CONTENTS

B	Rapporteur Member State summary, evaluation and assessement of the data and information	Page
B.1	Identity	1
B.1.1	Identity of the active substance (Annex IIA 1)	3
B.1.1.1	Name and address of applicant(s) for inclusion of the active substance in Annex I (Annex IIA 1.1)	3
B.1.1.2	Manufacturer of the active substance (Annex IIA 1.2)	3
B.1.1.3	ISO common name and synonyms (Annex IIA 1.3)	3
B.1.1.4	Chemical name (Annex IIA 1.4)	3
B.1.1.5	Manufacturer's development code number (Annex IIA 1.5)	3
B.1.1.6	CAS, EEC and CIPAC numbers (Annex IIA 1.6)	4
B.1.1.7	Molecular formula, molecular mass and structural formula (Annex IIA 1.7)	4
B.1.1.8	Method or methods of manufacture (Annex IIA 1.8)	4
B.1.1.9	Specification of the purity of the active substance (Annex IIA 1.9)	4
B.1.1.10	Identity of inactive isomers, impurities and additives (Annex IIA 1.10)	4
B.1.1.11	Analytical profile of batches (Annex IIA 1.11)	5
B.1.2a	Identity of the plant protection product RIDOMIL GOLD 480 EC (Annex IIIA 1)	6
B.1.2.1a	Current, former and proposed trade names and development code numbers (Annex IIIA 1.3)	6
B.1.2.2a	Manufacturer or manufacturers of the plant protection products (Annex IIIA 1.2)	6
B.1.2.3a	Type of the preparations and code (Annex IIIA 1.5)	6
B.1.2.4a	Function (Annex IIIA 1.6)	6
B.1.2.5a	Composition of the preparation (Annex IIIA 1.4)	7
B.1.2b	Identity of the plant protection product RIDOMIL GOLD MZ 68 WP (Annex IIIA 1)	8
B.1.2.1b	Current, former and proposed trade names and development code numbers (Annex IIIA 1.3)	8
B.1.2.2b	Manufacturer or manufacturers of the plant protection products (Annex IIIA 1.2)	8
B.1.2.3b	Type of the preparations and code (Annex IIIA 1.5)	8
B.1.2.4b	Function (Annex IIIA 1.6)	9
B.1.2.5b	Composition of the preparation (Annex IIIA 1.4)	9

B.1.3	References relied on	10
B.2	Physical and chemical properties	15
B.2.1	Physical and chemical properties of the active substance (Annex IIA 2)	17
B.2.1.1	Melting point, freezing point or solidification point (Annex IIA 2.1.1)	17
B.2.1.2	Boiling Point (Annex IIA 2.1.2)	17
B.2.1.3	Temperature of decomposition or sublimation (Annex IIA 2.1.3)	17
B.2.1.4	Relative density (Annex IIA 2.2)	18
B.2.1.5	Vapour pressure (Annex IIA 2.3.1)	18
B.2.1.6	Volatility, Henry's law constant (Annex IIA 2.3.2)	18
B.2.1.7	Physical state (Annex IIA 2.4.1)	18
B.2.1.8	Colour (Annex IIA 2.4.1)	19
B.2.1.9	Odour (Annex IIA 2.4.2)	19
B.2.1.10	Spectra of the active substance (Annex IIA 2.5.1)	19
B.2.1.11	Spectra for impurities (Annex IIA 2.5.2)	20
B.2.1.12	Solubility in water (Annex IIA 2.6)	20
B.2.1.13	Solubility in organic solvents (Annex IIA 2.7)	21
B.2.1.14	Partition coefficient n-octanol/water (Annex IIA 2.8)	21
B.2.1.15	Hydrolysis rate at pH 4, 7 and 9 under sterile conditions in the absence of light (Annex IIA 2.9.1)	21
B.2.1.16	Direct phototransformation of purified a.s. in water using artificial light under sterile conditions (Annex IIA 2.9.2)	22
B.2.1.17	Quantum yield of direct phototransformation (Annex IIA 2.9.3)	23
B.2.1.18	Dissociation in water of purified a.s.(Annex IIA 2.9.4)	23
B.2.1.19	Estimated photochemical oxidative degradation (Annex IIA 2.10)	23
B.2.1.20	Flammability (Annex IIA 2.11.1)	24
B.2.1.21	Auto-flammability (Annex IIA 2.11.2)	24
B.2.1.22	Flash point (Annex IIA 2.12)	24
B.2.1.23	Explosive properties (Annex IIA 2.13)	24
B.2.1.24	Surface tension (Annex IIA 2.14)	24
B.2.1.25	Oxidizing properties (Annex IIA 2.15)	25
B.2.2	Physical and chemical properties of the plant protection products (Annex IIIA 2)	26
B.2.2.1	Physical state (Annex IIIA 2.1)	26
B.2.2.2	Colour (Annex IIIA 2.1)	26
B.2.2.3	Odour (Annex IIIA 2.1)	26

