PART 4

OECD, EU, US, CANADIAN, JAPANESE AND AUSTRALIAN NUMBERING SYSTEMS FOR DATA AND INFORMATION ON PHEROMONE AND OTHER SEMIOCHEMICAL 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 pheromone and semiochemical 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 pheromone and semiochemical 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 EU, US, Canadian, Japanese and Australian systems, is intended to facilitate industry in converting from numbering systems used nationally to the OECD numbering system. The numbering system to be used for data and information included in dossiers submitted to the regulatory authorities in Japan is currently being developed. In order to assist prospective applicants, an indication is included as to the data and information required in Japan.

3. 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.

4. The numbering system in this document is based on the "*Guidelines and Criteria for Industry for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for Plant Protection Products and their Active Substances in Support of Regulatory Decisions in OECD Countries*" (Please consult the OECD Pesticide Web site at **http://www.oecd.org/ehs/pesticid.htm** or contact the OECD Secretariat for the latest version of this document). The numbering system in *this* document is not sequential, as requirements that do not relate to pheromones have been removed. However, in an attempt to avoid confusion, and to illustrate parallel data requirements for plant protection products, the numbering system used for plant protection products is retained.

5. In the table that follows, R means that information is required; the requirement may be satisfied, subject to approval by the relevant national regulatory authority:

   a. by data on the test substance,
   b. by published information,
   c. by surrogate information or bridging data to another substance, if both substances belong to a well-known group of substances, e.g. Straight-Chained Lepidopteran Pheromones (SCLPs), or
   d. by a rationale to waive the requirement because it is unnecessary or impractical.

6. In the table that follows, CR means that the information is only required under the conditions stated. Many of the data points marked CR represent types of information that are only required for high exposure scenarios, or if hazards are noted from other data points.

7. In the table that follows, CR/R means that the information is only required under the conditions stated, for Canada, USA and Switzerland; and that the data point must be addressed in all submissions to European States, with the understanding that an appropriate basis for waiver rationale is in the right column.

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 1 **Identity of the Active Substance**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 1.1	Applicant (name, address, contact, telephone and telefax numbers)	R	1.1	Forms 8570-1(1), 8570-4(5)	Forms 8570-1(1), 8570-4(5)	1 2.1	Yes	2-4.2
IIP 1.2	Manufacturer(s) (name, address, contact, telephone and telefax numbers)	R	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)
IIP 1.3	ISO common name proposed or accepted, and synonyms	R	1.3			2.4	Yes	2-4.3(a)
IIP 1.4	Pheromone or Semio Chemical Name as in Annex I to Directive 67/548/EEC, if not included in that Annex, in accordance with IUPAC and CA, nomenclature if applicable	R	1.4	Form 8570-4(10) 880.1100	Form 8570-4(10) 151-10	2.5	Yes	2-4.3(a)

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

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				OPPTS [9]	OPP [10]			
IIP1.5.1	Manufacturer's code number(s), for the pheromone and semiochemical active substance and formulations, materials concerned, countries in which used and periods for which used	R	1.5	Form 8570-1(1)	Form 8570-1(1)	2.3.1	Yes	2-4.3(a)
IIP 1.5.2	Trade Name(s)	R		Form 8570-1 (1)	Form 8570-1 (1)	1 2.3	Yes	2-4.3(a)
IIP 1.5.3	Patent Status	R				2.10	Yes	-
IIP 1.7	Molecular formula, molecular mass and structural formula	R	1.7	880-1100	151-10	2.7 2.8 2.9	Yes	2-4.3(a)

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OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 1.8.1	Method of manufacture (pathways, by-products and impurities) for each plant, whether or not relevant to a pilot plant	R If AIC[1] is made by or for TGAI manufacturer. If AIC is purchased commercially, name & address of manufacturer & specifications describing its composition are required	1.8	880.1200 880.1400	151-11 151-12	2.11.1 2.11.3 2.11.4	Yes	2-4.3(e) 2-4.3(h)
IIP 1.8.2	Description of starting materials	R Same as above		880-1200	151-11	2.11.2	Yes	2-4.3(f)
IIP 1.9.3	Control Product Specification Form or Confidential Statement of Formula	R To 0.1% as far as is feasible		Form 8570-4(10) 880-1100	Form 8570-4(10) 151-10	2.12.2	No	2-4.3(j)

