Part 3 Evaluation Form 3 -
for use in checking that all test and study reports required in accordance with Annex IIA have been provided

Active Substance: Applicant: Date:

OECD Annex IIA point	EC Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
1	1	Identity of the active substance				
1.1	1.1	Applicant (name, address, contact, telephone and telefax numbers)				☐
1.2	1.2	Manufacturer(s) (name, address, contact, telephone and telefax numbers)				☐
1.3	1.3	ISO common name proposed or accepted, and synonyms				☐
1.4	1.4	Chemical name as in Annex I to Directive 67/548/EEC, if not included in that Annex, in accordance with IUPAC and CA, nomenclature				☐
1.5	1.5	Manufacturer's codes, names and patent status.				☐
1.5.1	1.5	Manufacturer's code number(s), for the active substance and formulations, materials concerned, countries in which used and periods for which used				☐
1.5.2	#	Trade name(s)				☐
1.5.3	#	Patent status				☐
1.6	1.6	Existing CAS, CIPAC, EINECS and ELINCS numbers				☐
1.7	1.7	Molecular formula, molecular mass and structural formula				☐
1.8	1.8	Method of manufacture				☐
1.8.1	1.8	Method of manufacture (pathways, by-products and impurities) for each plant, whether or not relevant to a pilot plant				☐
1.8.2	1.8	Description of starting materials				☐
1.9	1.9	Specification of purity of the active substance				☐
1.9.1	1.9 (first part)	Minimum and/or nominal content (g/kg) of pure active substance (excluding inactive isomers), whether or not relevant to a pilot plant				☐
1.9.1.1	1.9	Minimum content (g/kg) of pure active substance (excluding inactive isomers), whether or not relevant to a pilot plant				☐
1.9.1.2	#	Nominal content (g/kg) of pure active substance (excluding inactive isomers), whether or not relevant to a pilot plant				☐
1.9.2	#	Certified limits of the active substances				☐
1.9.3	#	Control product specification form or confidential statement of formula				☐
1.10	1.10	Identity, content and structural formula of isomers, impurities and additives				
1.10.1	1.10	Inactive isomers – For each isomer:				
1.10.1.a	1.10.a	- IUPAC and CA names				☐
1.10.1.b	1.10.b	- ISO common name proposed or accepted				☐
1.10.1.c	1.10.c	- CAS, CIPAC, EINECS and ELINCS numbers				☐
1.10.1.d	1.10.d	- molecular and structural formula				☐
1.10.1.e	1.10.e	- molecular mass				☐
1.10.1.f	1.10.f	- ratio of the content of isomers/diastereo-isomers				☐
1.10.1.g	1.10.g	- maximum content in g/kg				☐
1.10.1.h	1.10.h	- whether or not relevant to a pilot plant				☐
1.10.2	1.10	Impurities and additives				

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1.10.2.a	1.10.i	- IUPAC and CA names				☐
1.10.2.b	1.10.j	- ISO common name proposed or accepted				☐
1.10.2.c	1.10.k	- CAS, CIPAC, EINECS and ELINCS numbers				☐
1.10.2.d	1.10.l	- molecular and structural formula				☐
1.10.2.e	1.10.m	- molecular mass				☐
1.10.2.f	1.10.n	- maximum content in g/kg				☐
1.10.2.g	1.10.o	- whether or not relevant to a pilot plant				☐
1.10.2.h	1.10.p	- in the case of additives, their function and trade names				☐
1.10.2.i	1.10.q	- in the case of impurities and by-products of particular environmental concern, details of the analytical methods				☐
1.10.2.j	1.10	- guidance in identifying impurities of toxicological concern				☐
1.11	1.11	Batch analysis data				
1.11.1	1.11.a	Analytical profile of batches				☐
1.11.2	1.11.b	Results of analyses of batches produced in laboratory or pilot scale production systems and used in toxicological testing				☐
1.12	1 *	Other/special studies				☐
2	2	Physcial and chemical properties of the active substance				
2.1	2.1	Melting point and boiling point				
2.1.1	2.1.1	Melting point, freezing point or solidification point of purified active substance				☐
2.1.2	2.1.2	Boiling point of purified active substance				☐
2.1.3	2.1.3	Temperature at which decomposition or sublimation occurs				☐
2.2	2.2	Relative density of purified active substance				☐
2.3	2.3	Vapour pressure and volatility				
2.3.1	2.3.1	Vapour pressure of purified active substance				☐
2.3.2	2.3.2	Henry's law constant				☐
2.4	2.4	Appearance				
2.4.1	2.4.1	Description of the physical state and colour of both the purified active substance and active substance as manufactured (or technical grade active substance)				☐
2.4.2	2.4.2	Description of the odour of the purified active substance and active substance as manufactured				☐
2.5	2.5	Spectra and molecular extinction at relevant wavelengths				
2.5.1	2.5.1	Spectra, a table of signal characteristics and molecular extinction at relevant wavelengths for purified active substance				
2.5.1.1	2.5.1.a	UV/VIS				☐
2.5.1.2	2.5.1.b	IR				☐
2.5.1.3	2.5.1.c	NMR				☐
2.5.1.4	2.5.1.d	MS				☐
2.5.1.5	2.5.1.e	Wavelengths at which UV/VIS molecular extinction occurs, where appropriate, to include a wavelength at the highest absorption above 290 nm				☐
2.5.1.6	2.5.1.f	Optical purity				☐