B.2.2.4	Explosive properties (Annex IIIA 2.2.1)	26
B.2.2.5	Oxidizing properties (Annex IIIA 2.2.2)	26
B.2.2.6	Flash point (Annex IIIA 2.3)	27
B.2.2.7	Flammability (Annex IIIA 2.3)	27
B.2.2.8	Auto-flammability (Annex IIIA 2.3)	27
B.2.2.9	Acidity or alkalinity and pH value (Annex IIIA 2.4.1)	27
B.2.2.10	pH of a 1 % aqueous dilution, emulsion or dispersion (Annex IIIA 2.4.2)	27
B.2.2.11	Kinematic viscosity (Annex IIIA 2.5.1)	27
B.2.2.12	Viscosity (Annex IIIA 2.5.2)	28
B.2.2.13	Surface tension (Annex IIIA 2.5.3)	28
B.2.2.14	Relative density (Annex IIIA 2.6.1)	29
B.2.2.15	Bulk or tap density (Annex IIIA 2.6.2)	29
B.2.2.16	Stability after storage for 14 days at 54 °C (Annex IIIA 2.7.1)	29
B.2.2.17	Stability after storage for other periods and temperatures (Annex IIIA 2.7.1)	30
B.2.2.18	Minimum content after heat stability testing (Annex IIIA 2.7.1)	30
B.2.2.19	Effect of low temperature on stability (Annex IIIA 2.7.2)	30
B.2.2.20	Shelf life (Annex IIIA 2.7.3)	30
B.2.2.21	Wettability (Annex IIIA 2.8.1)	31
B.2.2.22	Persistent foaming (Annex IIIA 2.8.2)	31
B.2.2.23	Suspensibility (Annex IIIA 2.8.3)	31
B.2.2.24	Spontaneity of dispersion (Annex IIIA 2.8.3)	31
B.2.2.25	Dilution stability (Annex IIIA 2.8.4)	32
B.2.2.26	Dry sieve test and wet sieve test (Annex IIIA 2.8.5)	32
B.2.2.27	Size distribution of particles - Nominal size range of particles (Annex IIIA 2.8.6.1)	32
B.2.2.28	Dust content and particle size of dust (Annex IIIA 2.8.6.2)	32
B.2.2.29	Friability and attrition characteristics of granules (Annex IIIA 2.8.6.3)	32
B.2.2.30	Emulsifiability, emulsion stability and re-emulsifiability (Annex IIIA 2.8.7.1)	33
B.2.2.31	Stability of emulsions (Annex IIIA 2.8.7.2)	33
B.2.2.32	Flowability (Annex IIIA 2.8.8.1)	33
B.2.2.33	Pourability (including rinsed residue) (Annex IIIA 2.8.8.2)	33
B.2.2.34	Dustability following accelerated storage (Annex IIIA 2.8.8.3)	34

B.2.2.35	Physical compatibility of tank mixes (Annex IIIA 2.9.1)	34
B.2.2.36	Chemical compatibility of tank mixes (Annex IIIA 2.9.2)	34
B.2.2.37	Distribution and adhesion (Annex IIIA 2.10)	34
B.2.2	Physical and chemical properties of the plant protection product RIDOMIL GOLD MZ 68 WP (Annex IIIA 2)	35
B.2.2.1	Physical state (Annex IIIA 2.1)	35
B.2.2.2	Colour (Annex IIIA 2.1)	35
B.2.2.3	Odour (Annex IIIA 2.1)	35
B.2.2.4	Explosive properties (Annex IIIA 2.2.1)	35
B.2.2.5	Oxidizing properties (Annex IIIA 2.2.2)	35
B.2.2.6	Flash point (Annex IIIA 2.3)	35
B.2.2.7	Flammability (Annex IIIA 2.3)	36
B.2.2.8	Auto-flammability (Annex IIIA 2.3)	36
B.2.2.9	Acidity or alkalinity and pH value (Annex IIIA 2.4.1)	36
B.2.2.10	pH of a 1 % aqueous dilution, emulsion or dispersion (Annex IIIA 2.4.2)	36
B.2.2.11	Kinematic viscosity (Annex IIIA 2.5.1)	36
B.2.2.12	Viscosity (Annex IIIA 2.5.2)	37
B.2.2.13	Surface tension (Annex IIIA 2.5.3)	37
B.2.2.14	Relative density (Annex IIIA 2.6.1)	37
B.2.2.15	Bulk or tap density (Annex IIIA 2.6.2)	37
B.2.2.16	Stability after storage for 14 days at 54 °C (Annex IIIA 2.7.1)	37
B.2.2.17	Stability after storage for other periods and temperatures (Annex IIIA 2.7.1)	38
B.2.2.18	Minimum content after heat stability testing (Annex IIIA 2.7.1)	38
B.2.2.19	Effect of low temperature on stability (Annex IIIA 2.7.2)	38
B.2.2.20	Shelf life (Annex IIIA 2.7.3)	39
B.2.2.21	Wettability (Annex IIIA 2.8.1)	41
B.2.2.22	Persistent foaming (Annex IIIA 2.8.2)	41
B.2.2.23	Suspensibility (Annex IIIA 2.8.3)	41
B.2.2.24	Spontaneity of dispersion (Annex IIIA 2.8.3)	42
B.2.2.25	Dilution stability (Annex IIIA 2.8.4)	42
B.2.2.26	Dry sieve test and wet sieve test (Annex IIIA 2.8.5)	42
B.2.2.27	Size distribution of particles - Nominal size range of particles (Annex IIIA 2.8.6.1)	42
B.2.2.28	Dust content and particle size of dust (Annex IIIA 2.8.6.2)	42