[1] AIC = Active Ingredient Component

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OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 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	R To 0.1% as far as is feasible	1.1	Form 8570-4(10) 880-1100 880-1400	Form 8570-4(10) 151-10 151-12	2.12.2 2.13.4	Yes	2-4.3(h)

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 1 **Identity of the Active Substance**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 1.11.1	Analytical profile of batches	R EU requires 5 batch data if feasible; Switzerland, US, Canada 3 production batches if feasible	1.11	830.1700		2.13.3	Yes	2-4.3(I)
IIP 1.11.2	Results of analyses of batches produced in laboratory or pilot scale production systems and used in toxicological testing	R Same as above	1.11	830.1700		2.13.3	Yes	2-4.3(I)
IIP 1.12	Other/special studies	CR				2.16	No	-

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 2 **Physical and Chemical Properties of the Active Substance**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 2.1.1	Melting' point, freezing point or solidification point of purified active substance	R	2.1.1	830.7200	63-5	2.14.4	Yes	2-4.3(b)
IIP 2.1.2	Boiling point of purified active substance	R	2.1.2	830.7220	63-6	2.14.5	Yes	2-4.3(b)
IIP 2.2	Relative density of purified active substance	R	2.2	Form 8570-4(7) 830.7300	Form 8570-4(7) 63-7	2.14.6	Yes	2-4.3(b)
IIP 2.3.1	Vapour pressure of purified active substance	R	2.3.1	830.7950	63-9	2.14.9	Yes	2-4.3(b)
IIP 2.3.2	Henry's law constant	R Calculated from vapour pressure and water solubility	2.3.2				No	2-4.3(b)
IIP 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 ingredient)	R	2.4.1	830.6302 830.6303	63-2 63-3	2.14.1 2.14.2	Yes	2-4.3(b)

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 2 **Physical and Chemical Properties of the Active Substance**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 2.4.2	Description of the odour of the purified active substance and active substance as manufactured	R	2.4.2	830.6304	63-4	2.14.3	Yes	2-4.3(b)
IIP 2.5.1.1	UV/VIS	R EU: required to estimate environmental fate. US / Canada / Switzerland: conditionally required for SCLPs if toxicity tests demonstrate hazard to biota	2.5.1	830.7050		2.14.12	Yes	2-4.3(b)
IIP 2.5.1.2	IR	R 1 of IR/ NMR/ MS to extent necessary to identify components	2.5.1			2.13.2	Yes	2-4.3(b)
IIP 2.5.1.3	NMR	R Same as above	2.5.1			2.13.2	Yes	2-4.3(b)
IIP 2.5.1.4	MS	R Same as above	2.5.1			2.13.2	Yes	2-4.3(b)
IIP 2.5.2.1	UV/VIS	See 2.5.1.1	2.5.2				No	2-4.3(g)
IIP 2.5.2.2	IR	See 2.5.1.2	2.5.2				No	2-4.3(g)
IIP 2.5.2.3	NMR	See 2.5.1.3	2.5.2				No	2-4.3(g)

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 2 **Physical and Chemical Properties of the Active Substance**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 2.5.2.4	MS	See 2.5.1.4	2.5.2				No	2-4.3(g)
IIP 2.6	Solubility of purified active substance in water • determined in the neutral range • determined in the acidic range (pH 4 to 6) • determined in the alkaline range (pH 8 to 10)	R	2.6	830.7840 830.7860	63-8	2.14.7	Yes	2-4.3(b)
IIP 2.7	Solubility in organic solvents at 15 to 25°C	R	2.7	830.7840 830.7860	63-8	2.14.8	Yes	2-4.3(b)
IIP 2.8.1	n-octanol/water partition coefficient	R May be waived if component hydrolyses in water or is soluble in water in all proportions	2.8	830.7550 830.7560 830.7570	63-11	2.14.11	Yes	2-4.3(b)
IIP 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	CR Required on a case-by-case basis, e.g. if ecotoxicity data or public literature indicate a hazard to biota	2.9.1	835.2110	161-1	8.2.3.2	Yes	2-4.3(b)

