Solubility in water (IIA 2.6)	- EEC-method A6 (shake flask procedure, resp. column elution method*) - GLP-compliance stated	metabolite E-1, 97.8% pure : solubility in water at 20 °C : pH 4.95 (buffered) :1.02 ± 0.079 g/L pH 8.99 (buffered) :11.8 ± 0.98 g/L pH 3.9 (unbuffered) :83.1 ± 8.4 mg/L metabolite E-2, 98.6% pure : solubility in water at 20 °C : pH 6.4 (unbuffered) :7.60 ± 0.83 mg/L metabolite E-3, 97.7% pure : solubility in water at 20 °C (*) : pH 6.3 (unbuffered) :0.53 ± 0.04 mg/L	- Acceptable as supplementary information	Bates, 1996b Bates, 1996c
B.2.1.14-2 Partition	- EEC-method A8 OECD-guideline 117 (HPLC)	metabolite E-1, 97.8% pure : at 25 °C :log Pow = 2.90	- Acceptable as supplementary information	Bates, 1996c

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
coefficient n-octanol/water (IIA 2.8)	- GLP-compliance stated	(aqueous part of mobile phase : pH 1.5) metabolite E-2, 98.6% pure : at 25 °C :log Pow = 2.88 (aqueous part of mobile phase : pH 4.0) metabolite E-3, 97.7% pure : at 25 °C :log Pow = 3.66 (aqueous part of mobile phase : water)		
B.2.1.15-2 Hydrolysis rate at pH 4, 7 and 9 under sterile conditions in the absence of light (IIA 2.9.1)	- EEC-method C7 - GLP-compliance stated	[pyrazole-5-^{14}C]-labelled metabolite E-1, radiochemical purity > 98% : <u>pre-test at 50 °C at pH 4, 7 and 9</u> : no degradation after 5 days incubation □ no further study required □ E-1 can be considered to be hydrolytically stable ($t_{½}$ > 1 year) under normal environmental conditions	- Acceptable as response to point II A 7.2.1.1	Lewis, 1997

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

All tests were conducted on batch N° OP951099

Table B.2.2-1 : Physical and chemical properties of MILAN™ (Suspension concentrate : 9 g/L pyraflufen-ethyl + 500 g/L bifenox) (EXP31279A)

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	Uceda and Yslan, 1997
B.2.2.2 Colour (IIIA 2.1)	- Visual observation (comparison to standard palette NF X 08-002) - GLP-compliance stated	white	- Acceptable	Uceda and Yslan, 1997
B.2.2.3 Odour (IIIA 2.1)	- GLP-compliance stated	no detectable odour	- Acceptable	Uceda and Yslan, 1997
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 □ EXP31279A shows no explosive properties	- Acceptable	Fillion, 1996
B.2.2.5 Oxidizing properties (IIIA 2.2.2)	- Applicant's statement	"As neither the active substances nor the formulants are oxidizing, the preparation is not expected to have oxidizing properties."	- Not acceptable : the study on oxidizing properties of pyraflufen-ethyl was considered to be inconclusive (see	Francois (1998) (study bifenox)

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
		Supporting information : · pyraflufen-ethyl :see B.2.1.25 · bifenox :study according to EEC A17 demonstrating that technical bifenox has no oxidizing properties under the conditions of the test · formulants :resp. MSDS	inconclusive (see B.2.1.25). - Additional information required (new test on oxidizing properties of pyraflufen-ethyl will be reported by the end of January 1999)	
B.2.2.6 Flash point (IIIA 2.3)	- Applicant's statement	"As the preparation does not contain any volatile flammable component, it is not expected to have a flash point up to 85 □C."	- Acceptable (flash point study only required for liquids that contain flammable solvents)	Fillion, 1996
B.2.2.7 Flammability (IIIA 2.3)			- Not applicable (liquid preparation)	
B.2.2.8 Auto-flammability (IIIA 2.3)	- EEC-method A15 (DIN 51794) - GLP-compliance stated	self-ignition temperature = 430 □C (atmospheric pressure : 993.4 - 1004 hPa) □ EXP31279A is auto-flammable at high temperature	- Acceptable	Fillion, 1996
B.2.2.9 Acidity or alkalinity and pH value (IIIA 2.4.1)			- Not applicable (preparation is not acidic (pH < 4) or alkaline (pH > 10))	
	- CIPAC MT 75.2		- Acceptable	Uceda and Yslan, 1997

