

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 - for each test and study report, an indication as to whether it is published or unpublished;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 - in the case of unpublished reports, an indication of the identity of the owner of the test or study concerned, where the owner is not the person or organization that submitted it; and
 - in the case of unpublished reports an indication as to whether or not data protection is claimed in accordance with the relevant requirements of the country to which the dossier is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 Microbial Pest Control Agent.

- 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 MPCA – *Beauvaria wendiensis* strain XYZ1 Company Name Month & Year
OECD Data Point List Compiled

Section 3, Toxicological and Toxicokinetic Studies on the Microbial Pest Control Agent

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

Microbial Pest Control Agent Data and Information

IIM 5.1	Greats W.	2002	Summary of the infectivity/pathogenicity potential for <i>B. wendiensis</i> strain XYZ1 in humans based on study results and taxonomic relationship to known pathogens. Vatrobe, Inc. Report No: V250 Not GLP, Unpublished	N	VAT
IIM 5.2	Greats W.	2002	Occupational health surveillance report on workers during production of <i>B. wendiensis</i> strain XYZ1 Vatrobe, Inc. Report No: V252 Not GLP, Unpublished	N	VAT
IIM 5.2.5	Greats W	2002	Proposed first aid measures and medical treatment. Vatrobe, Inc. Report No: V254 Not GLP, Unpublished	N	VAT
IIM 5.3.2	Kovac K Evans R Snowiffle J	2000	<i>B. wendiensis</i> strain XYZ1/ study for acute oral infectivity and toxicity in rats. Vatrobe, Inc. Report No: V459 GLP, Unpublished	N	VAT
IIM 5.3.2	Evans R Snowiffle J	1989	<i>B. wendiensis</i> strain XYZ1/ study for acute oral infectivity and pathogenicity. Bekab, Inc. Report No: BK 34569 Vatrobe, Inc. Report No: V460 GLP, Unpublished	N	BEK
IIM 5.3.3	Kovac K Jones JR Evans R	2001	<i>B. wendiensis</i> strain XYZ1/ study for acute intratracheal/inhalation infectivity and toxicity. Vatrobe, Inc. Report No: V462 GLP, Unpublished	Y ⁷	VAT
IIM 5.3.4	Kovac K Jones JR Evans R	2001	<i>B. wendiensis</i> strain XYZ1/ study for acute intravenous/intra peritoneal infectivity. Vatrobe, Inc. Report No: V467 GLP, Unpublished	Y ⁷	VAT
IIM 5.3.5	Greats W	2002	Discussion of potential for genotoxic toxin production. Vatrobe, Inc. Report No: V253 Not GLP, Unpublished	N	VAT
IIM 5.3.7.1/01	Elberg A	2001	<i>B. wendiensis</i> strain XYZ1/ study for Primary Dermal Irritation. Vatrobe, Inc. Report No: V470 GLP, Unpublished	N	VAT

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 MPCA – *Beauvaria wendensis* strain XYZ1 Company Name Month& Year
OECD Data Point List Compiled**

Section 3, Toxicological and Toxicokinetic Studies on the Microbial Pest Control Agent

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
IIM 5.3.7.1/02	Greats W.	2002	Justification for non-submission of data for 28-day inhalation toxicity (rodents) Vatrobe, Inc. Report No: V351 Not GLP, Unpublished	N	VAT
IIM 5.5 / 01	Parmon D Helpar G Washal B	1962a	Effects on Rodents of <i>Beauvaria</i> isolates. J. Bacteriol. 1962 2:45-49. Not GLP, Published	N	
IIM 5.5 / 02	Parmon D Helpar G Washal B	1962b	Pathogenicity and Toxicity of <i>Beauvaria</i> species. Microbiol. Rev. 1962 7:22-24. Not GLP, Published	N	
IIM 5.6	Greats W	2002	Summary of mammalian toxicity and overall evaluation Vatrobe, Inc. Report No: V259 Not GLP, Unpublished	N	VAT

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

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, *Microbial Pest Control Agent Beauvaria wendiensis* strain XYZ1.

