

PART 4

OECD, EU, US, CANADIAN, JAPANESE AND AUSTRALIAN NUMBERING SYSTEMS FOR DATA AND INFORMATION ON ACTIVE SUBSTANCES

- 1 As indicated in subparagraph 3.1.1 xvi, the numbering systems used in many OECD countries for the data and information relating to active substances to be submitted, are different. It is suggested that applicants use the OECD numbering system, for the purposes of submitting data and information appropriate to the country (or countries) to which application(s) is (are) being made. Alternatively, applicants can use the country-specific numbering system for the country to which application is being made. The OECD numbering system for data and information concerning active substances together with the numbering systems used in some OECD countries is provided in the following pages.
- 2 The OECD numbering system was developed to facilitate the development of a common format for dossiers prepared by industry. The tabular presentation of the OECD system side by side with the US, Canadian, Japanese, Australian and former EU systems, is intended to assist industry in converting from numbering systems used nationally to the OECD numbering system.
- 3 From January 2005, the OECD numbering system has been mandatory in the EU. To facilitate conversion from the earlier EU numbering system to other numbering systems, the system previously used in the EU is included.
- 4 Applicants and registrants are advised that use of a common numbering system does not imply a common set of data requirements. It is still necessary for applicants and registrants to ensure that each particular submission complies with the data requirements of the relevant national regulatory authority.

Point 1 Identity of the Active Substance

OECD data point number	Information, test or study	Former EU Annex IIA point number ⁹	US EPA Guideline/Requirement number		Canadian Data Code (DACO) ¹²	Japanese Data Code Yes / No ¹³	Australian Data Code
			OPPTS ¹⁰	OPP ¹¹			
IIA-1	Identity of the Active Substance	1					
IIA 1.1	Applicant (name, address, contact, telephone and telefax numbers)	1.1	Forms 8570-1(1), 8570-4(5)	Forms 8570-1(1), 8570-4(5)	1 2.1	Yes	2-4.2
IIA 1.2	Manufacturer(s) (name, address, contact, telephone and telefax numbers)	1.2	Forms 8570-1(1), 8570-4(2), 8570-4(11)	Forms 8570-1(1), 8570-4(2), 8570-4(11)	2.2	Yes	2-4.2 2-4.3(d)
IIA 1.3	ISO common name proposed or accepted, and synonyms	1.3	Form 8570-4(10) 830.1550	Form 8570-4(10)	2.4	Yes	2-4.3(a)
IIA 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	1.4	Form 8570-4(10) 830.1550	Form 8570-4(10)	2.5	Yes	2-4.3(a)
IIA 1.5	Manufacturer's codes, names and patent status	1.5				Yes	
IIA 1.5.1	Manufacturer's code number(s), for the active substance and formulations, materials concerned, countries in which used and periods for which used	1.5	Form 8570-1(1)	Form 8570-1(1)	2.3.1	Yes	2-4.3(a)
IIA 1.5.2	Trade Name(s)		Form 8570-1 (1)	Form 8570-1 (1)	1 2.3	Yes	2-4.3(a)
IIA 1.5.3	Patent Status				2.10	Yes	-

⁹ Numbering system used in the EU until the end of 2004. The OECD system has been mandatory in the EU from January 2005

¹⁰ Office of Pollution Prevention and Toxics of the US Environmental Protection Agency

¹¹ Office of Pesticide Programs of the US Environmental Protection Agency

¹² Data code used by the Canadian Pest Management Regulatory Agency

¹³ Data point numbering system being developed

Point 1 Identity of the Active Substance

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 1.6	Existing CAS, CIPAC, EINECS and ELINCS numbers	1.6	Form 8570-4(10) 830.1550	Form 8570-4(10)	2.6	Yes	2-4.3(a)
IIA 1.7	Molecular formula, molecular mass and structural formula	1.7	830.1550		2.7 2.8 2.9	Yes	2-4.3(a)
IIA 1.8	Method of Manufacture	1.8				Yes	
IIA 1.8.1	Method of manufacture (pathways, by-products and impurities) for each plant, whether or not relevant to a pilot plant	1.8	830.1620 830.1670		2.11.1 2.11.3 2.11.4	Yes	2-4.3(e) 2-4.3(h)
IIA 1.8.2	Description of starting materials	1.8	830.1600		2.11.2	Yes	2-4.3(f)
IIA 1.9	Specification of purity of the active substance	1.9				Yes	
IIA 1.9.1	Minimum and/or nominal content (g/kg) of pure active substance (excluding inactive isomers), whether or not relevant to a pilot plant	1.9	Form 8570-4(13) 830.1750 830.1550	Form 8570-4(13)	2.12.1 2.12.2	Yes	2-4.3(b)
IIA 1.9.1.1	Minimum content (g/kg) of pure active substance (excluding inactive isomers), whether or not relevant to a pilot plant	1.9	830.1750				
IIA 1.9.1.2	Nominal content (g/kg) of pure active substance (excluding inactive isomers), whether or not relevant to a pilot plant		830.1550				
IIA 1.9.2	Certified limits of the active substances		Form 8570-4(10) 830.1750	Form 8570-4(10)	2.12.1 2.12.2	Yes	2-4.3(i) 2-4.3(j)

Point 1 Identity of the Active Substance

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 1.9.3	Control Product Specification Form or Confidential Statement of Formula		Form 8570-4(10) 830.1550	Form 8570-4(10)	2.12.2	No	2-4.3(j)
IIA 1.10	Identity, content and structural formula of isomers, impurities and additives	1.10				Yes	
IIA 1.10.1	Inactive isomers For each isomer: - IUPAC and CA names - ISO common name proposed or accepted - CAS, CIPAC, EINECS and ELINCS numbers - molecular and structural formula - molecular mass - ratio of the content of isomers/diastereo-isomers - maximum content in g/kg - whether or not relevant to a pilot plant	1.10	Form 8570-4(10)	Form 8570-4(10)	2.12.2	Yes	2-4.3(a) 2-4.3(b)

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OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 1.10.2	Impurities and additives - IUPAC and CA names - ISO common name proposed or accepted - CAS, CIPAC, EINECS and ELINCS numbers - molecular and structural formula - molecular mass - maximum content in g/kg - whether or not relevant to a pilot plant - in the case of additives, their function and trade names - in the case of impurities and by-products of particular environmental concern, details of the analytical methods - guidance in identifying impurities of toxicological concern	1.10	Form 8570-4(10) 830.1550	Form 8570-4(10) 158.155	2.12.2 2.13.4	Yes	2-4.3(h)
IIA 1.11	Batch analysis data	1.11				Yes	
IIA 1.11.1	Analytical profile of batches	1.11	830.1700		2.13.3	Yes	2-4.3(i)
IIA 1.11.2	Results of analyses of batches produced in laboratory or pilot scale production systems and used in toxicological testing	1.11	830.1700		2.13.3	Yes	2-4.3(i)
IIA 1.12	Other/special studies				2.16	No	-