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.10 pH of a 1 % aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	- GLP-compliance stated	1% (w/v) aqueous dispersion at 22 □C : pH = 8.2		
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 EF-839-04-96 (rotating rheometer) - GLP-compliance stated	at 23 ± 0.5 □C : η = 34 mPa.s	- Acceptable (in-house method concurs with OECD No. 114 and ISO 3219 - 1993)	Uceda and Yslan, 1997
B.2.2.13 Surface tension (IIIA 2.5.3)	- EEC-method A5 (ring tensiometer) - GLP-compliance stated	at 20 ± 0.5 □C : σ = 29 mN/m(1% aqueous dispersion)	- Acceptable, although the report doesn't fully comply with the requirements as described in point 3.1 of EEC A5.	Uceda and Yslan, 1997
B.2.2.14 Relative density (IIIA 2.6.1)	- CIPAC MT 3.3.1 EEC-method A3 (mechanical oscillator) - GLP-compliance stated	at 20 ± 0.2 □C : density = 1.194 g/cm³	- Acceptable.	Uceda and Yslan, 1997

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.15 Bulk or tap density (IIIA 2.6.2)			- Not applicable (liquid preparation)	
B.2.2.16 Stability after storage for 14 days at 54 °C (IIIA 2.7.1)	- CIPAC MT 46	after storage for 14 d at 54 °C : · *chemical stability of a.s. :* bifenox content :523 g/L (initial : 526 g/L) ET-751 content :9.15 g/L (initial : 9.21 g/L) · *physical stability :* persistent foaming (1 min): 0 mL (initial : 0 mL) suspensibility:96% bifenox (initial : 98%) 99% ET-751 (initial : 102%) spontaneity of dispersion:96% bifenox (initial : 99%) 97% ET-751 (initial : 99%) pourability:R = 2.1% (initial : 2.4%) R' = 0.10% (initial : 0.17%) wet sieve test (40 µm): 0.1% (initial : 0.1%) pH:7.6 (initial : 8.2) □ EXP31279A shows no significant alteration of its a.s. content and continues to comply with the physical shelf-life specifications after accelerated storage test	- Acceptable	Uceda and Yslan, 1997
			- Not applicable	

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.17 Stability after storage for other periods and temperatures (IIIA 2.7.1)			(preparation is not heat sensitive)	
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)	- In-house method EF-790-01-95	freezing temperature = -7 °C Notifier argues that a study according to one of the methods proposed in the Directive (CIPAC MT 39, MT 48, MT 51 or MT 54) is not needed, since none of these methods is suitable for SC formulations.	- Acceptable. However, a better alternative would have been to test relevant physical properties of the formulation (suspensibility, spontaneity of dispersion, wet sieve test) after storage for 7 d at 0 °C, as indicated by FAO.	Uceda and Yslan, 1997
	- GIFAP n° 17	extrapolation from the results of the accelerated storage	- Acceptable; since no	Uceda and Yslan, 1997

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.20 Shelf life (IIIA 2.7.3)		test (see B.2.2.16): □ shelf-life : min. 2 years (preparation stored in its original unopened container)	significant chemical or physical changes occurred in the accelerated test, the product will most likely comply with a shelf-life specification of 2 years. - Study on 2 year stability at ambient temperature in commercial packaging is scheduled to be reported by December 1998	
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	dilution of the formulation with CIPAC water D to a concentration of 1% (w/v) at 20 ± 2 □C : after 1 min : 0 ml foam	- Water D was used instead of water C - Acceptable	Uceda and Yslan, 1997
B.2.2.23 Suspensibility	- CIPAC MT 161 (with a.s. content analysis)	1% (w/v) suspension in CIPAC water D at 20 ± 2 □C : suspensibility =98% w/w (bifenox)	- Acceptable : tested suspension is representative for the	Uceda and Yslan, 1997

Study (IIIA 2.8.3)	Guidelines and GLP	Findings 102% w/w (ET-751)	Evaluation and conclusion max. recommended rate of use (i.e. 1.5 L ppp/ha using 150 L water/ha). - An additional test at the lowest recommended rate of use (i.e. 1 L ppp/ha using 400 L water/ha) would be necessary to complete the information.	References
B.2.2.24 Spontaneity of dispersion (IIIA 2.8.3)	- CIPAC MT 160 (with a.s. content analysis)	in standard water D at 20 ± 2 □C : spontaneity of dispersion =99% (bifenox) 99% (ET-751)	- Acceptable	Uceda and Yslan, 1997
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	wet sieve residue on 40 µm sieve = 0.1% w/w	- Acceptable	Uceda and Yslan, 1997
B.2.2.27 Size distribution of particles - Nominal size range of	- In-house method EF-824-02-96 (light diffraction particle size analyser)	D 90 = 7.9 µm D 50 = 2.7 µm	- Acceptable, although not really required (preparation is not a powder nor a granule)	Uceda and Yslan, 1997

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
range of particles (IIIA 2.8.6.1)	- GLP-compliance stated			
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 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)	
	- CIPAC MT 148		- Acceptable	Uceda and Yslan, 1997

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.33 Pourability (including rinsed residue) (IIIA 2.8.8.2)		residue R = 2.4% w/w rinsed residue R' = 0.17% 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)			- Not applicable (no specific recommended tank-mix application)	
B.2.2.36 Chemical compatibility of tank mixes (IIIA 2.9.2)			- Not applicable (no specific recommended tank-mix application)	
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)