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 2 **Physical and Chemical Properties of the Active Substance**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 2.9.2	Direct phototransformation of purified active substance in water using artificial light (simulating sunlight and excluding wavelengths l < 290 nm) under sterile conditions, to include • photochemical half-life • mass balance to account for 90 % of the applied radioactivity • identity of breakdown products • dissociation constant(s) (pKa values) • identity of dissociated species formed • dissociation constant(s) (pKa values) of the active principle	CR Required on a case-by-case basis, e.g if ecotoxicity data or public literature indicate a hazard to biota R	2.9.2	835.2210	161-2	8.2.3.3.2	Yes	2-4.3(b)
IIP 2.17.2	Stability (temperature, metals)	R		830.6313	63-13	2.14.14	Yes	2-4.3(b)
IIP 2.18	Other/special studies	CR				2.16	No	-

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

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

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 3.1	Function *e.g.* fungicide	R	3.1	Form 8570-4(15) 860.1200	Form 8570-4(15) 171-2	10.2.1	Yes	1.2
IIP 3.3	Fields of use *e.g.* forestry	R	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
IIP 3.4.1	Details of existing and intended uses (crops, groups of crops, plants or plant products treated or protected)	R	3.4.1	860.1200	171-2	1	No	1.2
IIP 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	R	3.5.1			10.2.1	Yes	1.2
IIP 3.8.1.2	Detailed instructions for safe disposal	R	3.8.1	40 CFR 165.9 (a) - (d)	40 CFR 165.9 (a) - (d)	8.4.1	No	-
IIP 3.10	Other/special studies	CR				2.16 8.6 10.6	No	-

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 4 **Analytical Methods**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 4.1.1	Analytical standards for pure active substance	R	4	830.1800	64-1	2.15	Yes	2-4.3(g) 2-4.3(l)
IIP 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 For each method submitted, linearity over an appropriate range: • equation of the calibration line • correlation co-efficient • representative labelled documentation *e.g.* chromatograms	R	4.1.1	830.1800	62-3	2.13.1	Yes	2-4.3(g)

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 4 **Analytical Methods**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 4.2.1 (continued)	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							

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 4 **Analytical Methods**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 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 ^{3} 1 g/kg in 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	CR Only required if manufacturing methods and materials indicate potential for presence of a toxic impurity	4.1.2	830.1800	62-3	2.13.4	Yes	2-4.3(g)

Appendix 6 **Format for the listing of test and study reports and other documentation**

Part 4 **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 4 **Analytical Methods**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 4.2.3 (continued)	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							

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 4 **Analytical Methods**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 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	CR Required if use description information demonstrates significant exposure potential and/ or if toxicity tests or published data indicate a concern. Solid-matrix dispensers are unlikely to present significant exposure potential, but some sprayed applications might.	4.2.1	860.1300 860.1340 860.1360 830.1800	171-4a, b 171-4m	7.2.1 7.2.4	Yes	5A-4.9
IIP 4.9	Other/special studies	CR				2.16 5.14 7.8 8.6	No	

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 5 **Toxicological and Toxicokinetic Studies on the Active Substance**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 5.1.1	Toxicokinetic studies - Single dose, oral route, in rats	CR Trigger: required if tolerance/ MRL is required, i.e. if semiochemical is for use on food/ feed crops and if toxicity concern is raised by toxicity data	5.1	870.7485	85-1	4.5.9	Yes	4-5
IIP 5.2.1	Acute oral toxicity	R Data may be waived for TGAI if substance is a member of a well - characterized group e.g. SCLPs, & acute toxicity of that group is described	5.2.1	870.1100	81-1	4.2.1	Yes	3-4.2
IIP 5.2.2	Acute percutaneous toxicity	R See 5.2.1	5.2.2	870.1200	81-2	4.2.2	Yes	3-4.2
IIP 5.2.3	Acute inhalation toxicity	R See 5.2.1	5.2.3	870.1300	81-3	4.2.3	Yes	3-4.2
IIP 5.2.4	Skin irritation	R See 5.2.1	5.2.4	870.2500	81-5	4.2.5	No	3-4.2
IIP 5.2.5	Eye irritation	R See 5.2.1	5.2.5	870.2400	81-4	4.2.4	No	3-4.2