Point 2 Physical and Chemical Properties of the Active Substance

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA	Physical and Chemical Properties of the Active Substance	2					
IIA 2.1	Melting point and boiling point	2.1				Yes	
IIA 2.1.1	Melting point, freezing point or solidification point of purified active substance	2.1.1	830.7200	63-5	2.14.4	Yes	2-4.3(b)
IIA 2.1.2	Boiling point of purified active substance	2.1.2	830.7220	63-6	2.14.5	Yes	2-4.3(b)
IIA 2.1.3	Temperature at which decomposition or sublimation occurs	2.1.3				No	2-4.3(b)
IIA 2.2	Relative density of purified active substance	2.2	Form 8570-4(7) 830.7300	Form 8570-4(7) 63-7	2.14.6	Yes	2-4.3(b)
IIA 2.3	Vapour pressure and volatility	2.3				Yes	
IIA 2.3.1	Vapour pressure of purified active substance	2.3.1	830.7950	63-9	2.14.9	Yes	2-4.3(b)
IIA 2.3.2	Henry's law constant	2.3.2				No	2-4.3(b)
IIA 2.4	Appearance	2.4				Yes	
IIA 2.4.1	Description of the physical state and colour of both the purified active substance and the active substance as manufactured (or technical grade active substance)	2.4.1	830.6302 830.6303	63-2 63-3	2.14.1 2.14.2	Yes	2-4.3(b)
IIA 2.4.2	Description of the odour of the purified active substance and active substance as manufactured	2.4.2	830.6304	63-4	2.14.3	Yes	2-4.3(b)

Point 2 Physical and Chemical Properties of the Active Substance

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 2.5	Spectra and molecular extinction at relevant wavelengths	2.5				Yes	
IIA 2.5.1	Spectra, a table of signal characteristics and molecular extinction at relevant wavelengths for purified active substance	2.5.1			2.13.2 2.14.3	Yes	2-4.3(b)
IIA 2.5.1.1	- UV/VIS	2.5.1	830.7050		2.14.12	Yes	2-4.3(b)
IIA 2.5.1.2	- IR	2.5.1	830.7050		2.13.2	Yes	2-4.3(b)
IIA 2.5.1.3	- NMR	2.5.1			2.13.2	Yes	2-4.3(b)
IIA 2.5.1.4	- MS	2.5.1			2.13.2	Yes	2-4.3(b)
IIA 2.5.1.5	- wavelengths at which UV/VIS molecular extinction occurs, where appropriate, to include a wavelength at the highest absorption value above 290 nm	2.5.1	830.7050		2.13.2 2.14.12	Yes	2-4.3(b)
IIA 2.5.1.6	- optical purity	2.5.1			2.12.1 2.12.2	No	2-4.3(b)
IIA 2.5.2	Spectra for impurities	2.5.2			2.13.2	No	2-4.3(g)
IIA 2.5.2.1	- UV/VIS	2.5.2				No	2-4.3(g)
IIA 2.5.2.2	- IR	2.5.2				No	2-4.3(g)
IIA 2.5.2.3	- NMR	2.5.2				No	2-4.3(g)
IIA 2.5.2.4	- MS	2.5.2				No	2-4.3(g)
IIA 2.6	Solubility of purified active substance in water - determined in the neutral range	2.6	830.7840 830.7860	63-8	2.14.7	Yes	2-4.3(b)

Point 2 Physical and Chemical Properties of the Active Substance

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
	- determined in the acidic range (pH 4 to 6) - determined in the alkaline range (pH 8 to 10)						
IIA 2.7	Solubility in organic solvents at 15 to 25°C	2.7	830.1000 830.7840 830.7860	63-8	2.14.8	Yes	2-4.3(b)
IIA 2.8	Partition coefficient	2.8				Yes	
IIA 2.8.1	n-octanol/water partition coefficient	2.8	830.7550 830.7560 830.7570	63-11	2.14.11	Yes	2-4.3(b)
IIA 2.8.2	Effect of pH (4 to 10) on the n-octanol/water partition coefficient	2.8	830.7550 830.7560 830.7570	63-11	2.14.11	Yes	2-4.3(b)
IIA 2.9	Stability in water, hydrolysis rate, photochemical degradation, quantum yield and identity of breakdown products, dissociation constant	2.9				Yes	
IIA 2.9.1	Hydrolysis rate of purified active substance at pH values 4, 7 and 9 under sterile conditions, in the absence of light - identity of hydrolysis products - rate constant observed - estimated DT ₅₀ value	2.9.1	835.2120	161-1	8.2.3.2	Yes	2-4.3(b)
IIA 2.9.2	Direct phototransformation of purified active substance in water using artificial light (simulating sunlight and excluding wavelengths λ < 290 nm) under sterile conditions, to include - photochemical half-life - mass balance to account for 90 % of the applied radioactivity	2.9.2	835.2240	161-2	8.2.3.3.2	Yes	2-4.3(b)

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OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
	- identity of breakdown products						
IIA 2.9.3	Quantum yield of direct phototransformation	2.9.3				No	-
IIA 2.9.4	Calculated theoretical lifetime in the top layer of aqueous systems and the real lifetime of the active substance	2.9.3				No	-
IIA 2.9.5	Dissociation in water of purified active substance - dissociation constant(s) (pKa values) - identity of dissociated species formed - dissociation constant(s) (pKa values) of the active principle	2.9.4	830.7370	63-10	8.2.3.2 2.14.10	Yes	2-4.3(b)
IIA 2.10	Estimated photochemical oxidative degradation	2.10	835.2370	161-4	8.2.3.3.3	No	2-4.3(b)
IIA 2.11	Flammability including auto-flammability	2.11				No	
IIA 2.11.1	Flammability of the active substance as manufactured	2.11.1	830.6315	63-15		No	2-4.3(b)
IIA 2.11.2	Auto-flammability of the active substance as manufactured	2.11.2	830.6315			No	2-4.3(b)
IIA 2.12	Flash point of the active substance as manufactured	2.12	830.6315	63.15		No	2-4.3(b)
IIA 2.13	Explosive properties of the active substance as manufactured	2.13	830.6316	63-16		No	2-4.3(b)
IIA 2.14	Surface tension of the active substance as manufactured	2.14				No	2-4.3(b)