B.2.2.29	Friability and attrition characteristics of granules (Annex IIIA 2.8.6.3)	43
B.2.2.30	Emulsifiability, emulsion stability and re-emulsifiability (Annex IIIA 2.8.7.1)	43
B.2.2.31	Stability of emulsions (Annex IIIA 2.8.7.2)	43
B.2.2.32	Flowability (Annex IIIA 2.8.8.1)	43
B.2.2.33	Pourability (including rinsed residue) (Annex IIIA 2.8.8.2)	43
B.2.2.34	Dustability following accelerated storage (Annex IIIA 2.8.8.3)	44
B.2.2.35	Physical compatibility of tank mixes (Annex IIIA 2.9.1)	44
B.2.2.36	Chemical compatibility of tank mixes (Annex IIIA 2.9.2)	44
B.2.2.37	Distribution and adhesion (Annex IIIA 2.10)	44
B.2.3	References relied on	45
B.3	Data on application and further information	53
B.3.1	Data on application relevant to the active substance (Annex IIA 3.1 to 3.6)	55
B.3.1.1	Function (Annex IIA 3.1)	55
B.3.1.2	Effects on harmful organisms (Annex IIA 3.2.1)	55
B.3.1.3	Translocation in plants (Annex IIA 3.2.2)	55
B.3.1.4	Fields of use (Annex IIA 3.3)	55
B.3.1.5	Harmful organisms controlled and crops protected (Annex IIA 3.4.1, 3.4.2)	55
B.3.1.6	Effects achieved - mode of action (Annex IIA 3.4.3, 3.5.1)	56
B.3.1.7	Information relative to the formation of active metabolites and degradation products (Annex IIA 3.5.2, 3.5.3)	56
B.3.1.8	Information to the possible occurrence of the development of resistance or cross-resistance (Annex IIA 3.6)	57
B.3.2	Data on application relevant to the plant protection product (Annex IIIA 3)	57
B.3.2.1	Fields of uses (Annex IIIA 3.1)	57
B.3.2.2	Nature of the effects on harmful organisms (Annex IIIA 3.2)	57
B.3.2.3	Pests controlled and crops protected (Annex IIIA 3.3)	57
	Rate of application (Annex IIIA 3.4)	57
	Concentration of active substance in material used (Annex IIIA 3.5)	57
	Description of the method of application, type of equipment used and type and volume of diluent per unit of area or volume (Annex IIIA 3.6)	57
	Number and timing of applications and duration of protection afforded and their timing (Annex IIIA 3.7)	57
B.3.2.4	Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops - Limitations on choice of succeeding crops (Annex IIIA 3.8)	64

B.3.2.5	Proposed instructions for use as printed, or to be printed, on labels (Document C)	65
B.3.3	Summary of data on application	65
B.3.4	Further information on the active substance (Annex IIA 3.7 to 3.9)	65
B.3.4.1	Recommended methods and precautions relating to handling, warehouse storage, user level storage, transport, fire (Annex IIA 3.7)	65
B.3.4.2	Procedures for destruction or decontamination of the active substance	66
B.3.4.2.1	Controlled incineration - Pyrolitic behaviour under controlled conditions at 800°C (Annex IIA 3.8.1)	66
B.3.4.2.2	Methods other than controlled incineration for disposal of the active substance, contaminated packaging and contaminated materials (Annex IIA 3.8.2)	66
B.3.4.3	Methods for decontamination of water in the case of accident (Annex IIA 3.9)	66
B.3.5	Further infomation on the plant protection products RIDOMIL GOLD 480 EC and RIDOMIL GOLD MZ 68 WP (Annex IIIA 4)	67
B.3.5.1	Packagings, suitability of the packaging material to its content (Annex IIIA 4.1)	67
B.3.5.1.1	Description and specification of the packaging : materials used,manner of construction, size, capacity, size of openings, types of closure and seal (Annex IIIA 4.1.1)	67
B.3.5.1.2	Suitability of the packaging and closures (Annex IIIA 4.1.2)	69
B.3.5.1.3	Resistance of the packaging material to its contents (Annex IIIA 4.1.3)	69
B.3.5.2	Procedures for cleaning application equipment and protective clothing (Annex IIIA 4.2)	69
B.3.5.3	Re-entry intervals, waiting periods and other precautions to protect man, livestock and the environment	70
B.3.5.3.1	Pre-harvest intervals, re-entry periods or withholding periods to minimize residues in crops, plants, plant products, treated areas or spaces (Annex IIIA 4.3.1)	70
B.3.5.3.2	Information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used (Annex IIIA 4.3.2)	70
B.3.5.4	Recommended methods and precautions concerning handling procedures to minimize the risks relating to warehouse storage, user level storage, transport, fire - Detailed procedures for use in the event of an accident during transport, storage or use (Annex IIIA 4.4 and 4.5)	71
B.3.5.5	Procedures for destruction or decontamination of the formulation and its packaging	73
B.3.5.5.1	Neutralization procedures for use in the event of accidental spillages (Annex IIIA 4.6.1)	73
B.3.5.5.2	Contolled incineration - Pyrolytic behaviour of the formulation under controlled conditions at 800° C (Annex IIIA 4.6.2)	73

