

ANNEX B

Metalaxyl-M

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 : NOVARTIS Crop Protection AG

CH-4002 Basle
Switzerland

Contact person : ir. Johan Henken
Manager Regulatory affairs
NOVARTIS Agro Benelux B.V.
Crop Protection Sector
Postbus 1048
NL-4700 BA Roosendaal

Tel. No. : 00 31 (0) 165-574 741
Tfx. No. : 00 31 (0) 165-559 605

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

Manufacturer : Säurefabrik Schweizerhall

CH-4133 Schweizerhalle
Switzerland

Location of plant : CH-4133 Schweizerhalle
Switzerland

Contact point : NOVARTIS Crop Protection AG
Niklaus Burkhard
R-1058.8.14
CH-4002 Basle

Tel. No. : 00 41 (0) 61 697 25 94
Tfx. No. : 00 41 (0) 61 697 49 66

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

Common name : Metalaxyl-M (ISO-approved), Mefenoxam (unofficial)

B.1.1.4 Chemical name (Annex IIA 1.4)

IUPAC nomenclature : mixture of

(R)-2-[(2,6-dimethyl-phenyl)-methoxyacetyl-amino]-propionic acid methyl ester (min. 97 %)
(S)-2-[(2,6-dimethyl-phenyl)-methoxyacetyl-amino]-propionic acid methyl ester (max. 3 %)

CA nomenclature : mixture of

N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-D-alanine methyl ester (min. 97 %)
N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-L-alanine methyl ester (max. 3 %)

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

Code number of CIBA-GEIGY for the a.s. : CGA 329351 (R) + CGA 351920 (S) (since January 1994)
CGA 76539 (before January 1994)

Throughout the dossier, the notifier used CGA 329351 to refer to metalaxyl-M, as well as to indicate the

R-enantiomer as such, which was rather confusing.

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

CAS number : 70630-17-0 (R)

69516-34-3 (S)

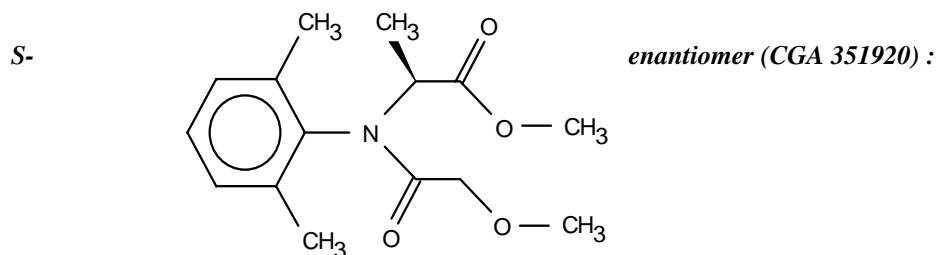
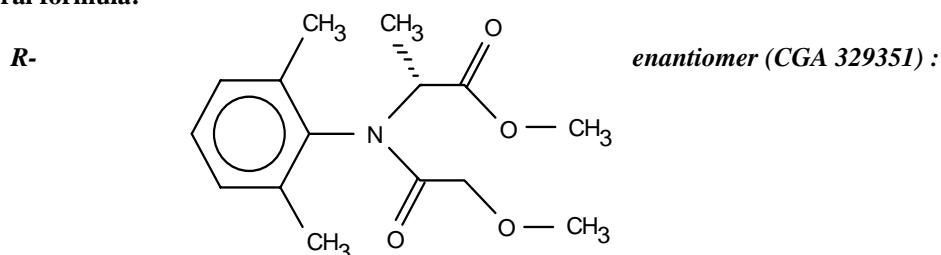
EEC number : not available

CIPAC number : 580

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

Molecular formula : $C_{15}H_{21}NO_4$

Structural formula:



Molecular mass: 279.3

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)

The minimum purity of the a.s. as manufactured, as stated by the notifier, is 940 g/kg;
i.e. the technical a.s. contains : min. 940 g/kgsum of CGA 329351 and CGA 351920
 min. 910 g/kgCGA 329351
 max. 40 g/kgCGA 351920

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.1.2a Identity of the plant protection product RIDOMIL GOLD 480 EC (Annex IIA 3.1; Annex IIIA 1)

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

Trade name : RIDOMIL GOLD 480 EC

Code number : A-9408 B

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

**Applicant : NOVARTIS Crop Protection AG
 CH-4002 Basle
 Switzerland**

**Contact person : Dr. F. Meier-Manz
 R-1058.7.54
 CH-4002 Basle**

**Tel. No. : 00 41 (0) 61 697 27 21
Tfx. No. : 00 41 (0) 61 697 23 00**

**Location of plant : NOVARTIS
 Usine de Monthey
 CH-1870 Monthey**

**Manufacturer of the active substance : Säurefabrik Schweizerhall
 CH-4133 Schweizerhalle
 Switzerland**

Location of plant : CH-4133 Schweizerhalle

**Contact point : NOVARTIS Crop Protection AG
 Niklaus Burkhard
 R-1058.8.14
 CH-4002 Basle**

**Tel. No. : 00 41 (0) 61 697 25 94
Tfx. No. : 00 41 (0) 61 697 49 66**

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

Physical state : emulsifiable concentrate, EC

B.1.2.4a Function (Annex IIIA 1.6)

Fungicide

B.1.2.5a Composition of the preparation (Annex IIIA 1.4)**Table 1.2.5a-1 : Composition of RIDOMIL GOLD 480 EC**

Component	Content		Function
	g/l	% w/w	
Metalaxyl-M - pure a.s. - T.C. (purity min. 94 %)	(480) 480-511	(46.2) 46.2-49.1	Active substance
Other components	Confidential information, see Annex C		

B.1.2b Identity of the plant protection product RIDOMIL GOLD MZ 68 WP

(Annex IIA 3.1; Annex IIIA 1)

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

Trade name : RIDOMIL GOLD MZ 68 WP

Code number : A-9407 A

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

**Applicant : NOVARTIS Crop Protection AG
 CH-4002 Basle
 Switzerland**

**Contact person : Dr. F. Meier-Manz
 R-1058.7.54
 CH-4002 Basle
 Tel. No. : 00 41 (0) 61 697 27 21
 Tfx. No. : 00 41 (0) 61 697 23 00**

**Location of plant : Dr. R. Maag AG
 Postfach 233
 CH-8157 Dielsdorf**

Manufacturers of the active substances :

***Metalaxyl-M :* Säurefabrik Schweizerhall
 CH-4133 Schweizerhalle
 Switzerland**

Location of plant : CH-4133 Schweizerhalle

**Contact point : NOVARTIS Crop Protection AG
 Niklaus Burkhard
 R-1058.8.14
 CH-4002 Basle
 Tel. No. : 00 41 (0) 61 697 25 94
 Tfx. No. : 00 41 (0) 61 697 49 66**