Author(s)	Year	Annex IIA Point Title Company, Report No.	GLP GEP Y/N	Published or not Y/N	Owner
Bates, M.	1996a	Annex IIA, 2.3.1/02 ET-751 E1 metabolite: Determination of the vapour pressure Nihon Nohyaku, Report No.: PC-5001	Y	N	NN
Bates, M.	1996b	Annex IIA, 2.6/02 ET-751 E-1 metabolite: Determination solubility in water buffered at specified pH values Nihon Nohyaku, Report No.: PC-5003	Y	N	NN
Bates, M.	1996c	Annex IIA, 2.6/03 E-1 soil metabolite of ET-751, E-2 soil metabolite of ET-751, E-3 soil metabolite of ET-751,: Determination of water solubility and Octanol:water partition coefficient Nihon Nohyaku, Report No.: PC-5006	Y	N	NN
Corgier, M.M.	1997a	IIA, 2.9.3/02 ET-751: Calculation of environmental photolytic half-life in water Nihon Nohyaku, Report No: E-5029	N	N	NN
Corgier, M.M.	1997b	IIA, 2.10 ET-751: Estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions Nihon Nohyaku, Report No.: E-5028	N	N	NN
Ikemoto, Y	1996	Annex IIA, 2.9.1/01 Aqueous hydrolysis study of ET-751 Nihon Nohyaku, Report No.: E-5008	Y	N	NN
Ikemoto, Y	1997	Annex IIA, 2.9.2 & 2.9.3/01 Aqueous photolysis study of ET-751 Nihon Nohyaku, Report No.: E-5025	Y	N	NN
Kubiak, R.	1996	Annex IIA, 2.3.2/02 Investigation of the volatilization of 14C-ET-751 formulated corresponding to EXP31279A from plant and soil surfaces under laboratory conditions Rhône-Poulenc, Report No. RPA22	Y	N	RPA
Lewis, C. J.	1996	Annex IIA, 2.9.1/02 (^{14}C)-E-1: Hydrolytic stability Nihon Nohyaku, Report No.: E-5024	Y	N	NN
Russell, S.	1996a	Annex IIA, 2.1.1, 2.1.2, 2.1.3, 2.2, 2.3.1/01, 2.3.2/01,	Y	N	NN

Author(s)	Year	Annex IIA Point Title Company, Report No.	GLP GEP Y/N	Published or not Y/N	Owner
		2.4.1/01, 2.4.2/01, 2.5.1, 2.6/01, 2.8/01 & 2.14/01 ET-751: Determination of physico-chemical properties of purified active substance Nihon Nohyaku, Report No.: PC-5005			
Russel, S.	1996b	Annex IIA, 2.4.1/02, 2.4.2/02, 2.7, 2.11.1, 2.11.2, 2.13, 2.14/02 & 2.15 ET-751: Determination of physico-chemical properties of the substance as manufactured Nihon Nohyaku, Report No.: PC-5004	Y	N	NN
Sakamoto, Y and Kudo, M.	1996a	Annex IIA, 2.5.2/01 Measurement of mass spectra of impurities presented in ET-751technical Nihon Nohyaku, Report No.: PC-5007	Y	N	NN
Sakamoto, Y and Kudo, M.	1996b	Annex IIA, 2.5.2/02 Measurement of IR, UV and NMRspectra of impurities presented inET-751 technical Nihon Nohyaku, Report No.: PC-5008	Y	N	NN
Sakamoto, Y and Kudo, M.	1996c	Annex IIA, 2.5.2/03 Absorption spectra (UV/VIS, IR, NMR,MS) of HME-Cl Nihon Nohyaku, Report No.: PC-5009	Y	N	NN
Tran Thanh Phong , J.	1999	Annex IIA, 2.15/02 Determination of the oxidizing properties of technical pyraflufen-ethyl Rhône-Poulenc, Report No.: 99-267-SEC	Y	N	RPA

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

Author(s)	Year	Annex IIA Point Title Company, Report No.	GLP GEP Y/N	Published or not Y/N	Owner
Filion, J.	1996	Annex IIIA, 2.2 & 2.3 Determination of the Flash point, the Auto-Flammability and the Explosion Properties of EXP31279A Report n□: 96-91, 18 November 1996 Rhône-Poulenc Industrialisation, Decines Charpieu, France	Y	N	RPA
Uceda, L.G. & Yslan, F.J	1997	Annex IIIA, 2.1, 2.4, 2.5, 2.6, 2.7, 2.8 EXP31279A Determination of Physico-Chemical Characteristics and Storage Stability Report n□: 96-90, 6 January 1997 Rhône-Poulenc Agro, Lyon, France	Y	N	RPA