

APPENDIX 6

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

PART 1

LISTING BY TEST AND STUDY TYPE

- 1 As indicated in subparagraphs 3.1.1 (x), (xi) and (xii) and subparagraphs 3.2.1 (xii), (xiii) and (xiv), the listing should cover each section of the dossier separately and should include:
 - for each test and study report included in the complete dossier submitted, its title, source, company and report number;
 - for each test and study report, an indication as to whether it is published or unpublished;
 - for each test and study report, an indication as to whether it has been conducted in compliance with the principles of GLP or the principles of GEP, as appropriate;
 - in the case of unpublished reports, an indication of the identity of the owner of the test or study concerned, where the owner is not the person or organization that submitted it; and
 - in the case of unpublished reports an indication as to whether or not data protection is claimed in accordance with the relevant requirements of the country to which the dossier is submitted, for the purposes of the registration of formulations containing the active substance.

- 2 As specified in subparagraph 3.1.1 (xi) and subparagraph 3.2.1 (xiii), in preparing the listing, applicants should conduct a detailed literature search - expert judgement is required to determine the nature and extent of the search to be conducted. The date on which the reference list was compiled, the identity of the data bases searched, the date range established for the purposes of the search (*e.g.* abstracts dated earlier than 1980 not requested), the language constraints, if any, imposed and the key words used for the purposes of the literature search, should be indicated.

- 3 For each point or sub-point, the documents should be listed alphabetically by author and where for a particular author there is more than one report, they should be listed in chronological order - the most recent study 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.

- 4 Where data protection is claimed, in accordance with the relevant rules or provisions in place in the country to which the dossier is submitted, footnotes should be included to indicate the basis on which each individual claim is made and the period for which protection is sought.

- 5 In the case of reports that are relevant to more than one point, sub-point or section, the entry should be repeated for each point for which it is relevant - the list that follows is intended to be illustrative of the required approach.

Reference List, by Active Substance - XXX 1111 Company Name Month & Year
OECD Data Point List Compiled

Section 3, Toxicological and Metabolism Studies on the Active Substance

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
---	-----------	------	---	-----------------------------	-------

Active Substance Data and Information

IIP 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	-
IIP 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
IIP 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
IIP 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 E1/water as formulation vehicle. Organics Inc Report No: 10715 Not GLP, Unpublished	N	ORG
IIP 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

Reference List, by Active Substance - XXX 1111 Company Name Month & Year
OECD Data Point List Compiled

Section 3, Toxicological and Metabolism Studies on the Active Substance

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
IIP 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
IIP 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
IIP 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
IIP 5.1.1 / 09	Klein O Weber H Suwelak D	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
IIP 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	-
IIP 5.1.1 / 11	Shaw HR Ayers J E McCann SA	1983	Metabolism of XXX 1111 in a dairy cow. Organics Inc Report No: MR86043 Not GLP, Unpublished	N	ORG

Reference List, by Active Substance - XXX 1111 Company Name Month & Year
OECD Data Point List Compiled

Section 3, Toxicological and Metabolism Studies on the Active Substance

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
IIP 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
IIP 5.2.1 / 01	Bomann W	1991	XXX 1111 / study for acute oral toxicity in rats. Organics Inc Report No: 19852 GLP, Unpublished	Y ⁷	ORG
IIP 5.2.1 / 02	Flucke W Thyssen J	1980a	XXX 1111 / acute toxicity studies. Organics Inc Report No: 8800 Not GLP, Unpublished	N	ORG
IIP 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
IIP 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
IIP 5.2.1 / 05	Heimann KG	1982b	Determination of acute toxicity (LD ₅₀). Organics Inc Not GLP, Unpublished	N	ORG
IIP 5.2.1 / 06	Heimann KG	1984	Determination of acute toxicity (LD ₅₀). Organics Inc Not GLP, Unpublished	N	ORG
IIP 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

⁷ protection for 5 years claimed from date of registration - the study report has not previously been submitted in support of an application for registration

Reference List, by Active Substance - XXX 1111 Company Name Month & Year
OECD Data Point List Compiled

Section 3, Toxicological and Metabolism Studies on the Active Substance

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
IIP 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
IIP 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
IIP 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
IIP 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
IIP 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
IIP 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
IIP 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
IIP 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

Reference List, by Active Substance - XXX 1111 Company Name Month & Year
OECD Data Point List Compiled

Section 3, Toxicological and Metabolism Studies on the Active Substance

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
IIP 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
IIP 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
IIP 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
IIP 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 ⁷	ORG
IIP 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
IIP 5.2.4 & 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
IIP 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

Reference List, by Active Substance - XXX 1111 Company Name Month & Year
OECD Data Point List Compiled

Section 3, Toxicological and Metabolism Studies on the Active Substance

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
IIP 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
IIP 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
IIP 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
IIP 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
IIP 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
IIP 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
IIP 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

.
. .
. .
. .