***Mancozeb :* Rohm & Haas France SA
 F-75579 Paris Cedex 12
 France**

Location of plant : F-67630 Lauterbourg

**Contact point : Rohm & Haas France SA
 Gérard de Cacqueray
 La Tour de Lyon
 185, Rue de Bercy
 F-75579 Paris Cedex 12
 Tel. No. : 00 33 1 4002 50 00
 Tfx. No. : 00 33 1 4345 28 19**

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

Physical state : wettable powder, WP

B.1.2.4b Function (Annex IIIA 1.6)**Fungicide****B.1.2.5b Composition of the preparation (Annex IIIA 1.4)****Table 1.2.5b-1 : Composition of RIDOMIL GOLD MZ 68 WP**

Component	Content % w/w	Function
Metalaxyl-M - pure a.s. - T.C. (purity min. 94 %)	(4) 4.0-4.3	Active substance
Mancozeb - pure a.s. - Mancozeb 80 WP	(64) 80	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)**

Annex point(s) 91/414/EEC	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	Ciba file N°	GLP GEP	Published Protected
IIA 1.8	Burkhard N., Manufacturing Process - CGA 329351 Ciba- Geigy Ltd., Basle, Process Description, 11.12.1995a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. CONFIDENTIAL INFORMATION	329351/111	no	unpublished protected
IIA 1.9 IIA 1.10	Burkhard N., Purity and By-products of techn. a.i. Ciba-Geigy Ltd., Basle, Data-Sheet, 13.12..1995b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. CONFIDENTIAL INFORMATION	329351/36	no	unpublished protected
IIA 1.11	Ceresa C., Purity of test material used in ecotoxicity tests Ciba-Geigy Ltd., Basle, 20.12.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. CONFIDENTIAL INFORMATION	-	no	unpublished protected
IIA 1.11	Kreuzer A., Report on nitrosamines, Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 38553, 11.12.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. CONFIDENTIAL INFORMATION	329351/85	yes	unpublished protected
IIA 1.11	Maier W.M., Purity of test material used in toxicity tests Ciba-Geigy Ltd., Basle, 18.12.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. CONFIDENTIAL INFORMATION	-	no	unpublished protected
IIA 1.11	Schneider B., Report on chemical composition (5 batches), Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 38555, 13.12.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. CONFIDENTIAL INFORMATION	329351/84	yes	unpublished protected
IIA 1.10	Stulz J., List of by-products, Ciba-Geigy Muenchwilen AG, Muenchwilen, 05.12.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. CONFIDENTIAL INFORMATION	329351/ 89	no	unpublished protected
IIA 1.11	Stutz W., Dioxine Statement CGA 329351 Ciba-Geigy Muenchwilen AG, Muenchwilen,	329351/1	no	unpublished protected

Annex point(s) 91/414/EEC	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	Ciba file N°	GLP GEP	Published Protected
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Statement, 18.05.1995
Owned by : Ciba-Geigy Ltd.
Submitted by : Ciba-Geigy Ltd.
CONFIDENTIAL INFORMATION

Identity of the formulation RIDOMIL GOLD 480 EC (Annex IIIA 1, 3.1 to 3.7, 3.9 and 12.1)

Annex point(s) 91/414/EEC	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	Ciba file N°	GLP GEP	Published Protected
IIIA 1.4	Burkhard N., Detailed Composition A-9408 B (RIDOMIL® GOLD 480 EC), Ciba-Geigy Ltd., Basle, Data Sheet, Dec.08, 1995c Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. CONFIDENTIAL INFORMATION	329351-70	no	unpublished protected

Identity of the formulation RIDOMIL GOLD MZ 68 WP (Annex IIIA 1, 3.1 to 3.7, 3.9 and 12.1)

Annex point(s) 91/414/EEC	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	Ciba file N°	GLP GEP	Published Protected
IIIA 1.4	Burkhard N., Detailed Composition A-9407 A (RIDOMIL® GOLD MZ 68 WP), Ciba-Geigy Ltd., Basle, Data Sheet, dated Dec.08, 1995d Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. CONFIDENTIAL INFORMATION	329351-24	no	unpublished protected

ANNEX B

Metalaxyl-M

B.2 Physical and chemical properties

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

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

- for the purified a.s. : 99.4 % (R+S) (Bourgeois et al., 1995a)
 97.2 % (R)
- for the a.s. as manufactured (TC) : 97.1 % (R+S) (Burkhard, 1997)
 95.2 % (R)
- for the a.s. ¹⁴C-ring labelled : 98.8 % radiochemical purity (R+S) (Burkhard, 1997)
 > 98.3 % (R)

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

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 (DSC) - The study is GLP	purified a.s. : freezing temp. (glass transition temp) = - 38.7 °C	- The study is acceptable	Geoffroy, 1994a
B.2.1.2 Boiling Point (IIA 2.1.2)	- EEC-method A2 (Siwoloboff-method with photocell detection) - The study is GLP	purified a.s. : boiling point could not be determined due to thermal decomposition at a temperature lower than that of the boiling point	- The study is acceptable	Das, 1994a
B.2.1.3 Temperature of decomposition or sublimation (IIA 2.1.3)	- EEC-method A2 (Siwoloboff-method with photocell detection) - The study is GLP	purified a.s. : thermal decomposition occurs at approx. 270 °C	- The study is acceptable	Das, 1994a
B.2.1.4 Relative density (IIA 2.2)	- EEC-method A3 OECD-guideline 109 (oscillating density meter)	purified a.s. : density at 20 °C = 1125 kg/m ³	- The study is acceptable	Das, 1994b

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	- The study is GLP			
B.2.1.5 Vapour pressure (IIA 2.3.1)	- EEC-method A4 OECD-guideline 104 (automized gas saturation method with online GC- detection) - The study is GLP	purified a.s. : vapour pressure at 25 °C = $3.3 \cdot 10^{-3}$ Pa (extrapolated)	- The study is acceptable	Geoffroy, 1994b
B.2.1.6 Volatility, Henry's law constant (IIA 2.3.2)	- Calculation only - GLP not relevant	purified a.s. : vapour pressure at 25 °C = $3.3 \cdot 10^{-3}$ Pa water solubility at 25 °C = 26 g/l \Rightarrow H at 25 °C : $3.5 \cdot 10^{-5}$ Pa.m ³ /mol	- The report is acceptable	Burkhard, 1995
B.2.1.7 Physical state (IIA 2.4.1)	- Visual test - The study is GLP	purified a.s. : at 20-25 °C : clear, viscous liquid a.s. as manufactured (TC) : at 20-25 °C : clear, viscous liquid	- The study is acceptable	Das, 1994c Das, 1994d
B.2.1.8 Colour (IIA 2.4.1)	- Visual test - The study is GLP	purified a.s. : at 20-25 °C : pale yellow a.s. as manufactured (TC) : at 20-25 °C : light brown	- The study is acceptable	Das, 1994c Das, 1994d
B.2.1.9	- Organoleptic test	purified a.s. :	- The study is acceptable	Das, 1994c

