

APPENDIX 8

FORMAT FOR THE LISTING OF TEST AND STUDY REPORTS AND OTHER DOCUMENTATION RELIED ON

(Annex B - list of information tests and studies relied on by the Regulatory authority)

- 1 As indicated in paragraph 4.6.9, a listing of the studies relied on by the regulatory authority should be included at the end of each chapter of the Annex B summary, evaluation and assessment of the data and information considered. The listing should include only those test and study reports, test guidelines, and published papers relied on by the regulatory authority in reaching its conclusions, whether submitted in support of the application (Documents J, K and L and where relevant I) or, consisting of other relevant information available to, or brought to the attention of the regulatory authority.
- 2 References which relate to more than one chapter should be listed in each relevant chapter. The listing should be arranged in the order of the relevant active substance or formulation data points, as appropriate, with the references for the active substance preceding those for formulations. For each separate data point, references should be listed alphabetically by first author. Where there is more than one reference for a particular author (first author), the references concerned should be listed in chronological order - the most recent being listed last. In cases where for a particular author, more than one reference is listed for any one year, the references should be distinguished by inserting letters after the year *i.e.* a, b, c, *etc.*, as appropriate.
- 3 In instances where a single study would suffice, but two or more acceptable studies are submitted with respect to any particular data requirement, a footnote should be included in the list of references to indicate that any one of the studies concerned can be relied on by applicants for registration of plant protection products containing the active substance concerned.
- 4 For each reference, the following indications should be provided -
 - (i) the reference number, authors and year of the report or of publication;
 - (ii) for each test and study report, test guidelines, and published paper, its title, source, company and report number;
 - (iii) whether it is published or unpublished;
 - (iv) whether, or not, it was conducted in compliance with the principles of GLP or the principles of GEP, as appropriate;
 - (v) the owner of the test or study concerned; and
 - (vi) whether or not protection in accordance with the rules or provisions in place in the country to which application is made, is claimed, together with the regulatory authority's assessment as to whether, or not, such protection is warranted.
- 5 The reference lists that follow are intended to be illustrative of the required approach and relate to a fictitious compound, *active substance XXX 1111*.

Active Substance - XXX 1111 Name of the Regulatory Authority Month & Year List Compiled

Section B.6 Toxicology and Metabolism

OECD data point number / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
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Active Substance Data and Information

IIA 5.1.1 / 01	Casida JE Gaughan LC Ruzo LO	1979	Comparative metabolism of pyrethroids derived from 3-phenoxybenzyl and α -cyano-3-phenoxybenzyl alcohols. Advances in pesticide science, Fourth International Congress of Pesticide Chemistry, Zürich, Switzerland, July 24-38, 1978, part 2, 182-189 Not GLP, Published	N	-
IIA 5.1.1 / 02	Chopade HM McCann SA Gentile CC	1983	The distribution and metabolism of XXX 1111 in laying hens. Organics Inc Report No: MR86044 Not GLP, Unpublished	N	ORG
IIA 5.1.1 / 03	Eben A Thyssen J	1981	Thiocyanate excretion in rats' urine after intraperitoneal administration of XXX 1111 and decamethrin in comparable doses and after exposure to defined XXX 1111 concentrations in the inhalation air. Organics Inc Report No: 10130 Not GLP, Unpublished	N	ORG
IIA 5.1.1 / 04	Eben A Heimann KG Machemer L	1982a	Comparative study of rats on absorption of XXX 1111 after single oral administration in polyethylene glycol 400 or cremophor El/water as formulation vehicle. Organics Inc Report No: 10715 Not GLP, Unpublished	N	ORG
IIA 5.1.1 / 05	Eben A Machemer L Thyssen J	1982b	Comparative study of inhibition of the Na ⁺ , K ⁺ and Mg ⁺⁺ -dependent ATPase from rats and chickens' brains in vitro by XXX 1722, some of its metabolites and further substances DDT, ouabain, some pyrethroids and phosphoric acid esters. Organics Inc Report No: 11116 Not GLP, Unpublished	N	ORG