Point 2 Physical and Chemical Properties of the Active Substance

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 2.15	Oxidizing properties of the active substance as manufactured	2.15	830.6314	63-14		No	2-4.3(b)
IIA 2.16	PH		Form 8570-4(8) 830.7000	Form 8570-4(8) 63-12		Yes	2-4.3(b)
IIA 2.17	Stability					No	
IIA 2.17.1	Storage stability		830.6317	63-17	2.14.14	No	2-4.3(c)
IIA 2.17.2	Stability (temperature, metals)		830.6313	63-13	2.14.13	Yes	2-4.3(b)
IIA 2.18	Other/special studies				2.16	No	-

Point 3 Further Information on the Active Substance (Function, Mode of Action, Handling)

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 3	Further Information on the Active Substance (Function, Mode of Action, Handling)	3					
IIA 3.1	Function <i>e.g.</i> fungicide	3.1	Form 8570-4(15) 860.1200	Form 8570-4(15) 171-2	10.2.1	Yes	1.2
IIA 3.2	Effects on harmful organisms	3.2				Yes	
IIA 3.2.1	Nature of the effects on harmful organisms <i>e.g.</i> contact action	3.2.1			10.2.1	Yes	1.2
IIA 3.2.2	Whether or not translocated in plants and if translocated whether such translocation is apoplasmic, symplasmic or both	3.2.2			10.2.1	Yes	1.2
IIA 3.3	Fields of use <i>e.g.</i> forestry	3.3	40CFR 156.10 (i)(c)(2)(iii) 860.1200	40CFR 156.10 (i)(c)(2)(iii) 171-2	10.2.1	No	1.2
IIA 3.4	Harmful organisms controlled and crops or products protected or treated	3.4				No	
IIA 3.4.1	Details of existing and intended uses (crops, groups of crops, plants or plant products treated or protected)	3.4.1	860.1200	171-2	1	No	1.2
IIA 3.4.2	Details of harmful organisms against which protection is afforded	3.4.2	860.1200	171-2	10.2.2	Yes	1.2
IIA 3.4.3	Effects achieved <i>e.g.</i> sprout suppression	3.4.3			10.2.3	Yes	1.2
IIA 3.5	Mode of action	3.5				Yes	

Point 3 Further Information on the Active Substance (Function, Mode of Action, Handling)

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 3.5.1	Statement of the mode of action of the active substance in terms of biochemical and physiological mechanism(s) and biochemical pathway(s) involved	3.5.1			10.2.1	Yes	1.2
IIA 3.5.2	Details of active metabolites and degradation products, cross referenced to the toxicological and residues data provided, to include - IUPAC and CA names - ISO common name proposed or accepted - CAS, CIPAC, EINECS and ELINCS numbers - molecular and structural formula - molecular mass	3.5.2	830.1550 830.1670		10.2.1	Yes	-
IIA 3.5.3	Information relative to the formation of active metabolites and degradation products, to include - the processes, mechanisms and reactions involved - kinetic and other data concerning the rate of conversion and if known the rate limiting step - environmental and other factors effecting the rate and extent of conversion	3.5.3	830.1670		10.2.1	No	-
IIA 3.6	Information on the possible occurrence of the development of resistance or cross-resistance	3.6			10.5.3	No	-
IIA 3.7	A material safety data sheet for the active substance	3.7			MSDS 2.11.2	No	-

Point 3 Further Information on the Active Substance (Function, Mode of Action, Handling)

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 3.8	Procedures for destruction or decontamination	3.8				No	
IIA 3.8.1	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	3.8.1					-
IIA 3.8.2	Detailed instructions for safe disposal	3.8.1	40 CFR 165.9 (a) - (d)	40 CFR 165.9 (a) - (d)	8.4.1	No	-
IIA 3.8.3	Methods other than controlled incineration for the disposal of the active substance, contaminated packaging and contaminated materials - Detailed description of such methods - Data to establish their effectiveness and safety	3.8.2	40 CFR 165.9 (a) - (d)	40 CFR 165.9 (a) - (d)	8.4.1	No	-
IIA 3.9	Procedures for the decontamination of water in case of an accident	3.9			8.4.1	No	-
IIA 3.10	Other/special studies				2.16, 8.6, 10.6	No	-

Point 4 Analytical Methods

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 4	Analytical Methods and Validation	4					
IIA 4.1	Analytical standards and samples	4				Yes	
IIA 4.1.1	Analytical standards for pure active substance	4	830.1900	64-1	2.15	Yes	2-4.3(g) 2-4.3(l)
IIA 4.1.2	Samples of the active substance as manufactured	4	830.1900	64-1	2.15	Yes	2-4.3(l)
IIA 4.1.3	Analytical standards for relevant metabolites and other components included in the residue definition	4	860.1650	171-13	2.15	No	2-4.3(l)
IIA 4.1.4	Samples of reference substances for relevant impurities	4			2.15	No	2-4.3(l)
IIA 4.2	Methods for the analysis of the active substance as manufactured	4.1				Yes	
IIA 4.2.1	Description of analytical methods for the analysis of the active substance as manufactured For each method submitted: - specificity - extent of interference by other substances present - explanation of interferences which contribute more than ± 3 % of the total quantity determined	4.1.1 4.1.3	830.1000		2.13.1	Yes	2-4.3(g)

Point 4 Analytical Methods

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			

For each method submitted, linearity over an appropriate range:

- equation of the calibration line
- correlation co-efficient
- representative labelled documentation *e.g.* chromatograms

For each method submitted, accuracy:

- pure active substance
- impurities

For each method submitted, repeatability (at least 5 determinations):

- % relative standard deviation (RSD)
- indication as to whether outliers identified have been discarded
- reasons for the occurrence of outliers

IIA 4.2.2	Applicability of existing CIPAC methods	4.1.1				No	2-4.3(g)
IIA 4.2.3	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	4.1.2 4.1.3	830.1000		2.13.4	Yes	2-4.3(g)

Point 4 Analytical Methods

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			

For each method submitted:

- specificity
- extent of interference by other substances present
- explanation of interferences which contribute more than $\pm 3\%$ of the total quantity determined

For each method submitted, linearity over an appropriate range:

- equation of the calibration line
- correlation co-efficient
- representative labelled documentation *e.g.* chromatograms

For each method submitted, accuracy:

- pure active substance
- impurities

For each method submitted, repeatability (at least 5 determinations):