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2.5.2	2.5.2	Spectra for impurities				
2.5.2.1	2.5.2.a	UV/VIS				☐
2.5.2.2	2.5.2.b	IR				☐
2.5.2.3	2.5.2.c	NMR				☐
2.5.2.4	2.5.2.d	MS				☐
2.6.	2.6.	Solubility of purified active substance in water				☐
2.6.a	2.6.a	- determined in the neutral range				☐
2.6.b	2.6.b	- determined in the acidic range (pH 4 to 6)				
2.6.c	2.6.b	- determined in the alkaline range (pH 8 to 10)				☐
2.7	2.7	Solubility in organic solvents at 15 to 25° C				☐
2.8	2.8	Partition coefficient				
2.8.1	2.8.a	n-octanol/water partition coefficient				☐
2.8.2	2.8.b	Effect of pH (4 to 10) on the n-octanol/water partition coefficient				☐
2.9	2.9	Stability in water, hydrolysis rate, photochemical degradation, quantum yield and identity of breakdown products, dissociation constant				
2.9.1	2.9.1	Hydrolysis rate of purified active substance at pH values 4, 7 and 9 under sterile conditions, in the absence of light				
2.9.1.a	2.9.1.a	- identity of hydrolysis products				☐
2.9.1.b	2.9.1.b	- rate constant observed				☐
2.9.1.c	2.9.1.c	- estimated DT_{50} value				☐
2.9.2	2.9.2	Direct phototransformation of purified active substance in water using artificial light (simulating sunlight and excluding wavelengths $\lambda < 290$ nm) under sterile conditions, to include				
2.9.2.a	2.9.2.a	- photochemical half-life				☐
2.9.2.b	2.9.2.b	- mass balance to account for 90 % of the applied radioactivity				☐
2.9.2.c	2.9.2.c	- identity of breakdown products				☐
2.9.3	2.9.3.a	Quantum yield of direct phototransformation				☐
2.9.4	2.9.3.b	Calculated theoretical lifetime in the top layer of aqueous systems and the real lifetime of the active substance				☐
2.9.5	2.9.4	Dissociation in water of purified active substance				
2.9.5.a	2.9.4.a	- dissociation constant(s) (pKa values)				☐
2.9.5.b	2.9.4.b	- identity of dissociated species formed				☐
2.9.5.c	2.9.4.c	- dissociation constant(s) (pKa values) of the active principle				☐
2.10	2.10	Estimated photochemical oxidative degradation				☐
2.11	2.11	Flammability including auto-flammability				
2.11.1	2.11.1	Flammability of the active substance as manufactured				☐
2.11.2	2.11.2	Auto-flammability of the active substance as manufactured				☐
2.12	2.12	Flash point of the active substance as manufactured				☐
2.13	2.13	Explosive properties of the active substance as manufactured				☐
2.14	2.14	Surface tension of the active substance as manufactured				☐
2.15	2.15	Oxidizing properties of the active substance as manufactured				☐
2.16	#	pH				☐

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2.17	#	Stability				☐
2.17.1	#	Storage stability				☐
2.17.2	#	Stability (temperature, metals)				☐
2.18	2 *	Other/special studies				☐
3	3	Further information on the active substance (function, mode of action, handling)				
3.1	3.1	Function *e.g.* fungicide				☐
3.2	3.2	Effects on harmful organisms				
3.2.1	3.2.1	Nature of the effects on harmful organisms *e.g.* contact action				☐
3.2.2	3.2.2	Whether or not translocated in plants and if translocated whether such translocation is apoplastic, symplastic or both				☐
3.3	3.3	Fields of use *e.g.* forestry				☐
3.4	3.4	Harmful organisms controlled and crops or products protected or treated				
3.4.1	3.4.1	Details of existing and intended uses (crops, group of crops, plants or plant products treated or protected)				☐
3.4.2	3.4.2	Details of harmful organisms against which protection is afforded				☐
3.4.3	3.4.3	Effects achieved *e.g.* sprout suppression				☐
3.5	3.5	Mode of action				
3.5.1	3.5.1	Statement of the mode of action of the active substance				☐
3.5.2	3.5.2	Details of active metabolites and degradation products cross referenced to the toxicological and residues data provided, to include				
3.5.2.a	3.5.2.a	- IUPAC and CA names				☐
3.5.2.b	3.5.2.b	- ISO common name proposed or accepted				☐
3.5.2.c	3.5.2.c	- CAS, CIPAC, EINECS and ELINCS numbers				☐
3.5.2.d	3.5.2.d	- molecular and structural formula				☐
3.5.2.e	3.5.2.e	- molecular mass				☐
3.5.3	3.5.3	Information relative to the formation of active metabolites and degradation products, to include				
3.5.3.a	3.5.3.a	- the processes, mechanisms and reactions involved				☐
3.5.3.b	3.5.3.b	- kinetic and other data concerning the rate of conversion and if known the rate limiting step				☐
3.5.3.c	3.5.3.c	- environmental and other factors effecting the rate and extent of conversion				☐
3.6	3.6	Information on the possible occurrence of the development of resistance or cross-resistance				☐
3.7	3.7	A safety data sheet for the active substance				☐
3.8	3.8	Procedures for destrution or decontamination				
3.8.1	3.8.1.a	Pyrolytic behaviour of the active substance under controlled conditions at 800 °C and the content of polyhalogenated dibenzo-p-dioxins in the products of pyrolysis				☐
3.8.2	3.8.1.b	Detailed instructions for safe disposal				☐
3.8.3	3.8.2	Methods other than controlled incineration for disposal of the active substance, contaminated packaging and contaminated materials				
3.8.3.a	3.8.2.a	- detailed description of such methods				☐
3.8.3.b	3.8.2.b	- data to establish their effectiveness and safety				☐
3.9	3.9	Procedures for the decontamination of water in the				☐