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

Microbial Pest Control Agent Data and Information

Elberg A	IIM 5.3.7.1/01	2001	<i>B. wendiensis</i> strain XYZ1/ study for Primary Dermal Irritation. Vatrobe, Inc. Report No: V470 GLP, Unpublished	N	VAT
Evans R Snowiffle J	IIM 5.3.2	1989	<i>B. wendiensis</i> strain XYZ1/ study for acute oral infectivity and pathogenicity. Bekab, Inc. Report No: BK 34569 Vatrobe, Inc. Report No: V460 GLP, Unpublished	N	BEK
Greats W.	IIM 5.1	2002	Summary of the infectivity/pathogenicity potential for <i>B. wendiensis</i> strain XYZ1 in humans based on study results and taxonomic relationship to known pathogens. Vatrobe, Inc. Report No: V250 Not GLP, Unpublished	N	VAT
Greats W.	IIM 5.2	2002	Occupational health surveillance report on workers during production of <i>B. wendiensis</i> strain XYZ1 Vatrobe, Inc. Report No: V252 Not GLP, Unpublished	N	VAT
Greats W.	IIM 5.3.7.1/02	2002	Justification for non-submission of data for 28-day inhalation toxicity (rodents) Vatrobe, Inc. Report No: V351 Not GLP, Unpublished	N	VAT
Greats W	IIM 5.3.5	2002	Discussion of potential for genotoxic toxin production. Vatrobe, Inc. Report No: V253 Not GLP, Unpublished	N	VAT
Greats W	IIM 5.2.5	2002	Proposed first aid measures and medical treatment. Vatrobe, Inc. Report No: V254 Not GLP, Unpublished	N	VAT
Greats W	IIM 5.6	2002	Summary of mammalian toxicity and overall evaluation Vatrobe, Inc. Report No: V259 Not GLP, Unpublished	N	VAT
Kovac K Evans R Snowiffle J	IIM 5.3.2	2000	<i>B. wendiensis</i> strain XYZ1/ study for acute oral infectivity and toxicity in rats. Vatrobe, Inc. Report No: V459 GLP, Unpublished	Y ¹	VAT
Kovac K Jones JR Evans R	IIM 5.3.3	2001	<i>B. wendiensis</i> strain XYZ1/ study for acute intratracheal/inhalation infectivity and toxicity. Vatrobe, Inc. Report No: V462 GLP, Unpublished	Y ⁷	VAT
Kovac K Jones JR Evans R	IIM 5.3.4	2001	<i>B. wendiensis</i> strain XYZ1/ study for acute intravenous/intra peritoneal infectivity. Vatrobe, Inc. Report No: V467 GLP, Unpublished	Y ⁷	VAT

¹ protection for 5 years claimed from date of registration - the study report has not previously been submitted in support of an application for registration

Appendix 6 Format for the listing of test and study reportsPart 2Listing by Author of test and study
 and other documentationreports and published papers submitted

Reference List, by MPCA – *Beauvaria wendensis* strain XYZ1 Company Name Month & Year
 OECD Data Point List Compiled

Section 3, Toxicological and Toxicokinetic Studies on the Microbial Pest Control Agent

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
Parmon D Helpar G Washal B	IIM 5.5/ 01	1962a	Effects on Rodents of <i>Beauvaria</i> isolates. J. Bacteriol. 1962 2:45-49. Not GLP, Published	N	
Parmon D Helpar G Washal B	IIM 5.5/ 02	1962b	Pathogenicity and Toxicity of <i>Beauvaria</i> species. Microbiol. Rev. 1962 7:22-24. Not GLP, Published	N	

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, *Microbial Pest Control Agent Beauvaria wendiensis* strain XYZ1.

Appendix 6 Format for the listing of test and study reportsPart 3Listing of test and study reports and
 and other documentation published papers not submitted

**Reference List, by MPCA – *Beauvaria wendensis* strain XYZ1 Company Name Month & Year
 OECD Data Point List Compiled**

Section 3, Toxicological and Toxicokinetic Studies on the Microbial Pest Control Agent

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
De Leath V Kane H	IIM 5.3.2	1998	Dose range-finding acute toxicity with <i>B. wendensis</i> strain XYZ1 Vatrobe, Inc. Report No: V415 Provides no useful information. Unpublished	N	VAT
Keeshan B	IIM 5.5	1972	Outdoor Fungal Pathogens. Colliers Science News. Aug 25, 1972. 10:25-27 No taxonomic relationships. Provides no useful information. Published	N	
Kent C	IIM 5.5	1998	Killer Fungi in Agriculture. Science Reports. June 3, 1998. 4:12-13. Unverified reports, subsequently retracted by Author. Published	N	
Neuman A	IIM 5.3.2	1999	<i>B. wendensis</i> strain XYZ1/ study for acute oral infectivity and toxicity in rats. Vatrobe, Inc. Report No: V420 Control failure, Provides no useful information Unpublished	N	VAT