- % relative standard deviation (RSD)
- indication as to whether outliers identified have been discarded
- reasons for the occurrence of outliers

IIA 4.2.4	Description of analytical methods for the determination of additives (<i>e.g.</i> stabilizers) in the active substance as manufactured	4.1.2 4.1.3	Yes	2-4.3(g)
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Point 4 Analytical Methods

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			OPPTS	OPP			

For each method submitted:

- specificity
- extent of interference by other substances present
- explanation of interferences which contribute more than $\pm 3\%$ of the total quantity determined

For each method submitted, linearity over an appropriate range:

- equation of the calibration line
- correlation co-efficient
- representative labelled documentation *e.g.* chromatograms

For each method submitted, accuracy:

- pure active substance
- impurities

For each method submitted, repeatability (at least 5 determinations):

- % relative standard deviation (RSD)
- indication as to whether outliers identified have been discarded
- reasons for the occurrence of outliers

IIA 4.2.5	Enforcement analytical methodology		830.1800		7.2.2	No	2-4.3(g)
IIA 4.2.6	Inter-Laboratory analytical methodology validation				7.2.3	No	2-4.3(g)
IIA 4.2.7	Storage stability of working solutions in analytical methodology				7.2.5	No	2-4.3(g)

Point 4 Analytical Methods

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
I/A 4.3	Description of analytical methods for the determination of residues (all components included in the residue definition proposed (see point 6) to enable compliance with MRLs to be determined or to determine dislogeable residues For each method and representative matrix: - Specificity (using a confirmatory method, if appropriate) - Repeatability - Validation - independent laboratory - Limit of determination - Individual and mean recovery, overall standard deviation and relative standard deviation at each fortification level	4.2.1	860.1300 860.1340 860.1360	171-4a, b 171-4m	7.2.1 7.2.4	Yes	5A-4.9
I/A 4.4	Description of methods for analysis of soil for parent compound and metabolites of toxicological, ecotoxicological or environmental concern For each method: - Specificity (using a confirmatory method, if appropriate) - Repeatability - Limit of determination - Individual and mean recovery, overall standard deviation at each fortification level	4.2.2			8.2.2.1	Yes	-

Point 4 Analytical Methods

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 4.5	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: - Specificity (using a confirmatory method, if appropriate) - Repeatability - Limit of determination - Individual and mean recovery, overall standard deviation at each fortification level	4.2.3	840.1400	171-4f	8.2.2.3	Yes	-
IIA 4.6	Method for determining pesticides in sediment For each method: - Specificity (using a confirmatory method, if appropriate) - Repeatability - Limit of determination - Individual and mean recovery, overall standard deviation at each fortification level		835.1220 835.1230	None 163-1	8.2.2.2	No	-
IIA 4.7	Description of methods for analysis of air for active substance and metabolites, formed during or shortly after application, of toxicological concern	4.2.4			5.10	Yes	-

Point 4 Analytical Methods

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			

For each method:
 - Specificity (using a confirmatory method, if appropriate)
 - Repeatability
 - Limit of determination
 - Individual and mean recovery, overall standard deviation at each fortification level

IIA 4.8	Analytical methods for parent compound and toxicologically, ecotoxicologically or environmentally significant metabolites in body fluids and tissues	4.2.5	875.2600	235	5.5 5.7 8.2.2.4	Yes	5A-4.9
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For each method:
 - Specificity (using a confirmatory method, if appropriate)
 - Repeatability
 - Limit of determination
 - Individual and mean recovery, overall standard deviation at each fortification level

IIA 4.9	Other/special studies				2.16, 5.14, 7.8, 8.6	No	-
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Point 5 Toxicological and Toxicokinetic Studies on the Active Substance

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 5	Toxicological and Toxicokinetic Studies on the Active Substance	5					
IIA 5.1	Absorption, distribution, excretion and metabolism in mammals	5.1				Yes	
IIA 5.1.1	Toxicokinetic studies – Single dose, oral route, in rats	5.1	870.7485	85-1	4.5.9	Yes	4-5
IIA 5.1.2	Toxicokinetic studies – Second single dose, oral route, in rats	5.1	870.7485	85-1	4.5.9	Yes	4-5
IIA 5.1.3	Toxicokinetic studies – Repeated dose, oral route, in rats	5.1			4.5.9	No	4-5
IIA 5.2	Acute toxicity	5.2				Yes	
IIA 5.2.1	Acute oral toxicity	5.2.1	870.1100	81-1	4.2.1	Yes	3-4.2
IIA 5.2.2	Acute percutaneous toxicity	5.2.2	870.1200	81-2	4.2.2	Yes	3-4.2
IIA 5.2.3	Acute inhalation toxicity	5.2.3	870.1300	81-3	4.2.3	Yes	3-4.2
IIA 5.2.4	Skin irritation	5.2.4	870.2500	81-5	4.2.5	No	3-4.2
IIA 5.2.5	Eye irritation	5.2.5	870.2400	81-4	4.2.4	No	3-4.2
IIA 5.2.6	Skin sensitization	5.2.6	870.2600	81-6	4.2.6	Yes	3-4.2
IIA 5.2.7	Potentiation/interactions of multiple active substances or products				4.2.7	No	3-4.9(c)
IIA 5.3	Short-term toxicity	5.3				Yes	
IIA 5.3.1	Oral 28-day toxicity	5.3.1			4.3.3	No	3-4.3
IIA 5.3.2	Oral 90-day toxicity (rodents)	5.3.2	870.3100	82-1	4.3.1	Yes	3-4.4
IIA 5.3.3	Oral 90-day toxicity (dog)	5.3.2	870.3150	82-1	4.3.2	Yes	3-4.4