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		case of an accident				
3.10	3 *	Other/special studies				☐
4	4	Analytical methods and validation				
4.1	4	Analytical standards and samples				
4.1.1	4.a	Analytical standards for pure active substance				☐
4.1.2	4.b	Samples of the active substance as manufactured				☐
4.1.3	4.c	Analytical standards for relevant metabolites and other components included in the residue definition				☐
4.1.4	4.d	Samples of reference substances for relevant impurities				☐
4.2	4.1	Methods of the analysis of the active substance as manufactured				
4.2.1	4.1.1.a	Description of analytical methods for the analysis of the active substance as manufactured For each method submitted:				☐
4.2.1.a	4.1.3.1.a	- specificity				☐
4.2.1.b	4.1.3.1.b	- extent of interference by other substances present				☐
4.2.1.c	4.1.3.1.c	- explantation of interferences which contribute more than ± 3 % of the total quantity determined				☐
4.2.1.d	4.1.3.2	Linearity over an appropriate range:				
4.2.1.e	4.1.3.2.a	- equation of the calibration line				☐
4.2.1.f	4.1.3.2.b	- correlation co-efficient				☐
4.2.1.g	4.1.3.2.c	- representative labelled documentation *e.g.* chromatograms				☐
4.2.1.h	4.1.3.3	Accuracy:				
4.2.1.i	4.1.3.3.a	- pure active substance				☐
4.2.1.j	4.1.3.3.b	- impurities				☐
4.2.1.k	4.1.3.4	Repeatability (at least 5 determinations):				
4.2.1.l	4.1.3.4.a	- % relative standard deviation (RSD)				☐
4.2.1.m	4.1.3.4.b	- indication as to whether outliers identified have been discarded				☐
4.2.1.n	4.1.3.4.c	- reasons for the occurrence of outliers				☐
4.2.2	4.1.1.b	Applicability of existing CIPAC methods				☐
4.2.3	4.1.2.a	Description of analytical methods for the determination of impurities (non-active components arising from the manufacturing process or from the degradation during storage), which are of toxicological, ecotoxicological or environmental concern or which are present in quantities ≥ 1 g/kg in the active substance as manufactured For each method submitted:				☐
4.2.3.a	4.1.3.1.a	- specificity				☐
4.2.3.b	4.1.3.1.b	- extent of interference by other substances present				☐
4.2.3.c	4.1.3.1.c	- explantation of interferences which contribute more than ± 3 % of the total quantity determined				☐
4.2.3.d	4.1.3.2	Linearity over an appropriate range:				
4.2.3.e	4.1.3.2.a	- equation of the calibration line				☐
4.2.3.f	4.1.3.2.b	- correlation co-efficient				☐
4.2.3.g	4.1.3.2.c	- representative labelled documentation *e.g.*				☐

