

## PART 5

### OECD, EU, US, CANADIAN, JAPANESE AND AUSTRALIAN NUMBERING SYSTEMS FOR DATA AND INFORMATION ON PHEROMONE AND OTHER SEMIOCHEMICAL FORMULATED PRODUCTS

1. As indicated in subparagraph 3.2.1 xviii, the numbering systems used in many OECD countries for the data and information relating to formulated products 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 formulated products 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:
  1. by data on the test substance,
  2. by published information,
  3. by surrogate information or bridging data to another substance, if both substances belong to a well-known group of substances, e.g. Straight-Chain Lepidopteran

4.      Pheromones (SCLPs), or  
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 5** OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Formulated Products

Point 1 OECD data point number	Identity of the Plant Protection Product Information, test or study	R or CR	EU Annex IIIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>
				OPPTS <sup>13</sup>	OPP <sup>14</sup>			
IIIP 1.1	Applicant (name, address, R contact, telephone and telefax numbers)	R	1.1	Forms 8570-1(5), 8570-4(1)	Forms 8570-1(5), 8570-4(1)	3.1.1	Yes	1.2
IIIP 1.2.1	Manufacturer(s) of the preparation (name, address, contact, telephone and telefax numbers)	R	1.2	Forms 8570-1(1), 8570-4(2)	Forms 8570-1(1), 8570-4(2)	3.1.2	Yes	25.2(f)
IIIP 1.2.2	Manufacturer(s) of the active substance(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	2-5.1
IIIP 1.2.3	Statement of purity (and detailed information on impurities) of the active substance	R	1.2	Forms 8570-4(13)	Forms 8570-4(13)	3.2.1	Yes	2-5.1

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

**Part 5**      **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Formulated Products**

<b>Point 1</b> OECD data point number	<b>Identity of the Plant Protection Product</b>				EU Annex IIIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>
	Information, test or study	R or CR	OPPTS <sup>13</sup>	OPP <sup>14</sup>						
IIIP 1.3	Trade name or proposed trade name and manufacturers code number(s), for the preparation and similar preparations (differences to be specified)	R			1.3	Forms 8570-1(1), 8570-1(4), 8570-4(3), 8570-4(10)	Forms 8570-1(1), 8570-1(4), 8570-4(3), 8570-4(10)	3.1.3 3.1.4	Yes	1.2
IIIP 1.4.1	Contents of: · Technical active substance · Pure active substance · Formulants	R			1.4.1	Form 8570-4(13) 880.1100	Form 8570-4(13) 151-10	3.3.3	Yes	2-5.2(d)
IIIP 1.4.2.1	ISO common name proposed or accepted for active substances, and synonyms	R			1.4.2			3.3.3	Yes	2-5.2(e)

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				OPPTS <sup>13</sup>	OPP <sup>14</sup>			

IIIP 1.4.4.3	For each formulant, or component in formulants	R	1.4.3	Form	Form	3.2.1	Yes	2-5.2(d)
	% w/w of all ingredients			8570-4(10)	8570-4(10)	3.3.1		
	· Chemical name as in Annex I to Directive 67/548/EEC, if not included in that Annex, in accordance with IUPAC and CA nomenclature			8570-4(15)	8570-4(15)	3.3.3		
	· Structure or structural formula			880.1100	151-10			

- Existing CAS, CIPAC, EINECS and ELINCS numbers
- Trade name
- Specification of the formulant
- Function of each formulant

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				OPPTS <sup>13</sup>	OPP <sup>14</sup>			

IIIP 1.4.4.1	Description of formulation process	R		880.1100	61-2	3.2.2	Yes	2-5.2(d)
	Required by US, Canada, Switzerland				151-10			

IIIP 1.4.4.2	Discussion of the	R		880.1400	61-3	3.2.3	Yes	2-5.2(d)
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formation of impurities of % w/w to 0.1% of toxicological concern  
 impurities of toxicological concern