PART 2

LISTING BY AUTHOR

- 1 As in the case of the listing by data point of test and study reports and other documentation submitted (see Part 1 of Appendix 6), the listing should cover each section of the dossier separately and should include:
 - for each test and study report included in the complete dossier submitted, its title, source, company and report number;
 - for each test and study report, an indication as to whether it is published or unpublished;
 - for each test and study report, an indication as to whether it has been conducted in compliance with the principles of GLP or the principles of GEP, as appropriate;
 - in the case of unpublished reports, an indication of the identity of the owner of the test or study concerned, where the owner is not the person or organization that submitted it; and
 - in the case of unpublished reports an indication as to whether or not data protection is claimed in accordance with the relevant requirements of the country to which the dossier is submitted.
- 2 As specified in subparagraph 3.1.1 (xi) and subparagraph 3.2.1 (xiii), in preparing the listing, applicants should conduct a detailed literature search - expert judgement is required to determine the nature and extent of the search to be conducted. The date on which the reference list was compiled, the identity of the data bases searched, the date range established for the purposes of the search (e.g. abstracts dated earlier than 1980 not requested), the language constraints, if any, imposed and the key words used for the purposes of the literature search, should be indicated.
- 3 Within sections, the listing should be arranged alphabetically by author. Where for particular authors, there is more than one reference, they should be listed in chronological order. 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.
- 4 Where data protection is claimed, in accordance with the relevant rules or provisions in place in the country to which the dossier is submitted, footnotes should be included to indicate the basis on which each individual claim is made and the period for which protection is sought.
- 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*.

Reference List, Active Substance - XXX 1111 Company Name Month & Year
by Author List Compiled

Section 3, Toxicological and Metabolism Studies on the Active Substance

Author(s)	OECD data point number / reference number	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
-----------	---	------	---	-----------------------------	-------

Active Substance Data and Information

Bomann W	IIP 5.2.1 / 01	1991	XXX 1111 / study for acute oral toxicity in rats. Organics Inc Report No: 19852 GLP, Unpublished	Y ⁸	ORG
Casida JE Gaughan LC Ruzo LO	IIP 5.1.1 / 01	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	-
Chopade HM McCann SA Gentile CC	IIP 5.1.1 / 02	1983	The distribution and metabolism of XXX 1111 in laying hens. Organics Inc Report No: MR86044 Not GLP, Unpublished	N	ORG
Eben A Fuchs R Kurz J Wunsche C Flucke W	IIP 5.1.1 / 06	1987	Biotransformation of XXX 1111 in the chicken after oral administration of a high dose. Organics Inc Report No: 15849 GLP, Unpublished	N	ORG
Eben A Heimann KG Machemer L	IIP 5.1.1 / 04	1982a	Comparative study of rats on absorption of XXX 1111 after single oral administration in polyethylene glycol 400 or cremophor E1/water as formulation vehicle. Organics Inc Report No: 10715 Not GLP, Unpublished	N	ORG

⁸ protection for 5 years claimed from date of registration - the study report has not previously been submitted in support of an application for registration

Reference List, Active Substance - XXX 1111 Company Name Month & Year
by Author List Compiled

Section 3, Toxicological and Metabolism Studies on the Active Substance

Author(s)	OECD data point number / reference number	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
Eben A Machemer L Thyssen J	IIP 5.1.1 / 05	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
Eben A Thyssen J	IIP 5.1.1 / 03	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
Ecker W	IIP 5.1.1 / 07	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
Ecker W	IIP 5.1.1 / 08	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
Flucke W Schilde B	IIP 5.3.1 / 01	1980b	XXX 1111 / subacute oral toxicity study on rats. Organics Inc Report No: 9039 Not GLP, Unpublished	N	ORG
Flucke W Thyssen J	IIP 5.2.1 / 02	1980a	XXX 1111 / acute toxicity studies. Organics Inc Report No: 8800 Not GLP, Unpublished	N	ORG

Reference List, Active Substance - XXX 1111 Company Name Month & Year
by Author List Compiled