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		chromatograms				
4.2.3.h	4.1.3.3	Accuracy:				
4.2.3.i	4.1.3.3.a	- pure active substance				☐
4.2.3.j	4.1.3.3.b	- impurities				☐
4.2.3.k	4.1.3.4	Repeatability (at least 5 determinations):				
4.2.3.l	4.1.3.4.a	- % relative standard deviation (RSD)				☐
4.2.3.m	4.1.3.4.b	- indication as to whether outliers identified have been discarded				☐
4.2.3.n	4.1.3.4.c	- reasons for the occurrence of outliers				☐
4.2.4	4.1.2.b	Description of analytical methods for the determination of additives (*e.g.* stabilizers) in the active substance as manufactured For each method submitted:				☐
4.2.4.a	4.1.3.1.a	- specificity				☐
4.2.4.b	4.1.3.1.b	- extent of interference by other substances present				☐
4.2.4.c	4.1.3.1.c	- explantation of interferences which contribute more than ± 3 % of the total quantity determined				☐
4.2.4.d	4.1.3.2	Linearity over an appropriate range:				
4.2.4.e	4.1.3.2.a	- equation of the calibration line				☐
4.2.4.f	4.1.3.2.b	- correlation co-efficient				☐
4.2.4.g	4.1.3.2.c	- representative labelled documentation *e.g.* chromatograms				☐
4.2.4.h	4.1.3.3	Accuracy:				
4.2.4.i	4.1.3.3.a	- pure active substance				☐
4.2.4.j	4.1.3.3.b	- impurities				☐
4.2.4.k	4.1.3.4	Repeatability (at least 5 determinations):				
4.2.4.l	4.1.3.4.a	- % relative standard deviation (RSD)				☐
4.2.4.m	4.1.3.4.b	- indication as to whether outliers identified have been discarded				☐
4.2.4.n	4.1.3.4.c	- reasons for the occurrence of outliers				☐
4.2.5	#	Enforcement analytical methodology				☐
4.2.6	#	Inter-Laboratory analytical methodology validation				☐
4.2.7	#	Storage stability of working solutions in analytical methodology				☐
4.3	4.2.1	Description of analytical methods for the determination of residues (all components included in the residue definition proposed (see point 6) to anable compliance with MRLs to be determined or to determine dislodgeable residues) For each method and representative matrix:				
4.3.a	4.2.1.a	- specificity (using a comfirmatory method, if appropriate)				☐
4.3.b	4.2.1.b	- repeatability				☐
4.3.c	4.2.1.c	- validation – independent laboratory				☐
4.3.d	4.2.1.d	- limit of determination				☐
4.3.e	4.2.1.e	- individual and mean recovery, overall standard deviation and relative standard deviation at each fortification level				☐
4.4.	4.2.2	Description of methods for analysis of soil for parent compound and metabolites of toxicological, ecotoxicological or environmental concern For each method:				☐

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4.4.a	4.2.2.a	- specificity (using a comfirmatory method, if appropriate)				☐
4.4.b	4.2.2.b	- repeatability				☐
4.4.c	4.2.2.c	- limit of determination				☐
4.4.d	4.2.2.d	- individual and mean recovery, overall standard deviation at each fortification level				☐
4.5.	4.2.3	Description of methods for analysis of water (drinking water, ground water and surface water) for parent compound and metabolites of toxicological, ecotoxicological or environmental concern For each method:				☐
4.5.a	4.2.3.a	- specificity (using a comfirmatory method, if appropriate)				☐
4.5.b	4.2.3.b	- repeatability				☐
4.5.c	4.2.3.c	- limit of determination				☐
4.5.d	4.2.3.d	- individual and mean recovery, overall standard deviation at each fortification level				☐
4.6	#	Method for determining pesticides in sediment For each method:				☐
4.6.a	#	- specificity (using a comfirmatory method, if appropriate)				☐
4.6.b	#	- repeatability				☐
4.6.c	#	- limit of determination				☐
4.6.d	#	- individual and mean recovery, overall standard deviation at each fortification level				☐
4.7.	4.2.4	Description of methods for analysis of air for active substance and metabolites, formed during or shortly after application, of toxicological concern For each method:				☐
4.7.a	4.2.4.a	- specificity (using a comfirmatory method, if appropriate)				☐
4.7.b	4.2.4.b	- repeatability				☐
4.7.c	4.2.4.c	- limit of determination				☐
4.7.d	4.2.4.d	- individual and mean recovery, overall standard deviation at each fortification level				☐
4.8.	4.2.5	Analytical methods for parent compound and toxicologically, ecotoxicologically or environmentally significant metabolites in body fluids and tissues For each method:				☐
4.8.a	4.2.5.a	- specificity (using a comfirmatory method, if appropriate)				☐
4.8.b	4.2.5.b	- repeatability				☐
4.8.c	4.2.5.c	- limit of determination				☐
4.8.d	4.2.5.d	- individual and mean recovery, overall standard deviation at each fortification level				☐
4.9	4 *	Other/special studies				☐
5	5	Toxicological and toxicokinetic studies on the active substance				
5.1	5.1	Absorption, distribution, excretion and metabolism in mammals				
5.1.1	5.1.a	Toxicokinetic studies - Single dose, oral route, in rats				☐
5.1.2	5.1.b	Toxicokinetic studies - Second single dose, oral route, in rats				☐