B.3.5.5.3	Methods other than controlled incineration for disposal of the plant protection product, contaminated packaging and contaminated materials (Annex IIIA 4.6.3)	73
B.3.6	References relied on	74
	Appendix A : Authorizations - Registrations	77
	Appendix B : Material Safety Data Sheets	81
B.4	Methods of analysis	85
B.4.1	Analytical methods for formulation analysis	87
B.4.1.1	Analytical methods for the determination of pure active substance in the active substance as manufactured (Annex IIA 4.1.1)	87
B.4.1.2	Analytical methods for the determination of isomers, impurities and additives in the active substance as manufactured (Annex IIA 4.1.2)	87
B.4.1.3	Analytical methods for the determination of pure active substance in plant protection products (Annex IIIA 5.1.1)	90
B.4.1.3.1	Determination of pure active substance in formulation A-9408 B	90
B.4.1.3.2	Determination of pure active substance in formulation A-9407 B	91
B.4.1.3.3	Determination of enantiomeric purity of the a.s. in formulations	91
B.4.1.4	Analytical methods for the determination of isomers, impurities, additives and formulants in plant protection products (Annex IIIA 5.1.2)	92
B.4.2	Analytical methods for determination of residues	93
B.4.2.1	Analytical methods (residue) for food and feed (Annex IIA 4.2.1; Annex IIIA 5.2.1)	93
B.4.2.1.1	Analytical methods (residue) for target crops	93
B.4.2.1.1.1	Residue methods for analyzing parent compound in target crops	93
B.4.2.1.1.2	Residue methods for analyzing total residues (parent compound + metabolites containing the 2,6-dimethylaniline moeity) in target crops	99
B.4.2.1.2	Analytical methods (residue) for food of animal origin	104
B.4.2.2	Analytical methods (residue) in soil, water, air (Annex IIA 4.2.2 to 4.2.4; Annex IIIA 5.2.2 to 5.2.4)	107
B.4.2.2.1	Analytical methods for soil (Annex IIA 4.2.2; Annex IIIA 5.2.2)	107
B.4.2.2.2	Analytical methods for water (Annex IIA 4.2.3; Annex IIIA 5.2.3)	109
B.4.2.2.3	Analytical methods for air (Annex IIA 4.2.4; Annex IIIA 5.2.4)	112
B.4.2.3	Analytical methods (residue) wildlife and for use in support of diagnostic and therapeutic regimes (Annex IIA 4.2.5; Annex IIIA 5.2.5)	113
B.4.3	Evaluation and assessment	114
B.4.3.1	Evaluation and assessment of analytical methods for technical active	114

	substance and formulation analysis	
B.4.3.2	Evaluation and assessment of analytical methods for determination of residues	114
B.4.3.2.1	Analytical methods (residue) for food and feed	115
B.4.3.2.2	Analytical methods (residue) in soil, water and air	118
B.4.3.2.3	Analytical methods (residue) wildlife and for use in support of diagnostic and therapeutic regimes	119
B.4.4	References relied on	120
B.5	Toxicology and metabolism	127
B.5.1	Absorption, distribution, excretion and metabolism in rats (toxicokinetics) (Annex IIA 5.1)	129
B.5.2	Acute toxicity including irritancy and skin sensitization (Annex IIA 5.2)	149
B.5.2.1	Acute oral toxicity (Annex IIA 5.2.1)	149
B.5.2.2	Acute percutaneous toxicity (Annex IIA 5.2.2)	149
B.5.2.3	Acute inhalation toxicity (Annex IIA 5.2.3)	150
B.5.2.4	Skin irritation (Annex IIA 5.2.4)	150
B.5.2.5	Eye irritation (Annex IIA 5.2.5)	151
B.5.2.6	Skin sensitization (Annex IIA 5.2.6)	152
B.5.2.7	Summary of acute toxicity (Annex IIA 5.2)	154
B.5.3	Short-term toxicity (Annex IIA 5.3)	155
B.5.3.1	Oral 28-day toxicity (Annex IIA 5.3.1)	155
B.5.3.2.1	Oral 90-day toxicity (rat) (Annex IIA 5.3.2)	157
B.5.3.2.2	Oral 90-day toxicity (dog) (Annex IIA 5.3.2)	161
B.5.3.2.3	Oral 2 year toxicity (dog) (Annex IIA 5.3.2)	164
B.5.3.3.1	28-day inhalation toxicity (rat) (Annex IIA 5.3.3)	166
B.5.3.3.2	90-day inhalation toxicity (rat) (Annex IIA 5.3.3)	166
B.5.3.3.3	Percutaneous 21-day toxicity (rat) (Annex IIA 5.3.3)	167
B.5.3.3.4	90-day dermal toxicity (rat) (Annex IIA 5.3.3)	168
B.5.3.3.5	Summary of the short-term toxicity studies of Ziram (Annex IIA 5.3.3)	169
B.5.4	Genotoxicity (Annex IIA 5.4)	170
B.5.4.1	*In vitro* genotoxicity testing (Annex IIA 5.4.1)	170
B.5.4.1.1	Gene mutation test in bacterial cells (Annex IIA 5.4.1)	170
B.5.4.1.2	Gene mutation test in mammalian cells (Annex IIA 5.4.1)	171
B.5.4.1.3	*In vitro* chromosome aberration assay (Annex IIA 5.4.1)	171
B.5.4.1.4	*In vitro* unscheduled DNA synthesis in mammalian cells (Annex IIA 5.4.1)	174