Section 3, Toxicological and Metabolism Studies on the Active Substance

Author(s)	OECD data point number / reference number	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
Flucke W Thyssen J	IIP 5.2.1 / 03	1981	XXX 1111 (cis:trans isomer ratio = 11:11) / acute toxicity studies. Organics Inc Report No: 9673 Not GLP, Unpublished	N	ORG
Heimann KG	IIP 5.2.1 / 05	1982b	Determination of acute toxicity (LD ₅₀). Organics Inc Not GLP, Unpublished	N	ORG
Heimann KG	IIP 5.2.1 / 04	1982a	XXX 1111 / comparative tests for acute toxicity with various formulation aids. Organics Inc Report No: 10931 Not GLP, Unpublished	N	ORG
Heimann KG	IIP 5.2.1 / 06	1984	Determination of acute toxicity (LD ₅₀). Organics Inc Not GLP, Unpublished	N	ORG
Heimann KG	IIP 5.2.1 / 07	1987	XXX 1111 / study for acute oral toxicity to rats (formulation acetone and peanut oil). Organics Inc Report No: 15847 GLP, Unpublished	N	ORG
Hoffmann K	IIP 5.2.1 / 08	1981a	XXX 1111 / acute toxicity for sheep after oral administration. Organics Inc Report No: 9750 Not GLP, Unpublished	N	ORG
Hoffmann K	IIP 5.2.1 / 09	1981b	XXX 1111 / Akute Toxizität am Hund nach oraler Verabreichung, Organics Inc Report No: Letter Not GLP, Unpublished	N	ORG
Iyatomi A	IIP 5.2.2 / 01	1982b	Report of acute toxicity - A. Nihon Tokushu Noyaku Seizo Report No: 5378 Organics Inc Report No: 10373 Not GLP, Unpublished	N	NTN

Reference List, Active Substance - XXX 1111 Company Name Month & Year
by Author List Compiled

Section 3, Toxicological and Metabolism Studies on the Active Substance

Author(s)	OECD data point number / reference number	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
Iyatomi A	IIP 5.2.2 / 02	1983	Report of acute toxicity - B. Nihon Tokushu Noyaku Seizo Report No: 59261 Organics Inc Report No: 11343 Not GLP, Unpublished	N	NTN
Iyatomi A Watanabe M Ohta K	IIP 5.2.4 & 5.2.5 / 01	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
Klein O Weber H Suwelak D	IIP 5.1.1 / 09	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
Löser E Schilde B	IIP 5.3.2 / 01	1980	XXX 1111 / subchronic toxicity study on rats (three-month feeding experiment). Organics Inc Report No: 9386 Not GLP, Unpublished	N	ORG
Mihail F	IIP 5.2.6 / 01	1981a	XXX 1111 / intracutaneous sensitisation test on guinea pigs (Draize-test). Organics Inc Report No: 10222 Not GLP, Unpublished	N	ORG
Mihail F	IIP 5.2.6 / 02	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
Miyamoto L Beynon KI Roberts TR Hemingway RJ Swaine H	IIP 5.1.1 / 10	1981	The chemistry, metabolism and residue analysis of synthetic pyrethroids. Pure & Appl. Chem., Vol. 53, pp. 1976-2022, 1981 Not GLP, Published	N	-

Reference List, Active Substance - XXX 1111 Company Name Month & Year
by Author List Compiled

Section 3, Toxicological and Metabolism Studies on the Active Substance

Author(s)	OECD data point number / reference number	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
Pauluhn J	IIP 5.2.3 / 03	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
Pauluhn J	IIP 5.2.5 / 02	1988a	XXX 1111 / study for sensory irritant potential in the rat (RD ₅₀ determination). Organics Inc Report No: 16693 GLP, Unpublished	N	ORG
Pauluhn J	IIP 5.2.5 / 03	1988b	XXX 1111 / study for sensory irritant potential in the mouse (RD ₅₀ determination). Organics Inc Report No: 16713 GLP, Unpublished	N	ORG
Pauluhn J	IIP 5.2.1 / 10	1988c	XXX 1111 / study of the blood gases in rats. Organics Inc Report No: 16763 GLP, Unpublished	N	ORG
Pauluhn J	IIP 5.2.3 / 04	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 ⁸	ORG
Pauluhn J Kaliner G	IIP 5.2.3 / 02 & 5.3.5 / 01	1983	XXX 1111 / study for acute and subacute inhalation toxicity on chickens. Organics Inc Report No: 11558 Not GLP, Unpublished	N	ORG
Pauluhn J Thyssen J	IIP 5.2.3 / 01	1982	XXX 1111 / Study for acute inhalation toxicology (effect of formulation agent on inhalation). Organics Inc Report No: 10965 Not GLP, Unpublished	N	ORG

Reference List, Active Substance - XXX 1111 Company Name Month & Year
by Author List Compiled