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
Odour (IIA 2.4.2)	- The study is GLP	at 20-25 °C : weak odour a.s. as manufactured (TC) : at 20-25 °C : weak odour		Das, 1994d
B.2.1.10 Spectra of the active substance (IIA 2.5.1)	- The study is GLP	purified a.s. : IR : 1680 cm ⁻¹ (C=O stretch of -CO-O); 1755 cm ⁻¹ (C=O stretch of =N-CO-) UV/VIS : 266.4 nm (512 l.mol ⁻¹ .cm ⁻¹) and 274.2 nm (477 l.mol ⁻¹ .cm ⁻¹); no absorption between 290 nm and 750 nm MS : m/z 279, 249, 234, 220, 206, 192, 174, 105, 45 NMR : 0.9 ppm (doublet), 2.2 ppm (singlet), 2.4 ppm (singlet), 3.2 ppm (singlet), 3.5 ppm (multiplet), 3.7 ppm (singlet), 4.4 ppm (quartet), 7.20-7.31 ppm (multiplet)	- The study is acceptable	Bourgeois, 1994a
B.2.1.11 Spectra for impurities (IIA 2.5.2)	- The study is GLP	2,6-dimethyl-phenylamine (CGA 72649), purity not specified : IR : 3473 cm ⁻¹ (NH ₂ stretch); 3388 cm ⁻¹ (NH ₂ stretch); 3000-2800 cm ⁻¹ (-C-H aromat. (Stretch)); 1620 cm ⁻¹ (-C=C- aromat.) UV/VIS : 283.5 nm (2000 l.mol ⁻¹ .cm ⁻¹) and 233.5 nm (7400 l.mol ⁻¹ .cm ⁻¹); no absorption between 340 nm and 750 nm MS : m/z 121, 106, 91 NMR : 2.07 ppm (singlet), 4.43 ppm (singlet), 6.4 ppm (triplet), 6.8 ppm (doublet)	- The study is acceptable	Schneider, 1995

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
B.2.1.12 Solubility in water (IIA 2.6)	- EEC-method A6 OECD-guideline 105 (flask method + HPLC-analysis) - The study is GLP	purified a.s. : solubility in pure water at 25 °C = 26 g/l (RSD = 0.41 %) the pH has no effect on the water solubility of the a.s. in the pH-range 4-10, because the a.s. has no dissociation constant in an accessible pH-range (see also B.2.1.18).	- EEC-method A6 was slightly adapted. Nevertheless the study is acceptable.	Stulz, 1994a
B.2.1.13 Solubility in organic solvents (IIA 2.7)	- SOP 209/4 - The study is GLP	a.s. as manufactured (TC) : solubility at 25 °C in n-hexane : 59 g/l toluene : completely miscible dichloromethane : completely miscible methanol : completely miscible n-octanol : completely miscible acetone : completely miscible ethyl acetate : completely miscible	- The study is acceptable	Stulz, 1994b
B.2.1.14 Partition coefficient n-octanol/water (IIA 2.8)	- EEC-method A8 OECD-guideline 117 (HPLC) - The study is GLP	purified a.s. : at 25 °C : $\log P_{ow} = 1.71 \pm 0.04$ (pH of mobile phase = 7.6)	- The study is acceptable	Stulz, 1994c
B.2.1.15	- OECD-guideline 111	a.s. ^{14}C -ring labelled :	- Method equivalent to	Ellgehausen, 1996

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
Hydrolysis rate at pH 4, 7 and 9 under sterile conditions in the absence of light (IIA 2.9.1)	- The study is GLP	<p>pre-test at 50 °C at pH 1, 5, 7 and 9 : hydrolytical stability up to pH 7 (= less than 10 % of degradation after 5 days)</p> <p>further tests at pH 9 :</p> <p>60 °C : $k = 2.97 \cdot 10^{-6} \text{ s}^{-1}$; $t_{1/2} = 2.7 \text{ d}$</p> <p>50 °C : $k = 1.04 \cdot 10^{-6} \text{ s}^{-1}$; $t_{1/2} = 7.7 \text{ d}$</p> <p>25 °C : $k = 6.89 \cdot 10^{-8} \text{ s}^{-1}$; $t_{1/2} = 116.4 \text{ d}$</p> <p>20 °C : $k = 3.72 \cdot 10^{-8} \text{ s}^{-1}$; $t_{1/2} = 215.8 \text{ d}$ (calculated)</p> <p>Hydrolysis proceeds via cleavage of the methylester bond, leaving (R)-2-[(2,6-dimethylphenyl)-methoxyacetylaminol]-propionic acid</p>	<p>EEC C7; pH 5 instead of pH 4 is not relevant</p> <p>- The study is acceptable</p>	
B.2.1.16 Direct phototransformation of purified a.s. in water using artificial light under sterile conditions (IIA 2.9.2)	<p>- US-EPA-161-2 (Heraeus Suntest apparatus : Xenon arc light source, $\lambda < 290 \text{ nm}$ filtered out)</p> <p>- The study is GLP</p>	<p>a.s. ^{14}C-ring labelled :</p> <p>at 25 °C, buffered at pH 7 : no significant degradation of parent molecule by light</p> <p>1) after 240 h continuous exposure : still 97.16 % of metalaxyl-M present (dark-control : after 240 h still 96.30-98.61 % of metalaxyl-M present) ⇒ no half-life was calculated</p> <p>2) only very minor amounts of degradates observed (ranging on average between 0.22 and 1.77 % of the radioactivity applied) ⇒ degradates were not further characterized</p>	<p>- Method concurs with the SETAC-procedures</p> <p>- The study is acceptable, but in fact it is not required since $\epsilon < 10 \text{ l.mol}^{-1}.\text{cm}^{-1}$ at $\lambda \geq 290 \text{ nm}$ (see B.2.1.10 and B.2.1.17)</p>	Ellgehausen, 1995
B.2.1.17 Quantum yield of direct phototransformation (IIA 2.9.3)	<p>- UBA-guideline : "Phototransformation of Chemicals in Water, Part A : Direct Phototransformation"</p>	<p>purified a.s. :</p> <p>UV-absorption in water at 290 nm : $\epsilon < 1 \text{ l.mol}^{-1}.\text{cm}^{-1}$, meaning no spectral overlap with sunlight ⇒ no direct photochemical degradation of metalaxyl-M</p>	<p>- The study is acceptable; determination of quantum yield is not required.</p>	Phaff, 1995