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IIA 5.1.1 / 06	Eben A Fuchs R Kurz J Wunsche C Flucke W	1987	Biotransformation of XXX 1111 in the chicken after oral administration of a high dose. Organics Inc Report No: 15849 GLP, Unpublished	N	ORG
IIA 5.1.1 / 07	Ecker W	1982	Biotransformation of [Fluorbenzene ring- U- ¹⁴ C]-XXX 1111; characterisation and provisional identification of metabolites. Organics Inc Report No: 10575 Not GLP, Unpublished	N	ORG
IIA 5.1.1 / 08	Ecker W	1993	[Fluorobenzene-UL- ¹⁴ C]XXX 1111; [fluorobenzene-UL- ¹⁴ C]XXX 1111: metabolism part of the general metabolism study in the rat. Organics Inc Report No: 2059 GLP, Unpublished	N	ORG
IIA 5.1.1 / 09	Klein O Weber H Suwelak DI	1983	[U- ¹⁴ C]-C ([U- ¹⁴ C]XXX 1111), fluorobenzene label): biokinetic part of the general metabolism study in the rat. Organics Inc Report No: 11872 Not GLP, Unpublished	N	ORG
IIA 5.1.1 / 10	Miyamoto L Beynon KI Roberts TR Hemingway RJ Swaine H	1981	The chemistry, metabolism and residue analysis of synthetic pyrethroids. Pure & Appl. Chem., Vol. 53, pp. 1976-2022, 1981 Not GLP, Published	N	-
IIA 5.1.1 / 11	Shaw HR Ayers JE McCann SA	1983	Metabolism of XXX 1111 in a dairy cow. Organics Inc Report No: MR86043 Not GLP, Unpublished	N	ORG

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IIA 5.1.1 / 12	Weber H Suwelack D	1983	Fluorophenyl-U- ¹⁴ C XXX 1111) biokinetic study on rats. Organics Inc Report No: PH11575(F) Not GLP, Unpublished	N	ORG
IIA 5.2.1 / 01	Bomann W	1991	XXX 1111 / study for acute oral toxicity in rats. Organics Inc Report No: 19852 GLP, Unpublished	Y ¹⁰	ORG
IIA 5.2.1 / 02	Flucke W Thyssen J	1980a	XXX 1111 / acute toxicity studies. Organics Inc Report No: 8800 Not GLP, Unpublished	N	ORG
IIA 5.2.1 / 03	Flucke W Thyssen J	1981	XXX 1111 (cis:trans isomer ratio = 11:11) / acute toxicity studies. Organics Inc Report No: 9673 Not GLP, Unpublished	N	ORG
IIA 5.2.1 / 04	Heimann KG	1982a	XXX 1111 / comparative tests for acute toxicity with various formulation aids. Organics Inc Report No: 10931 Not GLP, Unpublished	N	ORG
IIA 5.2.1 / 05	Heimann KG	1982b	Determination of acute toxicity (LD ₅₀). Organics Inc Not GLP, Unpublished	N	ORG
IIA 5.2.1 / 06	Heimann KG	1984	Determination of acute toxicity (LD ₅₀). Organics Inc Not GLP, Unpublished	N	ORG
IIA 5.2.1 / 07	Heimann KG	1987	XXX 1111 / study for acute oral toxicity to rats (formulation acetone and peanut oil). Organics Inc Report No: 15847 GLP, Unpublished	N	ORG

¹⁰ protection for xx years claimed from date of decision concerning registration - the owner of the study report indicated that it had not previously been submitted in support of an application for the registration of a plant protection product

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IIA 5.2.1 / 08	Hoffmann K	1981a	XXX 1111 / acute toxicity for sheep after oral administration. Organics Inc Report No: 9750 Not GLP, Unpublished	N	ORG
IIA 5.2.1 / 09	Hoffmann K	1981b	XXX 1111 / Akute Toxizität am Hund nach oraler Verabreichung, Organics Inc Report No: Letter Not GLP, Unpublished	N	ORG
IIA 5.2.1 / 10	Pauluhn J	1988c	XXX 1111 / study of the blood gases in rats. Organics Inc Report No: 16763 GLP, Unpublished	N	ORG
IIA 5.2.1 / 11	Sachsse K	1985a	Acute oral toxicity (LD ₅₀) study with XXX 1111 (c.n. XXX 1111) vehicle: cremophor EL 2% in distilled water in the hen. Organics Inc Report No: R3621 GLP, Unpublished	N	ORG
IIA 5.2.1 / 12	Sachsse K	1985b	Acute oral toxicity (LD ₅₀) study with XXX 1111 vehicle: PEG 400 in the hen. Organics Inc Report No: R3622 GLP, Unpublished	N	ORG
IIA 5.2.1 / 13	Thyssen J	1982	XXX 1111, formulation in water and influence on acute oral toxicity. Organics Inc Not GLP, Unpublished	N	ORG
IIA 5.2.2 / 01	Iyatomi A	1982b	Report of acute toxicity – A. Nihon Tokushu Noyaku Seizo Report No: 5378 Organics Inc Report No: 10373 Not GLP, Unpublished	N	NTN
IIA 5.2.2 / 02	Iyatomi A	1983	Report of acute toxicity – B. Nihon Tokushu Noyaku Seizo Report No: 59261 Organics Inc Report No: 11343 Not GLP, Unpublished	N	NTN