Section 3, Toxicological and Metabolism Studies on the Active Substance

Author(s)	OECD data point number / reference number	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
Sachsse K	IIP 5.2.1 / 11	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
Sachsse K	IIP 5.2.1 / 12	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
Shaw HR Ayers JE McCann SA	IIP 5.1.1 / 11	1983	Metabolism of XXX 1111 in a dairy cow. Organics Inc Report No: MR86043 Not GLP, Unpublished	N	ORG
Thyssen J	IIP 5.2.1 / 13	1982	XXX 1111, formulation in water and influence on acute oral toxicity. Organics Inc Not GLP, Unpublished	N	ORG
Thyssen J Kaliner G Gröning P	IIP 5.7.2 / 01	1981	XXX 1111 / neurotoxicity studies on hens. Organics Inc Report No: 9753 Not GLP, Unpublished	N	ORG
Watanabe M Iyatomi A	IIP 5.2.3 / 05	1984	Acute inhalation study of XXX 1111 on rats. Nihon Tokushu Noyaku Seizo Report No: 73126 Not GLP, Unpublished	N	NTN
Weber H Suwelack D	IIP 5.1.1 / 12	1983	Fluorophenyl-U- ¹⁴ C XXX 1111) biokinetic study on rats. Organics Inc Report No: PH11575(F) Not GLP, Unpublished	N	ORG

PART 3

LISTING OF TEST AND STUDY REPORTS AND PUBLISHED PAPERS NOT SUBMITTED

- 1 As in the case of the listing of test and study reports and other documentation submitted (see Parts 1 and 2 of Appendix 6), the listing of test and study reports and published papers not submitted as part of the complete dossier, should cover each section of the dossier separately and should include:
 - for each test and study report, its title, source, company and report number;
 - for each test and study report, an indication as to whether it is published or unpublished; and
 - for each test and study report, an indication as to the reason the test or study report or published paper was not submitted;

- 2 Within sections, the listing should be arranged alphabetically by author. Where for particular authors, there is more than one reference, they should be listed in chronological order. 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 The reference lists that follow are intended to be illustrative of the required approach and relate to a fictitious compound, *active substance XXX 1111*.

Reference List, by Author **Active Substance - XXX 1111** **Company Name** **Month & Year List Compiled**

Section 3, Toxicological and Metabolism Studies on the Active Substance

Author(s)	OECD data point number / reference number	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
Becker H	IIP 5.6.10	1983	Dose-finding embryotoxicity (including teratogenicity) study with XXX 1111 in the rat (preliminary study) Organics Inc Report No. R8128 Provides no useful information. Unpublished	N	ORG
Becker H	IIP 5.6.10	1992a	Second dose range-finding embryotoxicity study (including teratogenicity) with XXX 1111 in the rabbit Organics Inc Report No. R5513 Provides no useful information. Unpublished	N	ORG
Becker H	IIP 5.6.10	1993	Dose-finding embryotoxicity (including teratogenicity) study with XXX 1111 in the rat (preliminary study) Organics Inc Report No. R5980 Provides no useful information. Unpublished	N	ORG
Becker H Biedermann K	IIP 5.6.11	1992b	Dose range-finding embryotoxicity study (including teratogenicity) with XXX 1111 in the rabbit Organics Inc Report No. R5512 Provides no useful information. Unpublished	N	ORG
Flucke W	IIP 5.2.1	1980	XXX 1111, diastereomers - determination of the acute toxicity (LD ₅₀) Organics Inc Report No. R1398 Method used no longer accepted. Unpublished	N	ORG
Heimann KG	IIP 5.2.6	1982	Comparative study of Ethyl-4-Aminobenzoate, Formaldehyde, Potassium Penicillin G, and XXX 1111 to test for sensitisation effect using various test methods (Sensitization tests of Draize, Magnusson and Klingman, and Maurer) Organics Inc Report No. 10812 Method used no longer accepted. Unpublished	N	ORG

Reference List, by Author Active Substance - XXX 1111 Company Name Month & Year List Compiled

Section 3, Toxicological and Metabolism Studies on the Active Substance

Author(s)	OECD data point number / reference number	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
Heimann KG	IIP 5.2.2	1984	XXX 1111 - determination of acute toxicity (LD50) (Lutrol) Organics Inc Report No R2542, September 25, 1984 Method used no longer accepted. Unpublished	N	ORG
Kazda S	IIP 5.2.1	1979	XXX 1111 - Effect on arterial blood pressure and heart rate Organics Inc Report No. R7359 Test material not identified. Unpublished	N	ORG
Marshall JA	IIP 5.2.1	1985	Effects of pyrethroids on reactions of rats. Fund. Appl. Toxicol. 8, 742 - 748 Study design statistically faulty. Published	N	-
Mihail FL	IIP 5.2.1	1978	XXX 1111 - TOX I Organics Inc Report No. R8472 Test material not identified. Unpublished	N	ORG
Roberts MJ	IIP 5.2.1	1981	Impact of pyrethroid insecticides on vertebrates. Neuropathol. Appl. Neurobiol. 6, 285 - 289 Test material not identified. Published	N	-
Sanders WH	IIP 5.2.1	1986	Toxicological properties of pyrethroids. Critical Reviews in Toxicology 18, 286 - 291, Test material not identified. Published	N	-