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
	- The study is GLP	is expected in surface waters (see also B.2.1.16). This does however not exclude to some extent indirect photochemical degradation by the more efficient pathway of sensitized photolysis.		
B.2.1.18 Dissociation in water of purified active substance (IIA 2.9.4)	- UV-absorption spectra - The study is GLP	purified a.s. : absorption spectra (210-320 nm) taken at pH 1, 7 and 10 are identical ⇒ no dissociation constant (pKa) in an accessible pH-range	- The study is acceptable	Jäkel, 1995
B.2.1.19 Estimated photo chemical oxidative degradation (IIA 2.10)	- Atmospheric Oxidation Program V 1.55 a (1994) (based on Atkinson-method) - GLP not applicable	estimated half-life of metalaxyl-M in the atmosphere (by hydroxyl radical oxidation) : between 4 and 6 h (calculated with $1.5 \cdot 10^6$ OH-radicals/cm ³ and 12 h day)	- The study is acceptable	Stamm, 1995
B.2.1.20 Flammability (IIA 2.11.1)	- Applicant's statement	"This point is not applicable as the a.s. is a liquid and the requirement is only for solids, gases, or substances which evolve flammable gases"	- Acceptable	
B.2.1.21 Auto-flammability (IIA 2.11.2)	- EEC-method A15 (DIN 51794) - The study is GLP	a.s. as manufactured (TC) : auto-ignition temperature = 410 °C	- The study is acceptable	Schürch, 1994a
B.2.1.22 Flash point (IIA 2.12)	- EEC-method A9 (DIN 51758) - The study is GLP	a.s. as manufactured (TC) : flash point (1013 mbar) = 179 °C	- The study is acceptable	Schürch 1994b
B.2.1.23	- EEC-method A14	a.s. as manufactured (TC) :	- The study is acceptable	Schürch, 1994c

Study	Guidelines and GLP	Findings	Evaluation and conclusions	References
Explosive properties (IIA 2.13)	- The study is GLP	no thermal sensitivity no mechanical sensitivity (shock) ⇒ metalaxyl-M is not considered an explosive		
B.2.1.24 Surface tension (IIA 2.14)	- OECD-guideline 115 ISO 304 (Wilhelmy Plate method) - The study is GLP	a.s. as manufactured (TC) : at 20 °C : $\sigma = 57.6 - 57.8$ mN/m (solutions of 1.0 g/l) $\sigma = 68.0 - 68.2$ mN/m (dilutions of 0.1 g/l)	- Method is equivalent to EEC A5 - The study is acceptable	Ryser, 1994
B.2.1.25 Oxidizing properties (IIA 2.15)	- ASTM G 31-72 - The study is GLP	a.s. as manufactured (TC) : not corrosive to tin plate iron steel ST 37 stainless steel DIN 1.4541 polyethylene	- The study is acceptable (method EEC A17 is not suitable for liquids)	Stulz, 1997

B.2.2 Physical and chemical properties of the plant protection products (Annex IIIA 2)Table B.2.2-1 : Physical and chemical properties of **A-9408 B** (Emulsifiable concentrate : metalaxyl-M) (RIDOMIL GOLD 480 EC)

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.1 Physical state (IIIA 2.1)	- Visual test - The study is GLP	clear liquid	- The study is acceptable	Bourgeois, 1995b Rodler, 1995a
B.2.2.2 Colour (IIIA 2.1)	- Visual test - The study is GLP	light-brown to brown	- The study is acceptable	Bourgeois, 1995b Rodler, 1995a
B.2.2.3 Odour (IIIA 2.1)	- Organoleptic test - The study is GLP	intense, like lacquer	- The study is acceptable	Bourgeois, 1995b Rodler, 1995a
B.2.2.4 Explosive properties (IIIA 2.2.1)	- EEC-method A14 - The study is GLP	no thermal sensitivity no mechanical sensitivity (shock) ⇒ A-9408 B is not considered an explosive	- The study is acceptable	Schürch, 1995a
B.2.2.5 Oxidizing properties (IIIA 2.2.2)	UN recommendations on the Transport of Dangerous Goods, Part III, Section 34 (1995) The study is GLP	mean time for the pressure to rise from 690 to 2070 kPa (5 trials) : • for the 1:1 test substance and cellulose mixture : 16.20 s • for the 1:1 reference substance (65% aqueous nitric acid) and cellulose mixture : 5.35 s ⇒ the product is not considered an oxidizing substance	The study is acceptable (method EEC A17 is not suitable for liquids)	Angly, 1998
B.2.2.6 Flash point (IIIA 2.3)	- EEC-method A9 (DIN 51758) - The study is GLP	flash point (1013 mbar) = 83 °C	- The study is acceptable	Schürch, 1995b

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
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) - The study is GLP	auto-ignition temperature = 395 °C (atmospheric pressure : 1002 - 1006 mbar)	- The study is acceptable	Schürch, 1995c
B.2.2.9 Acidity or alkalinity and pH value (IIIA 2.4.1)			- see B.2.2.10	
B.2.2.10 pH of a 1 % aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	- CIPAC MT 75.2 - The study is GLP	1%-emulsion of A-9408 B in deionized water : pH = 4.5	- The study is acceptable	Rodler, 1995b
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)	- OECD-guideline 114 DIN 53019 (rotational viscometer) - The study is GLP	at 20 °C : $\eta = 34.15 \pm 0.26$ mPa.s at shear rate D : $0.870 \text{ s}^{-1} < D < 2.97 \text{ s}^{-1}$ at 40 °C : $\eta = 14.27 \pm 0.06$ mPa.s at shear rate D : $1.607 \text{ s}^{-1} < D < 7.46 \text{ s}^{-1}$	- The study is acceptable	Ryser, 1995a
B.2.2.13 Surface tension (IIIA 2.5.3)	- OECD-guideline 115 ISO 304 (Wilhelmy Plate method)	at 20 °C : $\sigma = 40.6 - 41.1$ mN/m (filtrates of 0.1 g/l emulsions) $\sigma = 54.5 - 54.9$ mN/m (filtrates of 0.01 g/l emulsions)	- Method equivalent to EEC A5 - The study is acceptable, although the tested	Ryser, 1995b

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
	- The study is GLP		concentrations are not fully representative for the intended use of the preparation.	
B.2.2.13 (cont'd)	- EEC-method A5 ISO 304 (Wilhelmy Plate method) - The study is GLP	at 20 °C : σ = 31.0 - 31.2 mN/m (filtrates of 25 g/l emulsions) σ = 32.2 - 32.3 mN/m (filtrates of 10 g/l emulsions) σ = 32.7 - 32.8 mN/m (filtrates of 1 g/l emulsions)	- The study is acceptable	Ryser, 1997
B.2.2.14 Relative density (IIIA 2.6.1)	- EEC-method A3 (oscillating density meter) - The study is GLP	density at 20 °C = 1040 kg/m ³	- The study is acceptable	Bourgeois, 1995b
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)	- OECD-guideline 113 - The study is GLP	1) reference content of metalaxyl-M : 480 g/l final content of metalaxyl-M : 483 g/l ⇒ a.s. content of the formulation shows no degradation after 2 weeks of storage at 54 °C 2) no change in appearance or density of the preparation	- Method equivalent to CIPAC MT 46 - The study is acceptable, although not all relevant tests were performed (e.g. pH and emulsion stability). However, since these relevant parameters were tested after storage for 18 weeks at 30 °C (see B.2.2.20), an additional study is not required.	Bourgeois, 1995c