Point 5 Toxicological and Toxicokinetic Studies on the Active Substance

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 5.3.4	Oral 1 year toxicity (dog)	5.3.2	870.3150	82-1	4.3.2	Yes	3-4.5
IIA 5.3.5	28-day inhalation toxicity (rodents)	5.3.3			4.3.7	No	3-4.3
IIA 5.3.6	90-day inhalation toxicity (rodents)	5.3.3	870.3465	82-4	4.3.6	Yes	3-4.4
IIA 5.3.7	Percutaneous 28-day toxicity (rodents)	5.3.3	870.3200	82-2	4.3.5	Yes	3-4.3
IIA 5.3.8	Percutaneous 90-day toxicity (rodents)	5.3.3	870.3250	82-3	4.3.4	No	3-4.4
IIA 5.4	Genotoxicity	5.4				Yes	
IIA 5.4.1	<i>In vitro</i> genotoxicity testing – Bacterial assay for gene mutation	5.4.1	870.5100 870.5140 870.5250	84-2	4.5.4	Yes	3-4.8
IIA 5.4.2	<i>In vitro</i> genotoxicity testing – Test for clastogenicity in mammalian cells	5.4.1	870.5195 870.5200 870.5300	84-2	4.5.6	Yes	3-4.8
IIA 5.4.3	<i>In vitro</i> genotoxicity testing – Test for gene mutation in mammalian cells	5.4.1	870.5375 870.5900	84-2	4.5.5	Yes	3-4.8
IIA 5.4.4	<i>In vivo</i> genotoxicity testing (somatic cells) - Metaphase analysis in rodent bone marrow, or micronucleus test in rodents	5.4.2	870.5380 870.5385 870.5395 870.5915	84-2	4.5.7	Yes	3-4.8
IIA 5.4.5	<i>In vivo</i> genotoxicity testing (somatic cells) - Unscheduled DNA synthesis or a mouse spot test	5.4.2	870.5500 870.5550 870.5575	84-2	4.5.8	Yes	3-4.8
IIA 5.4.6	<i>In vivo</i> studies in germ cells	5.4.3	870.5275 870.5450 870.5460	84-2	4.5.8	Yes	3-4.8

Point 5 Toxicological and Toxicokinetic Studies on the Active Substance

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 5.5	Long-term toxicity and carcinogenicity	5.5				Yes	
IIA 5.5.1	Long-term (2 years) oral toxicity in the rat (can be a combined long-term and carcinogenicity study)	5.5	870.4100	83-1	4.4.1 4.4.4	Yes	3-4.5
IIA 5.5.2	Carcinogenicity study in the rat (can be a combined long-term and carcinogenicity study)	5.5	870.4200	83-2	4.4.2 4.4.4	Yes	3-4.5
IIA 5.5.3	Carcinogenicity study in the mouse	5.5	870.4200	83-2	4.4.3	Yes	3-4.5
IIA 5.5.4	Mechanism of action and supporting data	5.8.2			4.8	No	3-4.9
IIA 5.6	Reproductive toxicity	5.6				Yes	
IIA 5.6.1	Two generation reproductive toxicity in the rat	5.6.1	870.3800	83-4	4.5.1	Yes	3-4.6
IIA 5.6.2	Separate male and female studies	5.6.1	870.3800	83-4	4.8	No	3-4.6
IIA 5.6.3	Three segment designs	5.6.1			4.8	No	3-4.6
IIA 5.6.4	Dominant lethal assay for male fertility	5.6.1	870.5450	84-2	4.5.8	No	3-4.8
IIA 5.6.5	Cross-matings of treated males with untreated females and <i>vice versa</i>	5.6.1	870.3800	83-4	4.8	No	3-4.6
IIA 5.6.6	Effects on spermatogenesis	5.6.1	870.3800	83-4	4.8	Yes	3-4.9
IIA 5.6.7	Effects on oogenesis	5.6.1	870.3800	83-4	4.8	No	3-4.9
IIA 5.6.8	Sperm motility, mobility and morphology	5.6.1	870.3800	83-4	4.8	Yes	3-4.9

Point 5 Toxicological and Toxicokinetic Studies on the Active Substance

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 5.6.9	Investigation of hormonal activity	5.8.2			4.8	Yes	3-4.9
IIA 5.6.10	Teratogenicity test by the oral route in the rat	5.6.2	870.3700	83-3	4.5.2	Yes	3-4.7
IIA 5.6.11	Teratogenicity test by the oral route in the rabbit	5.6.2	870.3700	83-3	4.5.3	Yes	3-4.7
IIA 5.7	Neurotoxicity					Yes	
IIA 5.7.1	Acute neurotoxicity - rat	5.8.2	870.6200	81-8	4.5.12	Yes	3-4.9
IIA 5.7.2	Delayed neurotoxicity following acute exposure	5.7	870.6100	81-7	4.5.10	Yes	3-4.9
IIA 5.7.3	28-day delayed neurotoxicity	5.8.2	870.6100	82-6	4.5.11	Yes	3-4.9
IIA 5.7.4	Subchronic neurotoxicity - rat – 90 day	5.8.2	870.6200	82-7	4.5.13	Yes	3-4.9
IIA 5.7.5	Postnatal developmental neurotoxicity	5.8.2	870.6300	83-6	4.5.14	No	3-4.9
IIA 5.8	Toxicity studies on metabolites	5.8.1				Yes	3-4.9
IIA 5.9	Medical data	5.9				No	
IIA 5.9.1	Report on medical surveillance on manufacturing plant personnel	5.9.1				No	3-4.10
IIA 5.9.2	Report on clinical cases and poisoning incidents	5.9.2				No	3-4.10
IIA 5.9.3	Observations on exposure of the general population and epidemiological studies	5.9.3			5.12	No	3-4.10
IIA 5.9.4	Clinical signs and symptoms of poisoning and details of clinical tests	5.9.4				No	3-4.10

Point 5 Toxicological and Toxicokinetic Studies on the Active Substance

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 5.9.5	First aid measures	5.9.5			4.2.8	No	3-7
IIA 5.9.6	Therapeutic regimes	5.9.5			4.2.8	Yes	3-4.10
IIA 5.9.7	Expected effects and duration of poisoning as a function of the type, level and duration of exposure or ingestion	5.9.6				No	3-4.10
IIA 5.9.8	Expected effects and duration of poisoning as a function of varying time periods between exposure or ingestion and commencement of treatment	5.9.6				No	3-4.10
IIA 5.9.9	Dermal penetration	5.1	870.7600	85-3	5.8	No	4-5
IIA 5.10	Other/special studies	5.8.2			4.2.9, 4.3.8, 4.4.5, 4.5.8, 4.8	Yes <i>(i.e. pharmacology study)</i>	3-4.9
IIA 5.11	Summary of mammalian toxicity and overall evaluation	5.10			4.1	Yes	3-2.2