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5.1.3	5.1.c	Toxicokinetic studies - Repeated dose, oral route, in rats				☐
5.2	5.2	Acute toxicity				
5.2.1	5.2.1	Acute oral toxicity				☐
5.2.2	5.2.2	Acute percutaneous toxicity				☐
5.2.3	5.2.3	Acute inhalation toxicity				☐
5.2.4	5.2.4	Skin irritation				☐
5.2.5	5.2.5	Eye irritation				☐
5.2.6	5.2.6	Skin sensitization				☐
5.2.7	#	Potentiation/interactions of multiple active substances or products				☐
5.3	5.3	Short-term toxicity				
5.3.1	5.3.1	Oral 28-day toxicity				☐
5.3.2	5.3.2.a	Oral 90-day toxicity (rodents)				☐
5.3.3	5.3.2.b	Oral 90-day toxicity (dog)				☐
5.3.4	5.3.2.c	Oral 1 year toxicity (dog)				☐
5.3.5	5.3.3.a	28-day inhalation toxicity (rodents)				☐
5.3.6	5.3.3.b	90-day inhalation toxicity (rodents)				☐
5.3.7	5.3.3.c	Percutaneous 28-day toxicity (rodents)				☐
5.3.8	5.3.3.d	Percutaneous 90-day toxicity (rodents)				☐
5.4	5.4	Genotixicity				
5.4.1	5.4.1.a	*In vitro* genotoxicity testing - Bacterial assay for gene mutation				☐
5.4.2	5.4.1.b	*In vitro* genotoxicity testing - Test for clastogenicity in mammalian cells				☐
5.4.3	5.4.1.c	*In vitro* genotoxicity testing - Test for gene mutation in mammalian cells				☐
5.4.4	5.4.2.a	*In vivo* genotoxicity testing (somatic cells) - Metaphase analysis in rodent bore marrow, or micronucleus test in rodents				☐
5.4.5	5.4.2.b	*In vivo* genotoxicity testing (somatic cells) - Unscheduled DNA synthesis or a mouse spot test				☐
5.4.6	5.4.3	*In vivo* studies in germ cells				☐
5.5	5.5	Long-term toxicity and carcinogenicity				
5.5.1	5.5.a	Long-term (2 years) oral toxicity in the rat (can be a combined long-term and carcinogenicity study)				☐
5.5.2	5.5.b	Carcinogenicity study in the rat (can be a combined long-term and carcinogenicity study)				☐
5.5.3	5.5.c	Carcinogenicity study in the mouse				☐
5.5.4	5.8.2	Mechanism of action and supporting data				☐
5.6	5.6	Reproductive toxicity				
5.6.1	5.6.1.a	Two generation reproductive toxicity in the rat				☐
5.6.2	5.6.1.b	Separate male and female studies				☐
5.6.3	5.6.1.c	Three segment designs				☐
5.6.4	5.6.1.d	Dominant lethal assay for male fertility				☐
5.6.5	5.6.1.e	Cross-matings of treated males with untreated females and *vice versa*				☐
5.6.6	5.6.1.f	Effect on spermatogenesis				☐
5.6.7	5.6.1.g	Effects on oogenesis				☐
5.6.8	5.6.1.h	Sperm motility, mobility and morphology				☐
5.6.9	5.8.2	Investigation of hormonal activity				☐
5.6.10	5.6.2.a	Teratogenicity test by the oral route in the rat				☐
5.6.11	5.6.2.b	Teratogenicity test by the oral route in the rabbit				☐
5.7	#	Neurotoxicity				☐

OECD Annex IIA point	EC Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
5.7.1	5.8.2	Acute neurotoxicity - rat				☐
5.7.2	5.7	Delayed neurotoxicity following acute exposure				☐
5.7.3	5.8.2	28-day delayed neurotoxicity				☐
5.7.4	5.8.2	Subchronic neurotoxicity – rat – 90 day				☐
5.7.5	5.8.2	Postnatal development neurotoxicity				☐
5.8	5.8.1	Toxicity studies on metabolites				☐
5.9	5.9	Medical data				
5.9.1	5.9.1	Report on medical surveillance on manufacturing plant personnel				☐
5.9.2	5.9.2	Report on clinical cases and poisoning incidents				☐
5.9.3	5.9.3	Observations on exposure of the general population and epidemiological studies				☐
5.9.4	5.9.4	Clinical signs and symptoms of poisoning and details of clinical tests				☐
5.9.5	5.9.5.a	First aid measures				☐
5.9.6	5.9.5.b	Therapeutic regimes				☐
5.9.7	5.9.6.a	Expected effects and duration of poisoning as a function of the type, level and duration of exposure or ingestion				☐
5.9.8	5.9.6.b	Expected effects and duration of poisoning as a function of varying time periods between exposure or ingestion and commencement of treatment				☐
5.9.9	5.1	Dermal penetration				☐
5.10	5.8.2	Other/special studies				☐
5.11	5.10	Summary of mammalian toxicity and overall evaluation				☐
6	6	Metabolism and residues data				
6.1	6	Stability of residues				
6.1.1	6.a	Stability of residues during storage of samples				☐
6.1.2	6.b	Stability of residues in sample extracts				☐
6.2.		Metabolism, distribution and expression of residues				
6.2.1	6.1	In plants, in at least three crops representative of the different crop groups (root vegetables; leafy crops; fruits; pulses and oilseed; cereals)				☐
6.2.2	6.2.a	Poultry				☐
6.2.3	6.2.a	Lactating ruminants (goat or cow)				☐
6.2.4	6.2.b	Pigs				☐
6.2.5	#	Nature of residue in fish				☐
6.2.6	#	Chemical identity (emphasis on impurities of residual concern)				☐
6.3	6.3	Residue trials (supervised field trials) for crops or plant products used as food or feed on which use is proposed or where residues from soil can be taken up				
6.3.1	6.3.a	Crop 1 (e.g. wheat)				☐
6.3.2	6.3.b	Crop 2 (e.g. oilseed rape)				☐
6.3.3	6.3.c	Crop 3				☐
6.3.4	6.3	Crop 4, *etc*.				☐
6.4	6.4	Livestock feeding studies				
6.4.1	6.4.a	Poultry				☐
6.4.2	6.4.a	Lactating ruminants (goat or cow)				☐
6.4.3	6.4.b	Pigs				☐
6.4.4	#	Fish				☐