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IIA 5.2.3 / 01	Pauluhn J Thyssen J	1982	XXX 1111 / Study for acute inhalation toxicology (effect of formulation agent on inhalation). Organics Inc Report No: 10965 Not GLP, Unpublished	N	ORG
IIA 5.2.3 / 02	Pauluhn J Kaliner G	1983	XXX 1111 / study for acute and subacute inhalation toxicity on chickens. Organics Inc Report No: 11558 Not GLP, Unpublished	N	ORG
IIA 5.2.3 / 03	Pauluhn J	1987	XXX 1111 / study of the acute inhalation toxicity to rats using OECD guideline No. 403. Organics Inc Report No: 15612 GLP, Unpublished	N	ORG
IIA 5.2.3 / 04	Pauluhn J	1989	XXX 1111 / studies of acute inhalation toxicity in the mouse, in accordance with OECD guideline No. 403. Organics Inc Report No: 17765 GLP, Unpublished	Y ¹⁰	ORG
IIA 5.2.3 / 05	Watanabe M Iyatomi A	1984	Acute inhalation study of XXX 1111 on rats. Nihon Tokushu Noyaku Seizo Report No: 73126 Not GLP, Unpublished	N	NTN
IIA 5.2.4 / 01	Iyatomi A Watanabe M Ohta K	1982a	XXX 1111 / eye and skin irritation study on rabbits. Nihon Tokushu Noyaku Seizo Report No: 54165 Organics Inc Report No: 10365 Not GLP, Unpublished	N	NTN
IIA 5.2.5 / 01	Iyatomi A Watanabe M Ohta K	1982a	XXX 1111 / eye and skin irritation study on rabbits. Nihon Tokushu Noyaku Seizo Report No: 54165 Organics Inc Report No: 10365 Not GLP, Unpublished	N	NTN

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IIA 5.2.5 / 02	Pauluhn J	1988a	XXX 1111 / study for sensory irritant potential in the rat (RD ₅₀ determination). Organics Inc Report No: 16693 GLP, Unpublished	N	ORG
IIA 5.2.5 / 03	Pauluhn J	1988b	XXX 1111 / study for sensory irritant potential in the mouse (RD ₅₀ determination). Organics Inc Report No: 16713 GLP, Unpublished	N	ORG
IIA 5.2.6 / 01	Mihail F	1981a	XXX 1111 / intracutaneous sensitisation test on guinea pigs (Draize-test). Organics Inc Report No: 10222 Not GLP, Unpublished	N	ORG
IIA 5.2.6 / 02	Mihail F	1981b	XXX 1111 / test for sensitising effect on guinea pigs (Maximization test according to Magnusson and Klingman). Organics Inc Report No: 10267 Not GLP, Unpublished	N	ORG
IIA 5.3.1 / 01	Flucke W Schilde B	1980b	XXX 1111 / subacute oral toxicity study on rats. Organics Inc Report No: 9039 Not GLP, Unpublished	N	ORG
IIA 5.3.2 / 01	Löser E Schilde B	1980	XXX 1111 / subchronic toxicity study on rats (three-month feeding experiment). Organics Inc Report No: 9386 Not GLP, Unpublished	N	ORG
IIA 5.3.5 / 01	Pauluhn J Kaliner G	1983	XXX 1111 / study for acute and subacute inhalation toxicity on chickens. Organics Inc Report No: 11558 Not GLP, Unpublished	N	ORG
IIA 5.7.2 / 01	Thyssen J Kaliner G Gröning P	1981	XXX 1111 / neurotoxicity studies on hens. Organics Inc Report No: 9753 Not GLP, Unpublished	N	ORG

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