B.5.4.1.5	Assay for other effects on the genetic material (Annex IIA 5.4.1)	175
B.5.4.2	*In vivo* genotoxicity testing (somatic cells) (Annex IIA 5.4.2)	175
B.5.4.2.1	*In vivo* mammalian bone-marrow micronucleus test (Annex IIA 5.4.2)	175
B.5.4.3	*In vivo* studies in germ cells (Annex IIA 5.4.3)	177
B.5.4.3.1	Cytogenetic assay in germ-cells (Annex IIA 5.4.3)	177
B.5.4.4	Summary of genotoxicity (Annex IIA 5.4)	178
B.5.5	Long-term toxicity and carcinogenicity (Annex IIA 5.5)	180
B.5.5.1	Long-term (2 years) oral toxicity in the rat (Annex IIA 5.5)	180
B.5.5.2	Carcinogenicity study in the rat (Annex IIA 5.5)	183
B.5.5.3	Carcinogenicity study in the mouse (Annex IIA 5.5)	184
B.5.5.4	Mechanism of action and supporting data (Annex IIA 5.5)	185
B.5.5.5	Summary of long-term oral toxicity (Annex IIA 5.5)	187
B.5.6	Reproductive toxicity (Annex IIA 5.6)	188
B.5.6.1.1	Three generation reproductive toxicity in the rat (Annex IIA 5.6.1)	188
B.5.6.1.2	Supplementary studies (Annex IIA 5.6.1)	191
B.5.6.2.1	Teratogenicity test by the oral route in the rat (Annex IIA 5.6.2)	191
B.5.6.2.2	Teratogenicity test by the oral route in the rabbit (Annex IIA 5.6.2)	195
B.5.6.3	Summary of reproductive and development toxicity	197
B.5.7	Delayed neurotoxicity (Annex IIA 5.7)	198
B.5.8	Further toxicological studies (Annex IIA 5.8)	198
B.5.8.1	Toxicity studies on metabolites (Annex IIA 5.8.1)	200
B.5.8.1.1	Acute oral toxicity (Annex IIA 5.8.1)	200
B.5.8.1.2	Acute dermal toxicity (Annex IIA 5.8.1)	201
B.5.8.1.3	Oral 28-day toxicity (Annex IIA 5.8.1)	202
B.5.8.1.4	Genotoxicity (Annex IIA 5.8.1)	204
B.5.8.2	Additional studies (Annex IIA 5.8.2)	205
B.5.8.3	Summary of toxicity studies on metabolites and supplementary studies (Annex IIA 5.8)	206
B.5.9	Medical data (Annex IIA 5.9)	208
B.5.9.1	Report on medical surveillance on manufacturing plant personnel (Annex IIA 5.9.1)	208
B.5.9.2	Report on clinical cases and poisoning incidents (Annex IIA 5.9.2)	208
B.5.9.3	Observations on exposure of the general population and epidemiological studies (Annex IIA 5.9.3)	208

B.5.9.4	Clinical signs and symptoms of poisoning and details of clinical tests (Annex IIA 5.9.5)	208
B.5.9.5	First aid measures - Therapeutic regimes (Annex IIA 5.9.5)	208
B.5.9.6.1	Expected effects and duration of poisoning as a function of the type, level and duration of exposure or ingestion (Annex IIA 5.9.6)	208
B.5.9.6.2	Expected effects and duration of poisoning as a function of varying time periods between exposure or ingestion and commencement of treatment (Annex IIA 5.9.6)	208
B.5.10	Summary of mammalian toxicology and proposed ADI, AOEL and drinking water limit (Annex IIA 5.10)	209
B.5.10.1	Establishment of an AcceptableDaily Intake (ADI)	211
B.5.10.2	Establishment of an Acceptable Operator Exposure Level (AOEL)	212
B.5.10.3	Establishment of the drinking water limit	212
B.5.11.a	Acute toxicity including irritancy and skin sensitization of the preparation RIDOMIL GOLD 480 EC (Annex IIIA 7.1)	213
B.5.11.1.a	Acute oral toxicity (Annex IIIA 7.1.1.1)	213
B.5.11.2.a	Acute percutaneous toxicity (Annex IIIA 7.1.2)	213
B.5.11.3.a	Acute inhalation toxicity to rats (Annex IIIA 7.1.3)	214
B.5.11.4.a	Skin irritation (Annex IIIA 7.1.4)	214
B.5.11.5.a	Eye Irritation (Annex IIIA 7.1.5)	214
B.5.11.6.a	Skin sensitization (Annex IIIA 7.1.6)	215
B.5.11.7.a	Additional studies for combinations of plant protection products (tests as at points 7.1.1 to 7.1.6) (Annex IIIA 7.1.7)	215
B.5.12.1.a	Dermal absorption, *in vivo* in the rat (Annex IIIA 7.3)	215
B.5.12.2.a	Comparative dermal absorption, in vitro using rat and human skin (Annex IIIA 7.3)	217
B.5.13.a	Toxicological data on non active substances (Annex IIIA 7.4 and point 4 of the introduction)	219
B.5.14.a	Summary of toxicity of the formulation RIDOMIL GOLD 480 EC	219
B.5.15.a	Exposure data (Annex IIIA 7.2)	220
B.5.15.1.a	Estimation of operator exposure (Annex IIIA 7.2.1.1)	220
B.5.15.2.a	Measurement of operator exposure (Annex IIIA 7.2.1.2)	222
B.5.15.3.a	Estimation of bystander exposure (Annex IIIA 7.2.2)	222
B.5.15.4.a	Estimation of worker exposure (Annex IIIA 7.2.3.1)	222
B.5.15.5.a	Measurement of worker exposure (Annex IIIA 7.2.3.2)	222
B.5.11.b	Acute toxicity including irritancy and skin sensitization of the preparations (Annex IIIA 7.1)	223
B.5.11.1.b	Acute oral toxicity (Annex IIIA 7.1.1.1)	223