OECD Annex IIA point	EC Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
6.5	6.5	Effects of industrial processing and/or household preparation (representative processing situations) on				
6.5.1	6.5.1.a	The nature of residue				☐
6.5.2	6.5.2	Distribution of the residue in peel/pulp				☐
6.5.3	6.5.2.a	Residue levels - balance studies on a core set of representative processes				☐
6.5.4	6.5.2.b	Residue levels - follow-up studies to determine concentration or dilution factors				☐
6.6	6.6	Residues in succeeding crops				
6.6.1	6.6.a	Theoretical consideration of the nature and level of the residue				☐
6.6.2	6.6.b	Metabolism and distribution studies on representative crops				☐
6.6.3	6.6.c	Field trials on representative crops				☐
6.7	6.7	Proposed residue definition and maximum residue levels				
6.7.1	6.7.a	Proposed residue definition				☐
6.7.2	6.7.b	Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed, including details of statistical analyses used				☐
6.8	6.8	Proposed pre-harvest intervals, re-entry intervals or withholding periods to minimize residues in crops, plants, plant products, treated areas or spaces and a justification for each proposal				
6.8.1	6.8.a	Pre-harvest interval (in days) for each relevant crop				☐
6.8.2	6.8.b	Re-entry period (in days) for livestock, to areas to be grazed				☐
6.8.3	6.8.c	Re-entry period (in hours or days) for man to crops, buildings or spaces treated				☐
6.8.4	6.8.d	Withholding period (in days) for animal feeding stuffs				☐
6.8.5	6.8.e	Waiting period (in days) between last application and sowing or planting the crop to be protected				☐
6.8.6	6.8.f	Waiting period (in days) between application and handling treated products				☐
6.8.7	6.8.g	Waiting period (in days) between last application and sowing or planting succeeding crops				☐
6.9	6.9	Estimation of the potential and actual exposure through diet and other means				
6.9.1	6.9.a	TMDI calculations				☐
6.9.2	6.9.b	NEDI calculations				☐
6.9.3	6.9	NESTI calculations				☐
6.10	6 *	Other/special studies				☐
6.11	6.10 (first part)	Summary and evaluation of residue behaviour; Reasonable grounds in support of the petition				
6.11.1	6.10	Summary and evaluation of residue behaviour				☐
6.11.2	#	Reasonable grounds in support of the petition				☐
7	7	Fate and behaviour in the environment				
7.1	7.1.1.1	Route of degradation in soil – laboratory studies				
7.1.1	7.1.1.1.1	Aerobic degradation				☐
7.1.2	7.1.1.1.2.a	Anaerobic degradation				☐
7.1.3	7.1.1.1.2.b	Soil photolysis				☐
7.2	7.1.1.2.1	Rate of degradation in soil(s) - laboratory studies				

OECD Annex IIA point	EC Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
7.2.1	7.1.1.2.1.a	Aerobic degradation of the active substance in soils at 20 °C				☐
7.2.2	7.1.1.2.1.b	Aerobic degradation of the active substance in soil at 10 °C				☐
7.2.3	7.1.1.2.1.c	Aerobic degradation of relevant metabolites, degradation and reaction products in soils at 20 °C				☐
7.2.4	7.1.1.2.1.d	Anaerobic degradation of the active substance in soil				☐
7.2.5	7.1.1.2.1.e	Anaerobic degradation of relevant metabolites, degradation and reaction products in soil				☐
7.3	7.1.1.2.2	Field studies				
7.3.1	7.1.1.2.2.a	Soil dissipation testing in a range of representative soils – (normally 4 soils)				☐
7.3.2	7.1.1.2.2.b	Soil residue testing				☐
7.3.3	7.1.1.2.2.c	Soil accumulation testing on relevant soils				☐
7.4		Mobility studies				
7.4.1	7.1.2.a	Adsorption and desorption of the active substance				☐
7.4.2	7.1.2.b	Adsorption and desorption of all relevant metabolites, degradation and reaction products in 3 soils				☐
7.4.3	7.1.3.1.a	Column leaching studies with the active substance				☐
7.4.4	7.1.3.1.b	Column leaching studies with relevant metabolites, degradation and reaction products				☐
7.4.5	7.1.3.2	Aged residue column leaching				☐
7.4.6	#	Leaching (TLC)				☐
7.4.7	7.1.3.3.a	Lysimeter studies				☐
7.4.8	7.1.3.3.b	Field leaching studies				☐
7.4.9	2.3.2, 7.2.2	Volatility – laboratory studies				☐
7.5	7.2.1.1	Hydrolysis rate of relevant metabolites, degradation and reaction products at pH values 4, 7 and 9 under sterile conditions, in the absence of light				
7.5.a	7.2.1.1.a	- identity of hydrolysis products				☐
7.5.b	7.2.1.1.b	- rate constant observed				☐
7.5.c	7.2.1.1.c	- estimated DT_{50} value				☐
7.6	7.2.1.2	Direct phototransformation of relevant metabolites, degradation and reaction products in water using artificial light (simulating sunlight and excited wavelengths $\lambda < 290$ nm) under sterile conditions, to include				
7.6.a	7.2.1.2.a	- photochemical half-life				☐
7.6.b	7.2.1.2.b	- mass balance to account for 90 % of the applied radioactivity				☐
7.6.c	7.2.1.2.c	- identity of breakdown products				☐
7.6.d	7.2.1.2.d	- quantum yield of direct phototransformation				☐
7.6.e	7.2.1.2.e	- calculated theoretical lifetime in the top layer of aqueous systems and the real lifetime of the substance added				☐
7.7	7.2.1.3.1	Ready biodegradability of the active substance				☐
7.8		Degradation in aquatic systems				
7.8.1	#	Aerobic biodegradation in aquatic systems, including identification of breakdown products and metabolites				☐