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 5 **Toxicological and Toxicokinetic Studies on the Active Substance**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 5.2.6	Skin sensitization	R Data may be waived as above (Canada, EU). US requires reporting of any hypersensitivity incidents, instead of test data.	5.2.6	870.2600	81-6	4.2.6	Yes	3-4.2
IIP 5.3.2	Oral 90-day toxicity (rodents)	CR/R Short-term study by appropriate route, required if there is a significant exposure potential, e.g. above background levels, or if a tolerance/ MRL will be set. Data may be waived if substance is a member of a well characterized group e.g. SCLPs and the repeated dose toxicity of that group is described	5.3.2	870.3100	82-1	4.3.1	Yes	3-4.4
IIP 5.3.6	90-day inhalation toxicity (rodents)	CR/R See 5.3.2	5.3.3	870.3465	82-4	4.3.6	Yes	3-4.4
IIP 5.3.8	Percutaneous 90-day toxicity (rodents)	CR/R See 5.3.2	5.3.3	870.3250	82-3	4.3.4	No	3-4.4

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 5 **Toxicological and Toxicokinetic Studies on the Active Substance**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 5.4.1	In vitro genotoxicity testing - Bacterial assay for gene mutation	R Data may be waived if substance is a member of well characterized group e.g. SCLPs and the mutagenicity of that group is described.	5.4.1	870.5100	84-2	4.5.4	Yes	3-4.8
IIP 5.4.3	*In vitro* genotoxicity testing - Test for gene mutation in mammalian cells	R Data may be waived if substance is a member of well characterized group e.g. SCLPs and the mutagenicity of that group is described.	5.4.1	870.5300 870.5375 870.5550	84-2	4.5.6	Yes	3-4.8
IIP 5.5.1	Long-term (2 years) oral toxicity in the rat (can be a combined long-term and carcinogenicity study)	CR Trigger: adverse effects in mutagenicity or short-term studies; waived if long term exposure above background can be excluded	5.5	870.4100	83-1	4.4.1 4.4.4	Yes	3-4.5
IIP 5.5.2	Carcinogenicity study in the rat (can be a combined long-term and carcinogenicity study)	CR See above	5.5	870.4200	83-2	4.4.2 4.4.4	Yes	3-4.5
IIP 5.5.4	Mechanism of action and supporting data	R	5.5				No	3-4.9

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 5 **Toxicological and Toxicokinetic Studies on the Active Substance**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 5.6.1	Two generation reproductive toxicity in the rat	CR Trigger: adverse effects or toxicity concerns arising from other data points for Health Risk	5.6.1	870.3800	83-4	4.5.1	Yes	3-4.6
IIP 5.6.2.1	Teratogenicity test by the oral route in the rat	CR/R Required if there is significant exposure potential e.g. above background levels, or if a tolerance/ MRL will be set. Data may be waived if substance is a member of well characterized group e.g. SCLPs and repeated dose toxicity of group is described.	5.6.2	870.3700	83-3	4.5.2	Yes	3-4.6
IIP 5.6.2.2	Teratogenicity test by the oral route in the rabbit	CR Trigger: adverse effects in mutagenicity or short-term studies: waived if long term exposure above background can be excluded.	5.6.2	870.3700	83-3	4.5.3	Yes	3-4.6

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OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 5.7.1	Acute neurotoxicity - rat	CR Trigger: adverse effects or toxicity concerns arising from other data points for Health Risk		870.6200	81-8	4.5.12	Yes	3-4.9
IIP 5.9.7	Dermal penetration	CR Required if use description information demonstrates significant exposure potential &/or if toxicity tests or published data indicate a concern. Solid matrix dispensers are unlikely to present significant exposure potential, but some sprayed applications might.		870.7600	85-3	5.8	No	3-4.10
IIP 5.10	Other/special studies	CR	5.8.2			4.2.9 4.3.8 4.4.5 4.5.8 4.5.12 4.8 5.1.4 10.3.2	Yes (*i.e. pharmacology study*)	3-4.9