B.5.11.2.b	Acute percutaneous toxicity (Annex IIIA 7.1.2)	223
B.5.11.3.b	Acute inhalation toxicity to rats (Annex IIIA 7.1.3)	224
B.5.11.4.b	Skin irritation (Annex IIIA 7.1.4)	224
B.5.11.5.b	Eye Irritation (Annex IIIA 7.1.5)	225
B.5.11.6.b	Skin sensitization (Annex IIIA 7.1.6)	225
B.5.11.7.b	Additional studies for combinations of plant protection products (tests as at points 7.1.1 to 7.1.6) (Annex IIIA 7.1.7)	225
B.5.12.1.b	Dermal absorption, *in vivo* in the rat (Annex IIIA 7.3)	225
B.5.12.2.b	Comparative dermal absorption, in vitro using rat and human skin (Annex IIIA 7.3)	226
B.5.13.b	Toxicological data on non active substances (Annex IIIA 7.4 and point 4 of the introduction)	226
B.5.14.b	Summary of toxicity of the formulation RIDOMIL GOLD MZ 68 WP	226
B.5.15.b	Exposure data (Annex IIIA 7.2)	227
B.5.15.1.b	Estimation of operator exposure (Annex IIIA 7.2.1.1)	227
B.5.15.2.b	Measurement of operator exposure (Annex IIIA 7.2.1.2)	229
B.5.15.3.b	Estimation of bystander exposure (Annex IIIA 7.2.2)	229
B.5.15.4.b	Estimation of worker exposure (Annex IIIA 7.2.3.1)	230
B.5.15.5.b	Measurement of worker exposure (Annex IIIA 7.2.3.2)	230
B.5.16	References relied on	231
	Appendix C : Estimation of the operator exposure	243
B.6	Residue data	261
B.6.1	Metabolism, distribution and expression of residues in plants (Annex IIA 6.1)	264
B.6.1.1	Metabolism, distribution and expression of residues of metalaxyl in grapevine	264
B.6.1.2	Metabolism, distribution and expression of residues of metalaxyl in lettuce	265
B.6.1.3	Metabolism, distribution and expression of residues of metalaxyl in potato plants	267
B.6.1.4	Metabolism, distribution and expression of residues of metalaxyl in potato plants	268
B.6.1.5	Metabolism, distribution and expression of residues of metalaxyl in potato plants	270
B.6.1.6	Metabolism, distribution and expression of residues of metalaxyl in tobacco plants	270

B.6.2	Metabolism, distribution and expression of residues in livestock (Annex IIA 6.2)	275
B.6.2.1	Metabolism, distribution and expression of residues in lactating cows or goats	275
B.6.2.2	Metabolism, distribution and expression of residues of metalaxyl in hens	278
B.6.2.3	Metabolism, distribution and expression of residues in pigs	283
B.6.3	Definition of the residue	284
B.6.4	Use pattern	285
B.6.5	Identification of critical GAPs	291
B.6.6	Residues resulting from supervised trials (Annex IIA 6.3; Annex IIIA 8.1)	293
B.6.6.1	Grapefruit	293
B.6.6.2	Lemons	293
B.6.6.3	Mandarins (including clementines)	293
B.6.6.4	Oranges	294
B.6.6.5	Apple	295
B.6.6.6	Pear	295
B.6.6.7	Apricot	295
B.6.6.8	Cherries	296
B.6.6.9	Peaches (including nectarines)	296
B.6.6.10	Table and wine grapes	297
B.6.6.11	Strawberries	299
B.6.6.12	Avocados	299
B.6.6.13	Kiwi fruit	299
B.6.6.14	Sugarbeet	300
B.6.6.15	Carrots	300
B.6.6.16	Bulb vegetables (garlic-onions-shallots-other)	301
B.6.6.17	Tomatoes	302
B.6.6.18	Sweet peppers	304
B.6.6.19	Cucumber	304
B.6.6.20	Melon	305
B.6.6.21	Watermelon	306
B.6.6.22	Broccoli	306
B.6.6.23	Cauliflower	307
B.6.6.24	Brussels sprouts	307