Point 6 Metabolism and Residues Data

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 6	Metabolism and Residues Data	6					
IIA 6.1	Stability of residues	6				Yes	
IIA 6.1.1	Stability of residues during storage of samples	6	860.1380	171-4	7.3	Yes	-
IIA 6.1.2	Stability of residues in sample extracts	6	860.1380	171-4		Yes	-
IIA 6.2	Metabolism, distribution and expression of residues		860.1300	171-4		Yes	-
IIA 6.2.1	In plants, in at least three crops representative of the different categories of crop (root vegetables; leafy crops; fruits; pulses and oilseed; cereals)	6.1	860.1300	171-4	6.3	Yes	-
IIA 6.2.2	Poultry	6.2	860.1300	171-4	6.2	No	-
IIA 6.2.3	Lactating ruminants (goat or cow)	6.2	860.1300	171-4	6.2	No	-
IIA 6.2.4	Pigs	6.2	860.1300	171-4	6.2	No	-
IIA 6.2.5	Nature of residue in fish		860.1400	171-4		No	-
IIA 6.2.6	Chemical identity (emphasis on impurities of residual concern)		860.1100	171-2	7.8	Yes	-
IIA 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	860.1500	171-4		No	-
IIA 6.3.1	Crop 1 (e.g. wheat)	6.3			7.4.1 7.4.2 7.4.6	No	-

Point 6 Metabolism and Residues Data

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 6.3.2	Crop 2 (<i>e.g.</i> oilseed rape)	6.3			7.4.1 7.4.2 7.4.6	No	-
IIA 6.3.3	Crop 3 (as required)	6.3			7.4.1 7.4.2 7.4.6	No	-
IIA 6.3.4	Crop 4, (<i>etc.</i>)	6.3			7.7	No	-
IIA 6.4	Livestock feeding studies	6.4	860.1480	171-4		Yes	-
IIA 6.4.1	Poultry	6.4	860.1480	171-4	7.5 7.6	Yes	-
IIA 6.4.2	Lactating ruminants (goat or cow)	6.4	860.1480	171-4	7.5 7.6	Yes	-
IIA 6.4.3	Pigs	6.4	860.1480	171-4	7.5 7.6 7.8	No	-
IIA 6.4.4	Fish		860.1480	171-4	7.8	No	-
IIA 6.5	Effects of industrial processing and/or household preparation (representative processing situations) on -	6.5.1	860.1520 (Industrial) 860.1520 (Household)	171-4		No	-
IIA 6.5.1	The nature of residue	6.5.1			7.4.5	No	-
IIA 6.5.2	Distribution of the residue in peel/pulp	6.5.2			7.4.5	No	-
IIA 6.5.3	Residue levels - balance studies on a core set of representative processes	6.5.2	860.1540	171-4	7.4.5	No	-
IIA 6.5.4	Residue levels - follow-up studies to determine concentration or dilution factors	6.5.2	860.1540	171-5	7.4.5	No	-
IIA 6.6	Residues in succeeding crops	6.6			7.4.4	Yes	-

Point 6 Metabolism and Residues Data

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 6.6.1	Theoretical consideration of the nature and level of the residue	6.6	860.1850	165-1	7.3.3 7.8	Yes	-
IIA 6.6.2	Metabolism and distribution studies on representative crops	6.6	860.1850	165-1	7.3.3 7.8	Yes	-
IIA 6.6.3	Field trials on representative crops	6.6	860.1900	165-2	7.3.2 7.8	Yes	-
IIA 6.7	Proposed residue definition and maximum residue levels	6.7				Yes	
IIA 6.7.1	Proposed residue definition	6.7				Yes	-
IIA 6.7.2	Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed, including details of statistical analyses used	6.7	860.1550	171-6	7.1 7.8	Yes	-
IIA 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	860.1200	171-3		No	-
IIA 6.8.1	Pre-harvest interval (in days) for each relevant crop	6.8	860.1200	171-3		No	-
IIA 6.8.2	Re-entry period (in days) for livestock, to areas to be grazed	6.8	860.1200	171-3		No	-
IIA 6.8.3	Re-entry period (in hours or days) for man to crops, buildings or spaces treated	6.8	860.1200	171-3		No	-
IIA 6.8.4	Withholding period (in days) for animal feedingstuffs	6.8	860.1200	171-3		No	-

Point 6 Metabolism and Residues Data

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 6.8.5	Waiting period (in days) between last application and sowing or planting the crops to be protected	6.8	860.1200	171-3		No	-
IIA 6.8.6	Waiting period (in days) between application and handling treated product	6.8	860.1200	171-3		No	-
IIA 6.8.7	Waiting period (in days) between last application and sowing or planting succeeding crops	6.8	860.1200	171-3	7.4.4	No	-
IIA 6.9	Estimation of the potential and actual exposure through diet and other means	6.9				Yes	-
IIA 6.9.1	TMDI calculations	6.9				Yes	-
IIA 6.9.2	NEDI calculations	6.9				No	-
IIA 6.9.3	NESTI calculations	6.9				No	-
IIA 6.10	Other/special studies				6.4, 7.8	No	-
IIA 6.11	Summary and evaluation of residue behaviour	6.10	860.1560	171-7	7.8	Yes	-
	Reasonable grounds in support of the petition						
IIA 6.11.1	Summary and evaluation of residue behaviour	6.10	860.1560	171-7			
IIA 6.11.2	Reasonable grounds in support of the petition		860.1560	171-7			

Point 7 Fate and Behaviour in the Environment

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 7	Fate and Behaviour in the Environment	7					
IIA 7.1	Route of degradation in soil – laboratory studies	7.1.1.1				Yes	-
IIA 7.1.1	Aerobic degradation	7.1.1.1.1	835.4100	162-1	8.2.3.4.2	Yes	-
IIA 7.1.2	Anaerobic degradation	7.1.1.1.2	835.4200	162-2	8.2.3.4.4	No	-
IIA 7.1.3	Soil photolysis	7.1.1.1.2	835.2410	161-3	8.2.3.3.1	No	-
IIA 7.2	Rate of degradation in soil(s) - laboratory studies	7.1.1.2.1				Yes	-
IIA 7.2.1	Aerobic degradation of the active substance in soils at 20°C	7.1.1.2.1	835.4100	162-1	8.2.3.4.2	Yes (at 25 - 30°C)	-
IIA 7.2.2	Aerobic degradation of the active substance in soil at 10°C	7.1.1.2.1			8.2.3.4.2	No	-
IIA 7.2.3	Aerobic degradation of relevant metabolites, degradation and reaction products in soils at 20°C	7.1.1.2.1	835.4100	162-1	8.2.3.4.2	Yes (at 25 - 30°C)	-
IIA 7.2.4	Anaerobic degradation of the active substance in soil	7.1.1.2.1	835.4200	162-2	8.2.3.4.4	No	-
IIA 7.2.5	Anaerobic degradation of relevant metabolites, degradation and reaction products in soil	7.1.1.2.1	835.4200	162-2	8.2.3.4.4	No	-
IIA 7.3	Field studies	7.1.1.2.2			8.3.2	No	-
IIA 7.3.1	Soil dissipation testing in a range of representative soils - (normally 4 soils)	7.1.1.2.2			8.3.2	No	-
IIA 7.3.2	Soil residue testing	7.1.1.2.2			8.3.2	No	-