151-12

IIIP 1.7	Other/special studies	CR		3.7	No	-
				10.6		

**Point 2** Physical, Chemical and Technical Properties of the Plant Protection Product

OECD data point number	Information, test or study	R or CR	EU Annex IIIA point number		US EPA Guideline / Requirement number	Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>
			OPPTS <sup>13</sup>	OPP <sup>14</sup>				
IIIP 2.1	Description of the physical state of the preparation (formulation) and its colour and odour	To be addressed where applicable	2.1	830.6303 830.6304	63-2 63-3	3.5.1 3.5.2 3.5.3	Yes	2-5.2(e)
IIIP 2.2.1	Explosive properties of the preparation	R See 2.1	2.2.1	830.6316	63-16	3.5.12	Yes	2-5.2(e)
IIIP 2.4.1	Acidity or alkalinity and pH value	R See 2.1	2.4.1	830.7	63-12	3.5.7	Yes	2-5.2(e)
IIIP 2.5.2	Viscosity of the preparation and details of the test conditions	R See 2.1	2.5.2	830.71	63-18	3.5.9	Yes	2-5.2(e)
IIIP 2.7.2	Stability after storage for other periods and/or temperatures	R Stability of formulation during storage not required by US	2.7.1	830.6317	63-17	3.5.10	Yes	2-5.2(k)
IIIP 2.13	Corrosion characteristics	R Stability of formulation during storage not required by US		830.632	63-20	3.5.14	No	2-5.2(e)

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IIIP 2.14	Container Material	R	To be addressed where applicable	Form 8570-1(2)	Form 8570-1(2)	3.5.5	Yes	2-5.2(m)	
<b>Point 3</b>									
OECD data point number	Information, test or study	R or CR	EU Annex IIIA point number	US EPA Guideline / Requirement number	US EPA Guideline / Requirement number	Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>	
IIIP 3.1	Fields of use e.g. forestry	R	3.1	40CFR 156.10 (i)(c)(2)(iii) 860.1200	40CFR 156.10 (i)(c)(2)(iii) 171-2	10.2.2	Yes	8-3.3	
IIIP 3.4	Rate of application per unit treated (ha, m <sup>2</sup> , m <sup>3</sup> , tonne) treated, in terms of g or kg of preparation and active substance	R	3.4	860.1200	171-2	1 5.2 10.2.3.1 10.2.3.2 10.2.3.3	Yes	8-3.3	
IIIP 3.6	Description of the method of application, type of equipment used and type and volume of diluent per unit of area or volume	R	3.6	860.1200	171-2	1 5.2 10.2.3.1 10.2.3.2 10.2.3.3	Yes	8-3.3	
IIIP 3.7.1	Maximum number of applications and their timing	R	3.7	860.1200	171-2	1 5.2 10.2.3.1 10.2.3.2 10.2.3.3	Yes	8-3.3	
IIIP 3.9	Proposed instructions for use as printed, or to be printed, on labels	R	3.9	40CFR 156.10 (i) 860.1200	171-2	1	Yes	1-3.5	
IIIP 3.10	Other/special studies	CR				5.14 10.6	No	8-6.1 to	

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8-6.7

**Point 4 Further Information on the Plant Protection Product**

OECD data point number	Information, test or study	R or CR	EU Annex IIIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>
				OPPTS <sup>13</sup>	OPP <sup>14</sup>			
IIIP 4.1.2	Suitability of the packaging and closures · Strength · Leakproofness · Resistance to normal transport and handling	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.	4.1.2			5.13	No	2-5.2(m)
IIIP 4.2.1	Procedures for cleaning application equipment and protective clothing	R	4.2	40CFR 156.10 (i)(c)(2)(viii)		5.2	Yes	-
IIIP 4.3.1	Pre-harvest interval (in days) for each relevant crop	R	4.3.1	40CFR 156.10 (i)(c)(2)(x)(a) 860.1200	171-3		Yes	Residue Guideline 10



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**Point 4 Further Information on the Plant Protection Product**

OECD data point number	Information, test or study R or CR	EU Annex IIIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>
			OPPTS <sup>13</sup>	OPP <sup>14</sup>			
IIIP 4.8.1	Detailed instructions for safe disposal of the plant protection product and its packaging	4.6.2		OPP	8.5.2	Yes	7.1.10
IIIP 4.9	Other/special studies				3.7 5.14 8.6	No	-

**Point 5 Methods of Analysis**

OECD data point number	Information, test or study R or CR	EU Annex IIIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>
			OPPTS <sup>13</sup>	OPP <sup>14</sup>			
IIIP 5.1.2	Analytical standards for pure active substance	5	830.1800	64-1 171-13	3.6	Yes	-
IIIP 5.9	Other/special studies				3.7 5.14 7.8 8.6	No	-

**Point 6 Efficacy Data and Information (including Value Data)**

OECD data point number	Information, test or study R or CR	EU Annex IIIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>
			OPPTS <sup>13</sup>	OPP <sup>14</sup>			
IIIP 6.1.3	Efficacy trials: operational, large scale	6.2			10.2.3.4	Yes	8-4
IIIP 6.2.1	Phytotoxicity to host crop	6.5			10.3.2	Yes	8-5.2

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IIIP 6.2.3 Adverse effects on site of R application (discoloration, corrosion, etc.) 10.3.2 Yes 8-5.2

IIIP 6.2.4 Adverse effects on beneficial organisms CR/R Info/ 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 6.6.4 Yes 8-6.4

**Point 6** Efficacy Data and Information (including Value Data)

OECD data point number	Information, test or study	R or CR	EU Annex IIIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>
				OPPTS <sup>13</sup>	OPP <sup>14</sup>			

IIIP 6.2.7 Impact on other plants including adjacent crops CR 6.6.2

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.