B.6.6.25	Head cabbage	308
B.6.6.26	Lettuce	308
B.6.6.27	Spinach	310
B.6.6.28	Beans (with pods)	311
B.6.6.29	Peas (with or without pods)	311
B.6.6.30	Globe artichoke	312
B.6.6.31	Leek	312
B.6.6.32	Peas (pulses)	313
B.6.6.33	Sunflower seed	313
B.6.6.34	Rapeseed	213
B.6.6.35	Soybean	313
B.6.6.36	Potato	314
B.6.6.37	Hop	315
B.6.6.38	Maize	316
B.6.6.39	Rice	316
B.6.6.40	Wheat	316
B.6.6.41	Tobacco	316
B.6.7	Effects of industrial processing and/or household preparation on the residue (Annex IIA 6.5; Annex IIIA 8.4)	318
B.6.7.1	Effects on the nature of the residues	318
B.6.7.2	Effects on the level of residues	318
B.6.8	Livestock feeding studies (Annex IIA 6.4; Annex IIIA 8.3)	318
B.6.8.1	Livestock feeding studies in lactating cows or goats	318
B.6.8.2	Livestock feeding studies in poultry	319
B.6.8.3	Livestock feeding studies in pigs	320
B.6.9	Residues in succeeding or rotational crops (Annex IIA 6.6; Annex IIIA 8.5)	321
B.6.10	Proposed pre-harvest intervals, re-entry intervals or withholding periods to minimize residues in crops, plants, plant products, treated areas or spaces (Annex IIA 6.8; Annex IIIA 8.7)	328
B.6.11	Estimates of the potential and actual exposure through diet and other means (Annex IIA 6.9; Annex IIIA 8.8)	329
B.6.12	Community MRLs and MRLs in EU Member States (Document E-4)	332
B.6.13	Proposed MRLs and justification and for the acceptability of those residues (Annex IIA 6.7; Annex IIIA 8.6)	332
B.6.14	Storage stability of residue samples	334

B.6.15	Summary and evaluation of residue behaviour	337
B.6.16	References relied on	338
	Appendix D : Metabolic pathways in animals and plants	447
	Appendix E : Chemical names of synthetic reference compounds	453
	Appendix F : Residue data from supervised trials	459
B.7	Environmental fate and behaviour	463
B.7.1	Route and rate of degradation in soil (Annex IIA 7.1.1; Annex IIIA 9.1.1)	465
B.7.1.1	Route of degradation (Annex IIA 7.1.1.1)	465
B.7.1.1.1	Aerobic degradation in soil (Annex IIA 7.1.1.1.1)	465
B.7.1.1.2	Anaerobic degradation in soil (Annex IIA 7.1.1.1.2)	484
B.7.1.1.3	Soil photolysis (Annex IIA 7.1.1.1.2)	485
B.7.1.2	Rate of degradation (Annex IIA 7.1.1.2.1; Annex IIIA 9.1.1.1.1)	486
B.7.1.2.1	Aerobic degradation	486
B.7.1.2.2	Anaerobic degradation	486
B.7.1.3	Field studies (Annex IIA 7.1.1.2.2; Annex IIIA 9.1.1.2)	487
B.7.1.3.1	Soil dissipation testing	487
B.7.1.3.2	Soil residue testing - soil accumulation testing	487
B.7.2	Adsorption, desorption and mobility in soil (Annex IIA 7.1.2 and 7.1.3; Annex IIIA 9.1.2)	488
B.7.2.1	Adsorption and desorption of the active substance and relevant metabolites (Annex IIA 7.1.2)	488
B.7.2.2	Column leaching studies with the active substance and relevant metabolites (Annex IIA 7.1.3.1; Annex IIIA 9.1.2.1)	495
B.7.2.3	Aged residue column leaching (Annex IIA 7.1.3.2; Annex IIIA 9.1.2.1)	496
B.7.2.4	Lysimeter and field leaching studies (Annex IIA 7.1.3.3; Annex IIIA 9.1.2.2)	500
B.7.2.5	Monitoring data (Annex IIA 7.4)	507
B.7.3	Summary of behaviour in soil and predicted environmental concentration in soil (PECs) (Annex IIIA 9.1.3)	513
B.7.4	Fate and behaviour in water (Annex IIA 7.2.1; Annex IIIA 9.2)	527
B.7.4.1	Hydrolysis rate of relevant metabolites, degradation and reaction products (Annex IIA 7.2.1.1)	527
B.7.4.2	Direct phototransformation of relevant metabolites, degradation and reaction products in water (Annex IIA 7.2.1.2)	527

B.7.4.3	Ready biodegradability of the active substance (Annex IIA 7.2.1.3.1)	527
B.7.4.4	Water/sediment study (Annex IIA 7.2.1.3.2)	528
B.7.4.5	Degradation in the saturated zone of active substance, metabolites, degradation and reaction products (Annex IIA 7.2.1.4)	533
B.7.5	Impact on water treatment procedures (Annex IIIA 9.2.2)	533
B.7.6	Summary of behaviour in water and predicted environmental concentrations in surface water and in ground water (PECsw, PECgw) (Annex IIIA 9.2.1, 9.2.3)	534
B.7.7	Fate and behaviour in air (Annex IIA 7.2.2; Annex IIIA 9.3)	544
B.7.8	Summary of behaviour in air and predicted environmental concentrations in air (PECa) (Annex IIIA 9.3)	545
B.7.9	Definition of the residue (Annex IIA 7.3)	546
B.7.10	References relied on	547
	Appendix G :	559
	Soil dissipation testing (metalaxyl) Soil residue testing - soil accumulation testing (metalaxyl) Water monitoring data (metalaxyl)	
B.8	Ecotoxicology	699
B.8.1	Effects on birds (Annex IIA 8.1; Annex IIIA 10.1)	701
B.8.1.1	Acute oral toxicity (Annex IIA 8.1.1)	701
B.8.1.2	Avian dietary toxicity (5day) (Annex IIA 8.1.2)	702
B.8.1.3	Subchronic and reproductive toxicity (Annex IIA 8.1.3)	704
B.8.1.4	Acute oral toxicity of the preparations (Annex IIIA 10.1.1)	706
B.8.1.5	Supervised cage or field trials (Annex IIIA 10.1.2)	706
B.8.1.6	Acceptance of bait, granules or treated seeds by birds (palatability test) (Annex IIIA 10.1.3)	707
B.8.1.7	Effects of secondary poisoning (Annex IIIA 10.1.4)	707
B.8.1.8	Summary of effects to birds - exposure and risk assessment for birds (Annex IIIA 10.1)	708
B.8.2	Effects on aquatic organisms (fish, aquatic invertebrates, algae) (Annex IIA 8.2; Annex IIIA 10.2)	710
B.8.2.1	Acute toxicity of the active substance and metabolites, degradation or reaction products to fish (Annex IIA 8.2.1)	710
B.8.2.2	Chronic toxicity to fish (Annex IIA 8.2.2)	716
B.8.2.3	Bioaccumulation potential in fish (Annex IIA 8.2.3)	717
B.8.2.4	Acute toxicity to invertebrates (Annex IIA 8.2.4)	718