Point 7 Fate and Behaviour in the Environment

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 7.3.3	Soil accumulation testing on relevant soils	7.1.1.2.2			8.3.2	No	-
IIA 7.4	Mobility studies						-
IIA 7.4.1	Adsorption and desorption of the active substance	7.1.2	835.1230	163-1	8.2.4.2	Yes	-
IIA 7.4.2	Adsorption and desorption of all relevant metabolites, degradation and reaction products	7.1.2	835.1230	163-1	8.2.4.2	No	-
IIA 7.4.3	Column leaching studies with the active substance	7.1.3.1	835.1240	163-1	8.2.4.3	No	-
IIA 7.4.4	Column leaching studies with relevant metabolites, degradation and reaction products	7.1.3.1	835.1240	163-1	8.2.4.3	No	-
IIA 7.4.5	Aged residue column leaching	7.1.3.2	835.1240	163-1	8.2.4.3.1	No	-
IIA 7.4.6	Leaching (TLC)				8.2.4.4	No	-
IIA 7.4.7	Lysimeter studies	7.1.3.3				No	-
IIA 7.4.8	Field leaching studies	7.1.3.3				No	-
IIA 7.4.9	Volatility - laboratory study	covered in part by 2.3.2			8.2.4.5	No	-
IIA 7.5	Hydrolysis rate of relevant metabolites, degradation and reaction products at pH values 4, 7 and 9 under sterile conditions, in the absence of light - identity of the hydrolysis products - rate constant observed - estimated DT ₅₀ value	7.2.1.1	835.2120	161-1	8.2.3.2	Yes	-

Point 7 Fate and Behaviour in the Environment

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 7.6	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 - photochemical half-life - mass balance to account for 90% of the applied radioactivity - identity of breakdown products - quantum yield of direct phototransformation - calculated theoretical lifetime in the top layer of aqueous systems and the real lifetime of the substance added	7.2.1.2	835.2240	161-2	8.2.3.3.2	Yes	-
IIA 7.7	Ready biodegradability of the active substance	7.2.1.3.1				No	-
IIA 7.8	Degradation in aquatic systems					No	-
IIA 7.8.1	Aerobic biodegradation in aquatic systems, including identification of breakdown products and metabolites		835.4300	162-4	8.2.3.5.2 8.2.3.5.4	No	-
IIA 7.8.2	Anaerobic biodegradation in aquatic systems, including identification of breakdown products and metabolites		835.4400	162-3	8.2.3.5.5 8.2.3.5.6	No	-
IIA 7.8.3	Water/sediment studies	7.2.1.3.2				No	-
IIA 7.9	Degradation in the saturated zone of the active substance, metabolites, degradation and reaction products	7.2.1.4				No	-

Point 7 Fate and Behaviour in the Environment

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 7.10	Rate and route of degradation in air	7.2.2	835.2370	161-4	8.2.3.3.3	No	-
IIA 7.11	Definition of the residue	7.3				No	-
IIA 7.12	Monitoring data concerning fate and behaviour of the active substance and of relevant metabolites, degradation and reaction products	7.4				No	-
IIA 7.13	Other/special studies				8.2.3.6, 8.2.4.6, 8.5, 8.6	No	-

Point 8 Ecotoxicological Studies on the Active Substance

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 8	Ecotoxicological Studies on the Active Substance	8					
IIA 8.1	Avian toxicity	8.1				No	-
IIA 8.1.1	Acute oral toxicity to a quail species (Japanese or Bobwhite), mallard duck, or other bird species	8.1.1	850.2100	71-1	9.6.2.1 9.6.2.2 9.6.2.3	No	-
IIA 8.1.2	Avian dietary toxicity (5-day) test in a quail species or in a mallard duck	8.1.2	850.2200	71-2	9.6.2.4 9.6.2.5	No	-
IIA 8.1.3	Avian dietary toxicity (5-day) test in a second unrelated species	8.1.2			9.6.2.6	No	-
IIA 8.1.4	Subchronic and reproductive toxicity to birds	8.1.3	850.2300	71-4	9.6.3.1 9.6.3.2 9.6.3.3	No	-
IIA 8.2	Fish toxicity	8.2.1 8.2.1 8.2.3				Yes	-
IIA 8.2.1	Acute toxicity of the active substance to fish	8.2.1	850.1075	72-1	9.5.2.1 9.5.2.2 9.5.2.3	Yes	-
IIA 8.2.1.1	Rainbow trout (<i>Oncorhynchus mykiss</i>) Analytical data on concentrations in the test media	8.2.1	850.1075	72-1	9.5.2.1 9.5.2.3	No	-
IIA 8.2.1.2	Warm water fish species Analytical data on concentrations in the test media	8.2.1	850.1075	72-1	9.5.2.2 9.5.2.3	Yes	-

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OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 8.2.1.3	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 Analytical data on concentrations in the test media	8.2.1				No	-
IIA 8.2.2	Chronic toxicity to fish	8.2.2					
IIA 8.2.3	Chronic toxicity (28 day exposure) to juvenile fish - growth and behaviour Analytical data on concentrations in the test media	8.2.2.1				No	-
IIA 8.2.4	Fish early life stage toxicity test Analytical data on concentrations in the test media	8.2.2.2	850.1400	72-4	9.5.3.1	No	-
IIA 8.2.5	Fish life cycle test Analytical data on concentrations in the test media	8.2.2.3	850.1500	72-5	9.5.3.2	No	-
IIA 8.2.6	Bioconcentration potential in fish	8.2.3					
IIA 8.2.6.1	Bioconcentration potential of the active substance in fish	8.2.3	850.1730	165-4	9.5.6	No	-
IIA 8.2.6.2	Bioconcentration potential of metabolites, degradation and reaction products	8.2.3	850.1730	165-4	9.5.6	No	-
IIA 8.2.7	Aquatic bioavailability/ biomagnification/depuration		850.1710 850.1850	72-6	9.4.8	No	-