Appendix 6 **Format for the listing of test and study reports and other documentation**

Part 4 **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 5 **Toxicological and Toxicokinetic Studies on the Active Substance**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 5.11	Summary of mammalian toxicity and overall evaluation	R	5.1				Yes	3-2.2

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 6 **Metabolism and Residues Data (not normally required)**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 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	CR Trigger: required if tolerance/ MRL is required i.e. if semiochemical is for use on food/ feed crops and if toxicity concern is raised by toxicity data.	6.3	860.1500	171-4		No	-
IIP 6.3.4	Tobacco	CR Trigger: required if tolerance/ MRL is required i.e. if semiochemical is for use on food/ feed crops and if toxicity concern is raised by toxicity data.				7.7	No	-
IIP 6.4.1	Poultry and/or lactating ruminants (goat or cow)	CR Trigger: required if tolerance/ MRL is required i.e. if semiochemical is for use on food/ feed crops and if toxicity concern is raised by toxicity data.	6.4	860.1480	171-4©)	7.5 7.6	Yes	-

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Point 6 **Metabolism and Residues Data (not normally required)**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 6.6	Residues in succeeding crops	CR Trigger: required if tolerance/ MRL is required i.e. if semiochemical is for use on food/ feed crops and if toxicity concern is raised by toxicity data.	6.6			7.4.4	Yes	-
IIP 6.6.2	Metabolism and distribution studies on representative crops	CR Trigger: required if tolerance/ MRL is required i.e. if semiochemical is for use on food/ feed crops and if toxicity concern is raised by toxicity data.	6.6	860.1850	165-1	7.3.3 7.8	Yes	-
IIP 6.8.1	Pre-harvest interval (in days) for each relevant crop	CR	6.8	860.1200	171-3		No	-
IIP 6.10	Other/special studies	CR				6.4 7.8	No	-

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 7 **Fate and Behaviour in the Environment**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 7.4.1	Adsorption and desorption of the active substance	CR Required on a case-by-case basis e.g. if ecotoxicity data or public literature indicate a hazard to biota	7.1.2		163-1	8.2.4.2	Yes	-
IIP 7.4.3	Column leaching studies with the active substance	CR Required on case-by-case basis e.g. if ecotoxicity data or public literature indicate a hazard to biota.	7.1.3.1		163-1	8.2.4.3	No	-
IIP 7.4.9	Volatility - laboratory study	CR Required on case-by-case basis e.g. if ecotoxicity data or public literature indicate a hazard to biota.				8.2.4.5	No	-

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 7 **Fate and Behaviour in the Environment**

OECD data point number	Information, test or study	R or CR	EUAnnex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 7.6	Direct phototransformation of relevant metabolites, degradation and reaction products in water using, artificial light (simulating sunlight and excited wavelengths l < 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	CR Required on case-by-case basis e.g. if ecotoxicity data or public literature indicate a hazard to biota	7.2.1.2	835.2210	161-2	8.2.3.3.2	Yes	-

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OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 7.12	Monitoring data concerning fate and behaviour of the active substance and of relevant metabolites, degradation and reaction products	R EU requirement: may be waived if exposure is unlikely to exceed natural background levels (e.g. at > 375 g ai/ha/yr for SCLPs)	7.4				No	-
IIP 7.13	Other/special studies	CR				8.2.3.6 8.2.4.6 8.5 8.6	No	-

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Point 8 **Ecotoxicological Studies on the Active Substance**

OECD data point number	Information, test or study	R or CR	EUAnnex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 8.1.2	Avian dietary toxicity (5-day) test in a quail species or in a mallard duck	CR Required if an EP could be ingested by birds e.g. a granular EP	8.1.2	850.2100	71-2	9.6.2.4 9.6.2.5	No	-
IIP 8.2.1	Acute toxicity of the active substance to fish	CR/R Prefer EP	8.2.1	850.1075	72-1	9.5.2.1 9.5.2.2 9.5.2.3	Yes	-
IIP 8.3	Aquatic species other than fish and aquatic species field testing	CR Required on case-by-case basis when results of acute tests, observations from efficacy trials or literature indicate potential adverse effects and results of environmental fate tests indicate exposure of non-target organisms. Testing might include: bioaccumulation studies, chronic toxicology in freshwater invertebrates, long-term toxicology in freshwater fish.						-