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IIIP 6.4.2	Compatibility with current management practices including IPM	R	May be addressed by qualitative description						10.5.2	No	8-4.5
IIIP 6.4.3	Contribution to risk reduction	R	See 6.4.2						10.5.4	No	-

**Point 7** Toxicological Studies and Exposure Data and Information

OECD data point number	Information, test or study	R or CR	EU Annex IIIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>
				OPPTS <sup>13</sup>	OPP <sup>14</sup>			
IIIP 7.1.1	Acute oral toxicity	R	7.1.1	870.1100	81-1	4.6.1	Yes	3-4.2
	Data may be waived for EP if toxic potential of formulators are well known							
IIIP 7.1.2	Acute percutaneous (dermal) toxicity	R	7.1.2	870.1200	81-2	4.6.2	Yes	3-4.2
IIIP 7.1.3	Acute inhalation toxicity to rats	R	7.1.3	870.1300	81-3	4.6.3	Yes	3-4.2
IIIP 7.1.4	Skin irritation	R	7.1.4	870.2500	81-5	4.6.5	Yes	3-4.2
IIIP 7.1.5	Eye irritation	R	7.1.5	870.2400	81-4	4.6.4	Yes	3-4.2
IIIP 7.1.6	Skin sensitization	R	7.1.6	870.2600	81-6	4.6.6	Yes	3-4.2
	Data may be waived as above (Canada, EU). US requires reporting of any hypersensitivity incidents, instead of test data							

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**Point 7 Toxicological Studies and Exposure Data and Information**

OECD data point number	Information, test or study	R or CR	EU Annex IIIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>
				OPPTS <sup>13</sup>	OPP <sup>14</sup>			
IIIP 7.3.3	Measurement of operator exposure  (Mixer / Loader / Applicator)	CR Required if use description info 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	7.2.1.2	875.1100 875.1200 875.1300 875.1400 875.1500	OPP	5.4 5.5 5.11	No	6-7.5
IIIP 7.4.1	Estimation of bystander exposure assuming personal protective equipment is not used	R Estimation of exposure based on available info (application method, rate, physicochemical properties)	7.2.2	Optional	Optional	5.6 5.7 5.9 5.10	No	-
IIIP 7.5.2	Estimation of worker exposure assuming personal protective equipment is used	CR See 7.3.3	7.2.3.1	Optional	Optional	5.6 5.7 5.9 5.10	No	6-6.2
<b>Point 7</b>	<b>Toxicological Studies and Exposure Data and Information</b>							
OECD data point number	Information, test or study	R or CR	EU Annex IIIA point number	US EPA Guideline / Requirement number	OPP <sup>14</sup>	Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>
IIIP 7.5.3	Estimation of worker exposure assuming	CR- see 7.3.3	7.2.3.1	Optional	Optional	5.6 5.7	No	6-6.2

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IIIIP 7.6.1	personal protective equipment is used and using data generated on dislodgeable residues under the proposed conditions of use			5.9 5.10							
IIIIP 7.6.1	Dermal absorption, <i>in vivo</i> CR See 7.3.3	7.3	870.76	85-3	5.8	No				4-5	
IIIIP 7.6.2	Comparative dermal absorption, <i>in vitro</i> using rat and human skin	7.3			5.8	No				4-5	
IIIIP 7.8	Epidemiology				5.12	No				3-4.9	
IIIIP 7.10	Domestic animal/livestock safety Trigger: required if a tolerance/ MRL is required, i.e. if semiochemical is for use on food/feed crops and if a toxicity concern is raised by toxicity data		870.72	85-2	10.3.2	No				8-6.4	

**Point 7** Toxicological Studies and Exposure Data and Information

OECD data point number	Information, test or study	R or CR	EU Annex IIIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>
				OPPTS <sup>13</sup>	OPP <sup>14</sup>			

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IIIP 7.1.1	Other/special studies	CR							4.6.8 4.7.7 4.8 5.14	No	3-4.9
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**Point 8** Metabolism and Residues Data (not normally required)