OECD Annex IIA point	EC Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
7.8.2	#	Anaerobic biodegradation in aquatic systems, including identification of breakdown products and metabolites				☐
7.8.3	7.2.1.3.2	Water/sediment study				☐
7.9	7.2.1.4	Degradation in the saturated zone of the active substance, metabolites, degradation and reaction products				☐
7.10	7.2.2	Rate and route of degradation in air				☐
7.11	7.3	Definition of the residue				☐
7.12	7.4	Monitoring data concerning fate and behaviour of the active substance and of relevant metabolites, degradation and reaction products				☐
7.13	7 *	Other/special studies				☐
8	8	Ecotoxicological studies on the active substance				
8.1	8.1	Avian toxicity				
8.1.1	8.1.1	Acute oral toxicity to a quail species (Japanese or Bobwhite), mallard duck, or other bird species				☐
8.1.2	8.1.2.a	Avian dietary toxicity (5-day) test in a quail species or in mallard duck				☐
8.1.3	8.1.2.b	Avian dietary toxicity (5-day) test in a second unrelated species				☐
8.1.4	8.1.3	Subchronic and reproductive toxicity to birds				☐
8.2		Fish toxicity				
8.2.1	8.2.1	Acute toxicity of the active substance to fish				
8.2.1.1.a	8.2.1.a	Rainbow trout (*Oncorhynchus mykiss*)				☐
8.2.1.1.b	8.2.1.d	Analytical data on concentrations in the test media				☐
8.2.1.2.a	8.2.1.b	Warm water fish species				☐
8.2.1.2.b	8.2.1.d	Analytical data on concentrations in the test media				☐
8.2.1.3.a	8.2.1.c	Acute toxicity of metabolites,degradation or reaction products to the more sensitive of the fish species used to test the acute toxicity of the active substance				☐
8.2.1.3.b	8.2.1.d	Analytical data on concentrations in the test media				☐
8.2.2	8.2.2	Chronic toxicity to fish				☐
8.2.3.a	8.2.2.1.a	Chronic toxicity (28 day exposure) to juvenile fish growth and behaviour				☐
8.2.3.b	8.2.2.1.b	Analytical data on concentrations in the test media				☐
8.2.4.a	8.2.2.2.a	Fish early life stage toxicity test				☐
8.2.4.b	8.2.2.2.b	Analytical data on concentrations in the test media				☐
8.2.5.a	8.2.2.3.a	Fish life cycle test				☐
8.2.5.b	8.2.2.3.b	Analytical data on concentrations in the test media				☐
8.2.6	8.2.3	Bioconcentration in fish				
8.2.6.1	8.2.3.a	Bioconcentration potential of the active substance in fish				☐
8.2.6.2	8.2.3.b	Bioconcentration potential of metabolites, degradation and reaction products				☐
8.2.7	#	Aquatic bioavailability/biomagnification/ depuration				☐
8.3		Toxicity to aquatic species other than fish and aquatic species field testing				
8.3.1	8.2.4	Acute toxicity to aquatic invertebrates				
8.3.1.1.a	8.2.4.a	Acute toxicity (24 and 48 hour) for *Daphnia* preferably (*Daphnia magna)*				☐
8.3.1.1.b	8.2.4.f	Analytical data on concentrations in the test media				☐
8.3.1.2.a	8.2.4.c	Acute toxicity (24 and 48 hour) for representative				☐