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)			- Not required (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)	- CIPAC MT 39.1 - The study is GLP	storage at 0 °C for 1 h : 0 ml separation for 7 d : 0 ml separation ⇒ the formulation is stable at low temperatures	- The study is acceptable	Rodler, 1995a
B.2.2.20 Shelf life (IIIA 2.7.3)	- GIFAP n° 17 - The stability studies are GLP	<u>after storage for 18 weeks at 30 ± 2 °C in PE pack with solvent barrier (polyamide) :</u> - no change in a.s. content (46 % w/w), appearance (brown, clear liquid) and pH of 1% emulsion (4.5) - packaging material is resistant to its content but - significant change in emulsion characteristics of a 5% emulsion in CIPAC Water C at 30 °C : formation of oil at the top (< 1 ml after 0.5 h, 1 ml after 2 h and 24 h), also after re-emulsification (1 ml after 0.5 h)	- The accelerated study is acceptable as such, but considering the observed significant changes in emulsion characteristics, it does not allow to draw meaningful conclusions with regard to the shelf life.	Wochner, 1995a
B.2.2.20 (cont'd)	- GIFAP n° 17	<u>after storage for 2 years at 20 ± 2 °C in PE pack with solvent</u>	- The study is acceptable	Kundel, 1998

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
	- The stability studies are GLP	<u>barrier (polyamide) :</u> - no change in a.s. content, appearance and pH of 1% emulsion - no significant change in emulsion characteristics of a 5% emulsion in CIPAC water C at 30 °C : formation of froth or oil at the top (3 ml froth after 0.5 h, trace oil after 2 h, 1.5 ml oil after 24 h), also after re-emulsification (2 ml froth after 0.5 h) - packaging material is resistant to its content ⇒ shelf life : at least 2 years		
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 - The study is GLP	dilution of the formulation with CIPAC water C to a concentration of 1 % : after 3 min : 0 ml foam	- The study is acceptable.	Rodler, 1995a
B.2.2.23 Suspensibility (IIIA 2.8.3)			- Not applicable (emulsion forming preparation).	
B.2.2.24 Spontaneity of dispersion (IIIA 2.8.3)			- Not applicable (emulsion forming preparation).	
B.2.2.25 Dilution stability (IIIA 2.8.4)			- Not applicable (emulsion forming preparation).	

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.26 Dry sieve test and wet sieve test (IIIA 2.8.5)			- Not applicable (emulsion forming preparation).	
B.2.2.27 Size distribution of particles - Nominal size range of particles (IIIA 2.8.6.1)			- Not applicable (emulsion forming preparation).	
B.2.2.28 Dust content and particle size of dust (IIIA 2.8.6.2)			- Not applicable (emulsion forming preparation).	
B.2.2.29 Friability and attrition characteristics of granules (IIIA 2.8.6.3)			- Not applicable (emulsion forming preparation).	
B.2.2.30 Emulsifiability, emulsion stability, re-emulsifiability (IIIA 2.8.7.1)	- CIPAC MT 36.1 - The study is GLP	5 % emulsion in CIPAC water C at 30 °C : <u>emulsifiability</u> : spontaneity of the emulsion is complete <u>emulsion stability</u> on standing : after 0.5 h : 1 ml cream at the top after 2 h : 1 ml cream at the top after 24 h : 1 ml oil at the top <u>re-emulsification</u> : complete <u>stability after re-emulsification</u> : after 0.5 h : < 1 ml cream at the top	- CIPAC water C was used instead of CIPAC water D. - The study is acceptable, but it should be noted that the representative dilution concentration of the formulation is lower than 5% (i.e. 1%) (see also B.2.2.31).	Rodler, 1995b
B.2.2.31	- CIPAC MT 20	dilution of A-9408 B to a concentration of 1 %	- CIPAC water C was used	Rodler, 1995a

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
Stability of emulsions (IIIA 2.8.7.2)	- The study is GLP	with deionized water : < 1 ml cream on top with CIPAC water C : 0 ml separation	instead of CIPAC water D. - The study is acceptable.	
B.2.2.32 Flowability (IIIA 2.8.8.1)			- Not applicable (emulsion forming preparation).	
B.2.2.33 Pourability (including rinsed residue) (IIIA 2.8.8.2)			- Not applicable (emulsion forming preparation).	
B.2.2.34 Dustability following accelerated storage (IIIA 2.8.8.3)			- Not applicable (emulsion forming preparation).	
B.2.2.35 Physical compatibility of tank mixes (IIIA 2.9.1)			- Not applicable (no application is being made for the authorisation of the combined use of A-9408 B with any other product)	
B.2.2.36 Chemical compatibility of tank mixes (IIIA 2.9.2)			- Not applicable (no application is being made for the authorisation of the combined use of A-9408 B with any other product)	
B.2.2.37 Distribution and adhesion (IIIA 2.10)			- Not applicable (preparation is not intended for seed treatment)	

Table B.2.2-2 : Physical and chemical properties of **A-9407 A** (Wettable powder : metalaxyl-M + mancozeb)(RIDOMIL GOLD MZ 68 WP)

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.1 Physical state (IIIA 2.1)	- Visual test - The study is GLP	solid : fine powder	- The study is acceptable	Bourgeois, 1994b Rodler, 1995c Rodler, 1995d
B.2.2.2 Colour (IIIA 2.1)	- Visual test - The study is GLP	light yellow	- The study is acceptable	Bourgeois, 1994b Rodler, 1995c Rodler, 1995d
B.2.2.3 Odour (IIIA 2.1)	- Organoleptic test - The study is GLP	weak uncharacteristic odour	- The study is acceptable	Rodler, 1995c Rodler, 1995d
B.2.2.4 Explosive properties (IIIA 2.2.1)	- EEC-method A14 - The study is GLP	no thermal sensitivity (effect of a flame) no mechanical sensitivity (shock, friction) ⇒ A-9407 A is not considered an explosive	- The study is acceptable	Schürch, 1995d
B.2.2.5 Oxidizing properties (IIIA 2.2.2)	- EEC-method A17 - The study is GLP	max. burning rate of reference mixture (barium nitrate/cellulose 60:40) = 4.9 mm/s max. burning rate of test mixtures = 2.0 mm/s ⇒ A-9407 A is not considered an oxidizing substance	- The study is acceptable	Schürch, 1995e
B.2.2.6 Flash point (IIIA 2.3)			- Not applicable (solid preparation)	
B.2.2.7 Flammability (IIIA 2.3)	- EEC-method A10 - The study is GLP	preliminary test : burning time to 200 mm = 38 min (smouldering fire) ⇒ A-9407 A is not considered highly flammable	- The study is acceptable	Schürch, 1995f
B.2.2.8 Auto-	- Bowes-Cameron cage test (modified version)	oven temp. 140 °C, container 100x100x100 mm :	- The study is acceptable	Schürch, 1995g