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			OPPTS	OPP			
IIA 8.3	Toxicity to aquatic species other than fish and aquatic species field testing	8.2.4 8.2.5 8.2.6 8.2.7 8.2.8				Yes	-
IIA 8.3.1	Acute toxicity to aquatic invertebrates	8.2.4	850.1010	72-2	9.3.2 9.3.4	Yes	-
IIA 8.3.1.1	Acute toxicity (24 and 48 hour) for <i>Daphnia</i> preferably (<i>Daphnia magna</i>) Analytical data on concentrations in the test media	8.2.4	850.1010	72-2	9.3.2	Yes	-
IIA 8.3.1.2	Acute toxicity (24 and 48 hour) for representative species of aquatic insects Analytical data on concentrations in the test media	8.2.4			9.3.4	No	-
IIA 8.3.1.3	Acute toxicity (24 and 48 hour) for representative species of aquatic crustaceans (species unrelated to <i>Daphnia</i>) Analytical data on concentrations in the test media	8.2.4			9.3.4	No	-
IIA 8.3.1.4	Acute toxicity (24 and 48 hour) for representative species of aquatic gastropod molluscs Analytical data on concentrations in the test media	8.2.4				No	-
IIA 8.3.2	Chronic toxicity to aquatic invertebrates	8.2.5	850.1350	72-4	9.4.5	No	-

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			OPPTS	OPP			
IIA 8.3.2.1	Chronic toxicity in <i>Daphnia magna</i> (21-day) Analytical data on concentrations in the test media	8.2.5	850.1300	72-4	9.3.3	No	-
IIA 8.3.2.2	Chronic toxicity for representative species of aquatic insects Analytical data on concentrations in the test media	8.2.5			9.3.4	No	-
IIA 8.3.2.3	Chronic toxicity for representative species of aquatic gastropod molluscs Analytical data on concentrations in the test media	8.2.5	850.1350	72-4	9.4.5	No	-
IIA 8.3.3	Aquatic field testing		850.1950	72-7		No	-
IIA 8.4	Effects on algal growth and growth rate (2 species) Analytical data on concentrations in the test media	8.2.6	850.5400	123-2	9.8.2 9.8.3	Yes	-
IIA 8.5	Effects on sediment dwelling organisms	8.2.7	850.1735	73-1		No	-
IIA 8.5.1	Acute test Analytical data on concentrations in the test media	8.2.7	850.1735 850.1740	73-1 73-2		No	-
IIA 8.5.2	Chronic test Analytical data on concentrations in the test media	8.2.7				No	-

Point 8 Ecotoxicological Studies on the Active Substance

OECD data point number	Information, test or study	Former EU Annex IIA point number	US EPA Guideline/Requirement number		Canadian Data Code (DACO)	Japanese Data Code Yes / No	Australian Data Code
			OPPTS	OPP			
IIA 8.6	Effects on aquatic plants Analytical data on concentrations in the test media	8.2.8	850.4400	123-2	9.8.5	No	-
IIA 8.7	Effects on bees	8.3.1				Yes	-
IIA 8.7.1	Acute oral toxicity	8.3.1.1			9.2.4.2	Yes	-
IIA 8.7.2	Acute contact toxicity	8.3.1.1	850.3020	141-1	9.2.4.1	No	-
IIA 8.7.3	Toxicity of residues on foliage to honey bees		850.3030	141-2		No	-
IIA 8.7.4	Bee brood feeding test	8.3.1.2			9.2.4.3	No	-
IIA 8.8	Effects on non-target terrestrial arthropods	8.3.2				Yes	-
IIA 8.8.1	Effects on non-target terrestrial arthropods using artificial substrates	8.3.2				Yes	-
IIA 8.8.1.1	Parasitoid	8.3.2			9.2.6	Yes	-
IIA 8.8.1.2	Predatory mites	8.3.2			9.2.5	Yes	-
IIA 8.8.1.3	Ground dwelling predatory species (selected to be relevant to the intended uses of preparations)	8.3.2			9.2.5	Yes	-
IIA 8.8.1.4	Foliage dwelling predatory species (selected to be relevant to the intended uses of preparations)	8.3.2			9.2.5	Yes	-
IIA 8.8.2	Effects on non-target terrestrial arthropods in extended laboratory/semi-field tests	8.3.2				No	-
IIA 8.8.2.1	Parasitoid	8.3.2			9.2.6	No	-

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			OPPTS	OPP			
IIA 8.8.2.2	Predatory mites	8.3.2			9.2.5	No	-
IIA 8.8.2.3	Ground dwelling predatory species (selected to be relevant to the intended uses of preparations)	8.3.2			9.2.5	No	-
IIA 8.8.2.4	Foliage dwelling predatory species (selected to be relevant to the intended uses of preparations)	8.3.2			9.2.5	No	-
IIA 8.8.2.5	Other terrestrial invertebrates	8.3.2			9.2.7	No	-
IIA 8.9	Effects on earthworms	8.4					
IIA 8.9.1	Acute toxicity to earthworms	8.4.1			9.2.3.1	No	-
IIA 8.9.2	Sublethal effects on earthworms	8.4.2				No	-
IIA 8.10	Effects on soil microbial activity	8.5				No	-
IIA 8.10.1	Nitrogen transformation	8.5				No	-
IIA 8.10.2	Carbon mineralization	8.5				No	-
IIA 8.10.3	Rates of recovery following treatment	8.5				No	-
IIA 8.11	Effects on marine and estuarine organisms					No	-
IIA 8.11.1	Marine or estuarine organisms acute toxicity LC ₅₀ /EC ₅₀		850.1025 850.1035 850.1045 810.1055 810.1075	72-3	9.4.2 9.4.3 9.4.4	No	-
IIA 8.11.2	Marine/Estuarine fish - salinity challenge				9.5.2.4.1	No	-

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IIA 8.12	Effects on terrestrial vascular plants	8.6			9.8.4	No	-
IIA 8.13	Effects on terrestrial vertebrates other than birds / wild mammal toxicity		850.2400	71-3	9.7 9.7.1	No	-
IIA 8.14	Effects on other non-target organisms (flora and fauna) believed to be at risk	8.6					
IIA 8.14.1	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)	8.6				No	-
IIA 8.14.2	A critical assessment as to the relevance of the preliminary test data to potential impact on non-target species	8.6				No	-
IIA 8.15	Effects on biological methods for sewage treatment	8.7					-
IIA 8.16	Other/special studies	8					
IIA 8.16.1	Other/special studies - laboratory studies				9.3.4, 9.6.6, 9.9	No	-
IIA 8.16.2	Other/special studies - field studies				9.6.6, 9.9	No	-
IIA 8.17	Summary and evaluation of points IIA 7 and IIA 8.1 to 8.16	9					

Point 8 Ecotoxicological Studies on the Active Substance

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			OPPTS	OPP			

IIA 9 Proposals including justification for the proposals for the classification and labelling of the active substance:
 - hazard symbol(s)
 - indications of danger
 - risk phrases
 - safety phrases

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