OECD Annex IIA point	EC Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
		species of aquatic insects				
8.3.1.2.b	8.2.4.f	Analytical data on concentrations in the test media				☐
8.3.1.3.a	8.2.4.d	Acute toxicity (24 and 48 hour) for representative species of aquatic crustaceans (species unrelated to *Daphnia*)				☐
8.3.1.3.b	8.2.4.f	Analytical data on concentrations in the test media				☐
8.3.1.4.a	8.2.4.e	Acute toxicity (24 and 48 hour) for representative species of aquatic gastropod molluscs				☐
8.3.1.4.b	8.2.4.f	Analytical data on concentrations in the test media				☐
8.3.2	8.2.5	Chronic toxicity to aquatic invertebrates				
8.3.2.1.a	8.2.5.a	Chronic toxicity in *Daphnia magna* (21-day)				☐
8.3.2.1.b	8.2.5.e	Analytical data on concentrations in the test media				☐
		Chronic toxicity for at least one representative species from each of the following groups				
8.3.2.2.a	8.2.5.b	Chronic toxicity for representative species of aquatic insects				☐
8.3.2.2.b	8.2.5.e	Analytical data on concentrations in the test media				☐
8.3.2.3.a	8.2.5.d	Chronic toxicity for representative species of aquatic gastropod mollusc				☐
8.3.2.3.b	8.2.5.e	Analytical data on concentrations in the test media				☐
8.3.3	#	Aquatic field testing				☐
8.4.a	8.2.6	Effects on algal growth and growth rate (2 species)				☐
8.4.b	8.2.6.c	Analytical data on concentrations in the test media				☐
8.5	8.2.7	Effects on sediment dwelling organisms				
8.5.1.a	8.2.7.a	Acute test				☐
8.5.1.b	8.2.7.c	Analytical data on concentrations in the test media				☐
8.5.2.a	8.2.7.b	Chronic test				☐
8.5.2.b	8.2.7.c	Analytical data on concentrations in the test media				☐
8.6a	8.2.8.a	Effects on aquatic plants				☐
8.6b	8.2.8.b	Analytical data on concentrations in the test media				☐
8.7	8.3.1	Effects on bees				
8.7.1	8.3.1.1.a	Acute oral toxicity				☐
8.7.2	8.3.1.1.b	Acute contact toxicity				☐
8.7.3	#	Toxicity of residues on foliage to honey bees				☐
8.7.4	8.3.1.2	Bee brood feeding test				☐
8.8	8.3.2	Effects on non-target terrestrial arthropods				
8.8.1	8.3.2	Effects on non-target terrestrial arthropods using artificial substrates				
8.8.1.1	8.3.2.a	Parasitoid				☐
8.8.1.2	8.3.2.b	Predatory mites				☐
8.8.1.3	8.3.2.c	Ground dwelling predatory species (selected to be relevant to the intended uses of preparations)				☐
8.8.1.4	8.3.2.d	Foliage dwelling predatory species (selected to be relevant to the intended uses of preparations)				☐
8.8.2		Effects on non-target terrestrial arthropods in extended laboratory/semi field tests				
8.8.2.1	8.3.2.e	Parasitoid				☐
8.8.2.2	8.3.2.f	Predatory mites				☐
8.8.2.3	8.3.2.g	Ground dwelling predatory species (selected to be relevant to the intended uses of preparations)				☐
8.8.2.4	8.3.2.h	Foliage dwelling predatory species (selected to be relevant to the intended uses of preparations)				☐
8.8.2.5	8.3.2	Other terrestrial invertebrates				☐
8.9	8.4	Effects on earthworms				

OECD Annex IIA point	EC Annex IIA point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
8.9.1	8.4.1	Acute toxicity to earthworms				☐
8.9.2	8.4.2	Sublethal effects on earthworms				☐
8.10	8.5	Impact on soil microbial activity				
8.10.1	8.5.a	Nitrogen transformation				☐
8.10.2	8.5.b	Carbon mineralization				☐
8.10.3	8.5.c	Rates of recovery following treatment				☐
8.11	#	Effects on marine and estuarine organisms				☐
8.11.1	#	Marine or estuarine organisms - Acute toxicity LC_{50}/EC_{50}				☐
8.11.2	#	Marine/estuarine fish - Salinity challenge				☐
8.12	8.6	Effects on terrestrial vascular plants				☐
8.13	#	Effects on terrestrial vertebrates other than birds/wild mammal toxicity				☐
8.14	8.6	Effects on other non-target organisms (flora and fauna) believed to be at risk				☐
8.14.1	8.6.a	Summary of all available data from preliminary tests used to assess biological activity and dose range finding, which may provide information on other non-target species (flora and fauna)				☐
8.14.2	8.6.b	A critical assessment as to the relevance of the preliminary test data to potential impact on non-target species				☐
8.15	8.7	Effects on biological methods for sewage treatment				☐
8.16	8	Other/special studies				
8.16.1	8 *	Other/special laboratory studies				☐
8.16.2	8 *	Other/special field studies				☐
8.17	9	Summary and evaluation of points IIA 7 and IIA 8.1 to 8.16				☐
9	10	Justified proposals for the classification and labelling of the active substance according to Directive 67/548/EEC				
9.a	10.a	- Hazard symbol(s)				☐
9.b	10.b	- Indications of danger				☐
9.c	10.c	- Risk phrases				☐
9.d	10.d	- Safety phrases				☐

Explanations:

= No EC data requirement (the OECD point concerned is not a data requirement according to Council Directive 91/414/EEC)

* = If no information, test or study is provided for the relevant OECD point, this is not a data gap as the item "Other/special studies" is not explicitly stated in the EC point concerned. However, the possibility should be given to submit information, tests or studies.