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
flammability (IIIA 2.3)	- The study is GLP	_max > 400 °C after ± 1 3/4 h (spontaneous reaction) oven temp. 140 °C, container 25x25x25 mm : _max > 400 °C after ± 6 h (spontaneous reaction) ⇒ A-9407 A is a self-heating substance		
B.2.2.9 Acidity or alkalinity and pH value (IIIA 2.4.1)			- Not applicable	
B.2.2.10 pH of a 1 % aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	- CIPAC MT 75 - The study is GLP	1%-suspension of A-9407 A in deionized water : pH = 6.6 (same result was obtained using deionized water containing 2% of water-soluble-bag material, relative to the formulation)	- The study is accep- table	Rodler, 1995e Rodler, 1995f
B.2.2.11 Kinematic viscosity (IIIA 2.5.1)			- Not applicable (solid preparation)	
B.2.2.12 Viscosity (III 2.5.2)			- Not applicable (solid preparation)	
B.2.2.13 Surface tension (IIIA 2.5.3)			- Not applicable (solid preparation)	
B.2.2.14 Relative density (IIIA 2.6.1)			- Not applicable (solid preparation)	
B.2.2.15	- CIPAC MT 33	tap density = 0.39 g/cm ³ (50 taps)	- The study is accep-	Rodler, 1995c

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
Bulk or tap density (IIIA 2.6.2)	- The study is GLP		table	Rodler, 1995d
B.2.2.16 Stability after storage for 14 days at 54 °C (IIIA 2.7.1)	- OECD-guideline 113 - The study is GLP	1) reference content : 4.17 % metalaxyl-M 63.5 % mancozeb final content : 4.02 % metalaxyl-M 63.6 % mancozeb ⇒ small degradation (3.6 % relative) of metalaxyl-M after 2 weeks of storage at 54 °C 2) no change in appearance of the preparation	- Method equivalent to CIPAC MT 46 - The study is acceptable, although not all relevant tests were performed (e.g. pH, wet sieve test, suspensibility). However, since these relevant parameters were tested after storage for 18 weeks at 30 °C (see B.2.2.20), an additional study is not required	Bourgeois, 1995d
B.2.2.17 Stability after storage for other periods and temperatures (IIIA 2.7.1)			- Not required (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)			- Not applicable (solid preparation)	

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.20 Shelf life (IIIA 2.7.3)	- GIFAP n° 17 - The stability studies are GLP	<p>a) <u>water soluble bag in paper / PE pack with water vapour barrier (aluminium)</u> after storage for 18 weeks at 30 ± 2 °C : - small degradation of mefenoxam (2.7 % relative) and mancozeb (2.5 % relative) compared to reference sample - no change in appearance (fine, light yellow powder; no compaction) - no significant changes in pH, suspensibility, wet sieve value, wettability and persistent foam - packaging material is resistant to its content</p> <p>b) <u>box with inner bag (paper / PE-laminate with water vapour barrier (aluminium))</u> after storage for 18 weeks at 30 ± 2 °C : - small degradation of metalaxyl-M (1.7 % relative) and mancozeb (0.6 % relative) compared to reference sample - no change in appearance (fine, light yellow powder; no compaction) - no significant changes in pH, suspensibility, wet sieve value, wettability and persistent foam - packaging material is resistant to its content</p>	<p>- The accelerated study is acceptable, but it only allows to conclude that the product will most likely comply with a shelf life specification of 2 years. The shelf life declarations of 3 years and 4 years resp., as stated by the applicant on the basis of this study, are thus not acceptable. To allow such declarations to be made, additional real-time studies at ambient temperature for the specified time intervals (3 or 4 years) are required.</p>	<p>Wochner, 1995b Wochner, 1995c</p>
B.2.2.20 (cont.)	- GIFAP n° 17	a) <u>water soluble bag in paper / PE pack with water vapour</u>	- The study is accep-	Kundel, 1997a

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
	<p>- The stability studies are GLP</p>	<p><u>barrier (aluminium)</u> after storage for 2 years at 20 ± 2 °C : - no degradation of metalaxyl-M and small degradation of mancozeb (3.6 % relative) compared to reference sample - no change in appearance (fine, light yellow powder; no compaction) - no significant changes in pH, suspensibility, wet sieve value, wettability and persistent foam - packaging material is resistant to its content</p> <p>⇒ shelf life : at least 2 years</p> <p>b) <u>box with inner bag (paper / PE-laminate with water vapour barrier (aluminium))</u> after storage for 2 years at 20 ± 2 °C : - no degradation of metalaxyl-M and small degradation of mancozeb (1.1 % relative) compared to reference sample - no change in appearance (fine, light yellow powder; no compaction) - no significant changes in pH, suspensibility, wet sieve value, wettability and persistent foam - packaging material is resistant to its content</p> <p>⇒ shelf life : at least 2 years</p>	<p>table.</p>	<p>Kundel, 1997b</p>
B.2.2.21	- CIPAC MT 53.3	a) using CIPAC water C :	- CIPAC water C was	Rodler, 1995e

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
Wettability (IIIA 2.8.1)	- The study is GLP	wetting time = 30 s b) using <u>CIPAC water C containing 2 % of water-soluble-bag material, relative to the formulation</u> : wetting time = 31 s	used instead of CIPAC water D - The study is acceptable.	Rodler, 1995f
B.2.2.22 Persistent foaming (IIIA 2.8.2)	- CIPAC MT 47.2 - The study is GLP	dilution of the formulation to a concentration of 1.25 % a) with <u>CIPAC water C</u> : 10 ml foam after 3 min b) with <u>CIPAC water C containing 2 % of water-soluble-bag material, relative to the formulation</u> : 12 ml foam after 3 min	- The study is acceptable.	Rodler, 1995e Rodler, 1995f
B.2.2.23 Suspensibility (IIIA 2.8.3)	- CIPAC MT 15.1 - The study is GLP	a) using <u>standard water C at 30 °C</u> : suspensibility of metalaxyl-M of 1.25 % susp. = 98 % of 0.125 % susp. = 99 % suspensibility of mancozeb of 1.25 % susp. = 72 % of 0.125 % susp. = 73 % b) using <u>standard water C containing 2 % of water-soluble-bag material relative to the formulation at 30 °C</u> : suspensibility of metalaxyl-M of 1.25 % susp. = 99 % of 0.125 % susp. = 100% suspensibility of mancozeb of 1.25 % susp. = 71 % of 0.125 % susp. = 74 %	- The study is acceptable	Rodler, 1995e Rodler, 1995f
B.2.2.24 Spontaneity of dispersion (IIIA 2.8.3)	- CIPAC MT 174 - The study is GLP	a) using <u>standard water C at 20 °C</u> : spontaneity of dispersion = 87 % b) using <u>standard water C containing 2 % of water-soluble-bag material relative to the formulation at 20 °C</u> : spontaneity of dispersion = 87 %	- The study is acceptable (although not required for WP)	Rodler, 1995c Rodler, 1995d
B.2.2.25			- Not applicable (not a	