OECD data point number	Information, test or study	R or CR	EU Annex IIIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>
				OPPTS <sup>13</sup>	OPP <sup>14</sup>			
IIIP 8.2	Supplementary studies on metabolism, distribution and expression of residues in plants or livestock	CR	8.1	860.1300	171-4	6.2 6.3 6.4 7.5 7.6 7.8	Yes	5A-4.6 Residue Guideline 1
IIIP 8.4.1	Poultry and/or lactating ruminants (goat or cow)	CR	8.3	860.1300	171-4	6.2 7.5 7.6	Yes	Residue Guideline 1
IIIP 8.4.2	Pigs	CR	8.3	860.1300	171-4	6.2 7.5 7.6	No	Residue Guideline 1

**Point 9** Fate and Behaviour in the Environment

OECD data point number	Information, test or study	R or CR	EU Annex IIIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>
				OPPTS <sup>13</sup>	OPP <sup>14</sup>			
IIIP 9.3.1	Column leaching	CR	9.1.2.1			8.2.4.3	No	7-1.6
IIIP 9.3.4	Volatility - laboratory study	CR		163-2		8.2.4.5	No	7-1.6

Required on case-by-case basis e.g. if ecotoxicity data or public literature indicate a hazard to biota.

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**Point 10 Ecotoxicological Studies on the Plant Protection Product**

OECD data point number	Information, test or study	R or CR	EU Annex IIIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>16</sup>	Australian data requirement Yes / No <sup>12</sup>
				OPPTS <sup>13</sup>	OPP <sup>14</sup>			
IIIP 10.1	Birds	CR Dietary toxicity required if an EP could be ingested by birds, e.g. a granular EP	10.1				No	7-2.3
IIIP 10.2.1.11	TER <sub>LT</sub> for algae	CR/R EU requirement: waived for EPs in affixed dispensers on land; may be waived if exposure 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.	10.2			9.8.6	No	7-2.7
IIIP 10.2.2.1	Fish acute toxicity LC <sub>50</sub> , freshwater, cold-water species	CR/R	10.2.1	850.1075	72-1	9.5.4	Yes	7-2.4

  

<b>Point 10 Ecotoxicological Studies on the Plant Protection Product</b>								
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				OPPTS <sup>13</sup>	OPP <sup>14</sup>			
IIIP 10.3	Terrestrial vertebrates other than birds	CR Required on case-by-case	10.3				No	7-2.3

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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.

**IIIP 10.4**      **Bees**      **CR/R**      **Info/ 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**      **7-2.7**

**IIIA 10.5**      **Arthropods other than bees**      **CR/R**      **See 10.4**      **10.5**      **7-2.5**

**Point 10 Ecotoxicological Studies on the Plant Protection Product**

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				OPPTS <sup>13</sup>	OPP <sup>14</sup>	Yes / No <sup>16</sup>	Yes / No <sup>12</sup>
IIIP 10.6	Earthworms and other soil macro-organisms	CR/R	10.6			No	7-2.5
	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)						
IIIP 10.7	Soil microbial activity	CR/R	10.7			No	7-2.5
	See 10.6						
IIIP 10.8	Effects on non-target plants	CR				Yes	7-2.6
	See 10.3						

**Point 10 Ecotoxicological Studies on the Plant Protection Product**

OECD data point number	Information, test or study	R or CR	EU Annex IIIA point number	US EPA Guideline / Requirement number		Canadian Data Code (DACO) <sup>15</sup>	Japanese data requirement Yes / No <sup>12</sup>	Australian data requirement Yes / No <sup>12</sup>
				OPPTS <sup>13</sup>	OPP <sup>14</sup>			
IIIP 10.10.2	Other/special studies - field studies	CR					No	7-2.7
						9.2.9		
						9.3.6		
						9.4.7		
						9.5.5		
						9.6.5		
						9.6.6		
						9.7.2		
						9.8.7		
						9.9		

**Appendix 6**      **Format for the listing of test and study reports and other documentation**      **Part 5**      **OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Pheromone and other Semiochemical Formulated Products**

- 13      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 8x.x.xxx series, which are now available from the EPA Web Site at [http://www.epa.gov/OPPTS\\_Harmonized/](http://www.epa.gov/OPPTS_Harmonized/).
- 14      Office of Pesticide Programs of the US Environmental Protection Agency - This column includes the old pesticide guideline numbers.
- 15      Data code used by the Canadian Pest Management Regulatory Agency
- 12      Data point numbering system being developed