B.8.2.5	Chronic toxicity to aquatic invertebrates (Annex IIA 8.2.5)	723
B.8.2.6	Effects on algal growth (Annex IIA 8.2.6)	724
B.8.2.7	Effects on the organisms of the sediments (Annex IIA 8.2.7)	727
B.8.2.8	Effects on aquatic plants (Annex IIA 8.2.8)	727
B.8.2.9	Acute toxicity of the preparations (Annex IIIA 10.2.1)	727
B.8.2.10	Microcosm and mesocosm study (Annex IIIA 10.2.2)	727
B.8.2.11	Residue data in fish (Annex IIIA 10.2.3)	727
B.8.2.12	Supplementary studies of toxicity to fish and aquatic invertebrates (Annex IIIA 10.2.4)	727
B.8.2.13	Summary of effects to water organisms	728
B.8.2.14	Exposure and risk assessment for aquatic organisms (Annex IIIA 10.2)	731
B.8.3	Effects on other terrestrial vertebrates (Annex IIIA 10.3.1)	732
B.8.4	Effects on bees (Annex IIA 8.3.1; Annex IIIA 10.3.2)	734
B.8.4.1	Acute toxicity to bees (Annex IIA 8.3.1.1)	734
B.8.4.2	Bee brood feeding test (Annex IIA 8.3.1.2)	734
B.8.4.3	Acute toxicity of the preparations to bees (Annex IIIA 10.4.1)	735
B.8.4.4	Effects on bees of residues on crops (Annex IIIA 10.4.2)	735
B.8.4.5	Cage tests (Annex IIIA 10.4.3)	735
B.8.4.6	Field tests to investigate special effects (Annex IIIA 10.4.4)	735
B.8.4.7	Tunnel testing to investigate effects of feeding on contaminated honey (Annex IIIA 10.4.5)	735
B.8.4.8	Exposure and risk assessment for bees (Annex IIIA 10.4)	736
B.8.5	Effects on other arthropods species (Annex IIA 8.3.2; Annex IIIA 10.5)	738
B.8.5.1	Effects of the active substance on non-target terrestrial arthropods (Annex IIA 8.3.2)	738
B.8.5.2	Summary of effects, exposure and risk assessment for non-target terrestrial arthropods	741
B.8.6	Effects on earthworms (Annex IIA 8.4; Annex IIIA 10.3.6)	742
B.8.6.1	Acute toxicity to earthworms (Annex IIA 8.4.1)	742
B.8.6.2	Sublethal effects on earthworms (Annex IIA 8.4.2)	743
B.8.6.3	Acute toxicity of the formulations to earthworms (Annex IIIA 10.6.1.1)	743
B.8.6.4	Sublethal effects of the formulation on earthworms (Annex IIIA 10.6.1.2)	743
B.8.6.5	Field tests - residue content of earthworms (Annex IIIA 10.6.1.3)	743
B.8.6.6	Summary and risk assessment for earthworms (Annex IIIA 10.6.1.1)	743
B.8.7	Effects on other soil non-target macro-organisms (Annex IIIA 10.6.2)	744

B.8.8	Effects on soil non-target micro-organisms (Annex IIA 8.5; Annex IIIA 10.7)	744
B.8.8.1	Impact of the active substance on soil microbial activity (Annex IIA 8.5)	744
B.8.8.2	Impact of the formulations on soil microbial activity (laboratory) (Annex IIIA 10.7.1)	746
B.8.8.3	Further laboratory, glasshouse of field testing to investigate impact on soil microbial activity (Annex IIIA 10.7.2)	746
B.8.8.4	Summary of studies on non-target micro-organisms - exposure and risk assessment for non-target micro-organisms	746
B.8.9	Effects on other non-target organisms (flora and fauna) believed to be at risk (Annex IIA 8.6; Annex IIIA 10.8)	746
B.8.10	Effects on biological methods of sewage treatment (Annex IIA 8.7)	746
B.8.11	References relied on	748
B.9	Proposals for classification and labelling	759
B.9.1	Proposals for the classification and labelling of the active substance (Annex IIA 10)	761
B.9.2	Proposals for the classification and labelling of the formulations (Annex IIIA 12.3)	762

	Appendix H : Standard terms and abbreviations	765
	Appendix I : Preparation (Formulation) types and codes	777