

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 - (iii) whether it is published or unpublished;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, *Microbial Pest Control Agent Beauvaria wendensis* strain XYZ1.

MPCA – *Beauveria wendensis* strain XYZ1 Name of the Regulatory Authority Month & Year List Compiled

Section B.6 Toxicology

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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Microbial Pest Control Agent Data and Information

IIM 5.1	Greats W.	2002	Summary of the infectivity/pathogenicity potential for <i>B. wendensis</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. wendensis</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. wendensis</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. wendensis</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. wendensis</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. wendensis</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

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

MPCA – *Beauvaria wendensis* strain XYZ1 Name of the Regulatory Authority Month & Year List Compiled

Section B.6 Toxicology

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 5.3.7.1/01	Elberg A	2001	<i>B. wendensis</i> strain XYZ1/ study for Primary Dermal Irritation. Vatrobe, Inc. Report No: V470 GLP, Unpublished	N	VAT
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