Study	Guidelines and GLP	Findings	Evaluation and conclusion water soluble product)	References
Dilution stability (IIIA 2.8.4)				
B.2.2.26 Dry sieve test and wet sieve test (IIIA 2.8.5)	- CIPAC MT 59.3 - The study is GLP	wet sieve residue on sieve mesh 75 µm = 0.20 % using water containing 2 % of water-soluble-bag material, relative to the formulation : wet sieve residue on sieve mesh 75 µm = 0.18 %	- The study is acceptable	Rodler, 1995e Rodler, 1995f
B.2.2.27 Size distribution of particles - Nominal size range of particles (IIIA 2.8.6.1)	- SOP FD3-TE-M 05/4 (method of light diffraction) - The study is GLP	median of mass distribution (diameter) = 2.52 µm percent mass > 400 µm (diameter) : 0 % percent mass < 4 µm (diameter) : 67.62 %	- OECD-guideline 110 could not be used, because the particle size of the product is too fine to be analyzed by any of the suggested methods. - The study is acceptable.	Fueldner, 1995
B.2.2.28 Dust content and particle size of dust (IIIA 2.8.6.2)			- Not applicable (not a granular preparation)	
B.2.2.29 Friability and attrition characteristics of granules (IIIA 2.8.6.3)			- Not applicable (not a granular preparation)	
B.2.2.30 Emulsifiability, emulsion stability, stability of emulsions (IIIA 2.8.7.1)			- Not applicable (not an emulsion forming preparation)	

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
B.2.2.31 Stability of emulsions (IIIA 2.8.7.2)			- Not applicable (not an emulsion forming preparation)	
B.2.2.32 Flowability (IIIA 2.8.8.1)			- Not applicable (not a granular preparation)	
B.2.2.33 Pourability (including rinsed residue) (IIIA 2.8.8.2)			- Not applicable (preparation is not a suspension)	
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 application is being made for the authorization of the combined use of A-9407 A with any other product)	
B.2.2.36			- Not applicable (no	

Study	Guidelines and GLP	Findings	Evaluation and conclusion	References
Chemical compatibility of tank mixes (IIIA 2.9.2)			application is being made for the authorization of the combined use of A-9407 A with any other product)	
B.2.2.37 Distribution and adhesion (IIIA 2.10)			- Not applicable (preparation 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, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	Ciba file N°	GLP GEP	Published Protected
IIA 2.5.1	Bourgeois W., Report on spectra (CGA 329351) Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 22171, 11.07.1994a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/13	yes	unpublished protected
IIA 2	Bourgeois W., Meier P., Rätz V., Schneider B., Purification report Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° AMS 758 / 101, 15.11.1995a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/63	no	unpublished protected
IIA 2.3.2	Burkhard N., Henry's Law Constant Ciba-Geigy Ltd., Basle, Data-Sheet, 31.03.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/62	no	unpublished protected
IIA 2	Burkhard N., Metalaxyl-M/CGA 329351 : Content of R-enantiomer in test material used for physical/chemical tests Novartis Crop Protection AG, Basle, 20.08.1997 Owned by : Novartis Crop Protection AG Submitted by : Novartis Crop Protection AG	-	no	unpublished protected
IIA 2.1.2 IIA 2.1.3	Das R., Report on boiling point / boiling range Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 26165, 02.01.1994a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/34	yes	unpublished protected
IIA 2.2	Das R., Report on density Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 26166, 09.11.1994b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/17	yes	unpublished protected
IIA 2.4	Das R., Report on general physico-chemical properties (pure active ingredient), Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 26171, 11.11.1994c Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/21	yes	unpublished protected
IIA 2.4	Das R., Report on general physico-chemical properties (technical grade active ingredient), Ciba-Geigy Muenchwilen AG, Muenchwilen,	329351/20	yes	unpublished protected

Annex point(s) 91/414/EEC	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	Ciba file N°	GLP GEP	Published Protected
	Rep. N° 26831, 11.11.1994d Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.			
IIA 2.9.2	Ellgehausen H., Aqueous photolysis of ¹⁴ C CGA 329351 under artificial sunlight conditions Ciba-Geigy Ltd., Basle, Report N° 95EH04, 20.12.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/329	yes	unpublished protected
IIA 2.9.1	Ellgehausen H., Hydrolysis of ¹⁴ C-labelled CGA 329351 under laboratory conditions Ciba-Geigy Ltd., Basle, Report N° 95EH05, 03.01.1996 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/330	yes	unpublished protected
IIA 2.1.1	Geoffroy A., Report on melting / freezing temperature Ciba-Geigy Ltd., Basle, Rep. N° PP-94/45P.MPR, 28.12.1994a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/43	yes	unpublished protected
IIA 2.3.1	Geoffroy A., Report on vapour pressure curve Ciba-Geigy Ltd., Basle, Rep. N° PP-94/45P.VPC, 29.12.1994b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/44	yes	unpublished protected
IIA 2.9.4	Jäkel K., Report on dissociation constant in water Ciba-Geigy Ltd., Basle, Rep. N° PP-94 / 45P.DCW, 02.01.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/41	yes	unpublished protected
IIA 2.9.3	Phaff R., Rate and quantum yield of the direct phototransformation of CGA 329351 under laboratory conditions in water Ciba-Geigy Ltd., Basle, Rep.N° 59RP02, 26.10.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/297	yes	unpublished protected
IIA 2.14	Ryser M., Report on surface tension of aqueous solutions Ciba-Geigy Ltd., Basle, Rep N° PP-94/45T.SUR, 21.12.1994 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/42	yes	unpublished protected
IIA 2.5.2	Schneider B., Report on spectra (CGA 72649) Ciba-Geigy Muenchwilen AG, Muenchwilen,	72649/1	yes	unpublished

Annex point(s) 91/414/EEC	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	Ciba file N°	GLP GEP	Published Protected
	Rep. N° 34015, 07.08.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.			protected
IIA 2.11	Schürch H., Report on auto-ignition temperature of liquids Ciba-Geigy Ltd., Basle, Rep N° PP-94/45T.AFG, 09.12.1994a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/48	yes	unpublished protected
IIA 2.12	Schürch H., Report on determination of flashpoint Ciba-Geigy Ltd., Basle, Rep N° PP-94/45T.FLP, 09.12.1994b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/46	yes	unpublished protected
IIA 2.13	Schürch H., Report on explosive properties Ciba-Geigy Ltd., Basle, Rep N° PP-94/45T.EXP, 09.12.1994c Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/47	yes	unpublished protected
IIA 2.10	Stamm E., Atmospheric oxidation of CGA 329351 by hydroxyl radicals Rate estimation Ciba-Geigy Ltd., Basle, Rep. N° 95SM06, 09.05.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/72	no	unpublished protected
IIA 2.6	Stulz J., Report on water solubility Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 26169, 17.10.1994a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/16	yes	unpublished protected
IIA 2.7	Stulz J., Report on solubility in organic solvents Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 26833, 30.11.1994b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/22	yes	unpublished protected
IIA 2.8	Stulz J., Report on octanol/water partition coefficient Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 26168, 02.11.1994c Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351/18	yes	unpublished protected
IIA 2.15	Stulz J., CGA 329351 - Stability with respect to oxidizing or reducing agents Novartis Crop Protection Muenchwilen AG, Muenchwilen, 19.03.1997 Owned by : Novartis Crop Protection AG Submitted by : Novartis Crop Protection AG	329351/578	yes	unpublished protected