Appendix 6 **Format for the listing of test and study reports and other documentation** **Part 4** **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Active Substances and Japanese Data and Information Requirements**

Point 8 **Ecotoxicological Studies on the Active Substance**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 8.3.1	Acute toxicity to aquatic invertebrates	CR/R Prefer EP; Required if applied by air, or directly to water, or at rate exceeding natural background levels, e.g > 375 g ai/ha/yr for SCLPs. Not required for product in affixed dispensers on land. However, data may be required by EU for labeling (directive 67/ 565).	8.2.4	850.1010	72-2	9.3.2 9.3.4	Yes	-
IIP 8.4	Effects on algal growth and growth rate (2 species) Analytical data on concentrations in the test media	CR/R Prefer EP; EU requirement: waived for EPs in affixed dispensers on land; may be waived if exposure is unlikely to exceed natural background levels (e.g. at >375 g ai/ha/yr for SCLPs). Data may be required by EU for labeling (directive 67/ 565) although waivable based on structure-activity relationships	8.2.6		123-2	9.8.2 9.8.3	Yes	-

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OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 8.6	Effects on aquatic plants Analytical data on concentrations in the test media	See 8.3	8.2.8	850.4400	123-2	9.8.5	No	-
IIP 8.7	Bees	CR/R Prefer EP; Information / discussion, to address whether behaviour or reproduction would be affected, is required if exposure is likely to exceed natural background levels e.g. >375 g ai/ha/yr for SCLPs.	8.3.1.1				Yes	-
IIP 8.8	Non-target terrestrial arthropods	CR/R Prefer EP; Information / discussion, to address whether behaviour or reproduction would be affected, is required if exposure is likely to exceed natural background levels e.g. >375 g ai/ha/yr for SCLPs		880.4350	154-11			-

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OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 8.8.2	Effects on non-target terrestrial arthropods in extended laboratory/semi-field tests	See 8.3	8.3.2				No	-
IIP 8.8.2.5	Other terrestrial invertebrates	CR				9.2.7	No	-

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Point 8 **Ecotoxicological Studies on the Active Substance**

OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 8.9	Earthworms	CR/R EU requirement if product is applied to soil and can accumulate in soil. Required if exposure exceeds natural background levels (e.g. at >375 g ai/ha/yr for SCLPs)						-
IIP 8.10	Soil microbial activity	CR/R EU requirement if product is applied to soil and can accumulate in soil. Required if exposure exceeds natural background levels (e.g. at >375 g ai/ha/yr for SCLPs)	8.5				No	-
IIP 8.12	Terrestrial vascular plants	See 8.3		850.4000		9.8.4	No	-

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OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 8.13	Effects on terrestrial vertebrates other than birds / wild mammal toxicity	CR Required on case-by-case basis, when results of acute tests, observations from efficacy trials or literature indicate potential advserse effects and results of environmental fate tests indicate exposure of non-target organisms.		850.2400	71-3	9.7 9.7.1	No	-

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OECD data point number	Information, test or study	R or CR	EU Annex IIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) [11]	Japanese data requirement Yes / No [12]	Australian data requirement Yes / No [12]
				OPPTS [9]	OPP [10]			
IIP 8.16.1	Other/special studies - laboratory studies	CR				9.3.4 9.6.6 9.9	No	
IIP 8.16.2	Other/special studies - field studies	CR				9.6.6 9.9	No	-

[9] Office of Pollution Prevention and Toxics of the US Environmental Protection Agency - This column includes the new EPA-harmonized guidelines for recommended study protocols in the 8xx.xxxx series, which are now available from the EPA Web Site at http://www.epa.gov/OPPTS_Harmonized/.

[10] Office of Pesticide Programs of the US Environmental Protection Agency - This column includes the old pesticide guideline numbers.

[11] Data code used by the Canadian Pest Management Regulatory Agency

[12] Data point numbering system being developed