Physical and chemical properties of the formulation RIDOMIL GOLD 480 EC (Annex IIIA 2)

Annex point(s) 91/414/EEC	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	Ciba file N°	GLP GEP	Published Protected
IIIA 2.1 IIIA 2.6.1	Bourgeois W., Report on Chemical Composition, Ciba-Geigy Muenchwilen Ltd., Muenchwilen, Project Report 30073, dated Feb. 22, 1995b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-175	yes	unpublished protected
IIIA 2.7.1	Bourgeois W., Report on Chemical Stability Ciba-Geigy Muenchwilen Ltd., Muenchwilen Project Report 30082, dated Mar. 27, 1995c Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-179	yes	unpublished protected
IIIA 2.7.3	Kundel P., Final report on product stability Novartis Crop Protection Muenchwilen AG, Muenchwilen, January 12, 1998 Owned by : Novartis Crop Protection AG Submitted by : Novartis Crop Protection AG	329351-753	no	unpublished protected
IIIA 2.1 IIIA 2.7.2 IIIA 2.8.2 IIIA 2.8.7.2	Rodler M., Report on Physico-Chemical Properties Ciba-Geigy Muenchwilen Ltd., Muenchwilen, Project Report 30077, dated May 17, 1995a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-176	yes	unpublished protected
IIIA 2.4.2 IIIA 2.8.7.1	Rodler M., Report on Physico-Chemical Properties Ciba-Geigy Muenchwilen Ltd., Muenchwilen, Project Report 30076, dated May 17, 1995b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-177	yes	unpublished protected
IIIA 2.5.2	Ryser M., Report on Viscosity of Liquids Ciba-Geigy Ltd., Basle, Project Report 30078, dated May 08, 1995a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-99	yes	unpublished protected
IIIA 2.5.3	Ryser M., Report on surface tension of aqueous solutions Ciba-Geigy Ltd., Basle, Project Report 30078, dated May 08, 1995b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-178	yes	unpublished protected
IIIA 2.5.3	Ryser M., Report on surface tension Novartis Crop Protection AG, Basle, December 15, 1997 Owned by : Novartis Crop Protection AG Submitted by : Novartis Crop Protection AG	329351-748	yes	unpublished protected
IIIA 2.2.1	Schürch H., Report on Explosive Properties, Ciba-Geigy Ltd., Basle, Project Report 30079, dated Apr. 24, 1995a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-94	yes	unpublished protected

Annex point(s) 91/414/EEC	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	Ciba file N°	GLP GEP	Published Protected
IIIA 2.3	Schürch H., Report on Determination of Flash-Point Ciba-Geigy Ltd., Basle, Project Report 30079, dated Apr. 24, 1995b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-95	yes	unpublished protected
IIIA 2.3	Schürch H., Report on Auto-Ignition Temperature of Liquids, Ciba-Geigy Ltd., Basle, Project Report 30079, dated Apr. 24, 1995c Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-96	yes	unpublished protected
IIIA 2.7.3	Wochner F., Report on Product Stability Ciba-Geigy Muenchwilen Ltd., Muenchwilen Report dated Jul. 18, 1995a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-180	no	unpublished protected

Physical and chemical properties of the formulation RIDOMILGOLD MZ 68 WP (Annex IIIA 2)

Annex point(s) 91/414/EEC	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	Ciba file N°	GLP GEP	Published Protected
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IIIA 2.7.1	Bourgeois W., Report on Chemical Stability, Ciba-Geigy Muenchwilen Ltd., Muenchwilen, Project Report 28702, dated Mar. 23, 1995d Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-162	yes	unpublished protected
IIIA 2.8.6.1	Fueldner H.H., Report on Particle Size Distribution, Ciba-Geigy Ltd., Basle, Project Report 28697, dated Apr. 25, 1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-165	yes	unpublished protected
IIIA 2.7.3	Kundel P., Final report on product stability Novartis Crop Protection Muenchwilen AG, Muenchwilen, December 9, 1997a Owned by : Novartis Crop Protection AG Submitted by : Novartis Crop Protection AG	329351-738	no	unpublished protected
IIIA 2.7.3	Kundel P., Final report on product stability Novartis Crop Protection Muenchwilen AG, Muenchwilen, December 9, 1997b Owned by : Novartis Crop Protection AG Submitted by : Novartis Crop Protection AG	329351-740	no	unpublished protected
IIIA 2.1 IIIA 2.6.2 IIIA 2.8.3	Rodler M., Report on Physico-Chemical Properties Ciba-Geigy Muenchwilen Ltd., Muenchwilen, Project Report 28696, dated Feb. 24, 1995c Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-158	yes	unpublished protected
IIIA 2.1 IIIA 2.6.2 IIIA 2.8.3	Rodler M., Report on Physico-Chemical Properties Ciba-Geigy Muenchwilen Ltd., Muenchwilen, Project Report 28700, dated Feb. 24, 1995d Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-159	yes	unpublished protected
IIIA 2.4.2 IIIA 2.8.1 IIIA 2.8.2 IIIA 2.8.3 IIIA 2.8.5	Rodler M., Report on Physico-Chemical Properties, Ciba-Geigy Muenchwilen Ltd., Muenchwilen, Project Report 28694, dated Mar. 21, 1995e Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-161	yes	unpublished protected
IIIA 2.4.2 IIIA 2.8.1 IIIA 2.8.2 IIIA 2.8.3 IIIA 2.8.5	Rodler M., Report on Physico-Chemical Properties, Ciba-Geigy Muenchwilen Ltd., Muenchwilen, Project Report 28699, dated Mar. 21, 1995f Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-160	yes	unpublished protected

Annex point(s) 91/414/EEC	Author, title, report number, test institute, date of report Owner of the report (company or organisation) Submitted by (company or organisation) For publications: reference	Ciba file N°	GLP GEP	Published Protected
IIIA 2.2.1	Schürch H., Report on Explosive Properties, Ciba-Geigy Ltd., Basle, Project Report 28698, dated Apr. 24, 1995d Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd	329351-104	yes	unpublished protected
IIIA 2.2.2	Schürch H., Report on Oxidizing Properties of Solids, Ciba-Geigy Ltd., Basle, Project Report 28698, dated Apr. 24, 1995e Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-107	yes	unpublished protected
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IIIA 2.3	Schürch H., Report on Self-heating Properties of Solids, Ciba-Geigy Ltd., Basle, Project Report 28698, dated Apr. 24, 1995g Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-105	yes	unpublished protected
IIIA 2.7.3	Wochner F., Interim Report on Product Stability, Ciba-Geigy Muenchwilen Ltd., Muenchwilen Report dated July 18, 1995b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-164	no	unpublished protected
IIIA 2.7.3.	Wochner F., Interim Report on Product Stability, Ciba-Geigy Muenchwilen Ltd., Muenchwilen Report dated July 18, 1995c Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd.	329351-163	no	unpublished protected