

PART 4

OECD, EU, US, CANADIAN, JAPANESE AND AUSTRALIAN NUMBERING SYSTEMS FOR DATA AND INFORMATION ON MICROBIAL PEST CONTROL AGENTS

1. As indicated in subparagraph 3.1.1 xvi, the numbering systems used in many OECD countries for the data and information relating to microbial pest control agents 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 microbial pest control agents 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. From January 2005, the OECD numbering system has been mandatory in the EU. To facilitate conversion from the earlier EU numbering system to other numbering systems, the system previously used in the EU is included.
4. 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.
5. 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 slightly different, as requirements are different than those of plant protection products.~~
6. 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:
 - a. by data on the test substance,
 - b. by published information,
 - c. by surrogate information or bridging data to another microbial substance
 - d. by a rationale to waive the requirement because it is unnecessary or impractical.
7. In the table that follows, CR means that the information is conditionally required.
8. The following tables list the types of information that the pesticide regulatory authorities of most OECD member countries consider to be the basic requirements for microbial pesticides. Basic requirements are those which are sufficient to assess and register those products which meet the following criteria:
 - the microorganism and its metabolites pose no concerns of pathogenicity or toxicity to mammals and other non-target organisms which will likely be exposed to the microbial product.
 - the microorganism does not produce a known genotoxin

- all additives in the microbial manufacturing product and in end-use formulations are of low toxicity and suggest little potential for human health or environmental hazard.
9. Member countries may require additional information on a proposed product to address potential hazards and exposure scenarios specific to the proposal.
 10. If a microbial pesticide does not meet the above criteria, member countries may require additional information or refuse registration.

Appendix 6 Format for the listing of test and study reports and other documentation		Part 4 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Agents					
Point 1 Identity of the Microbial Pest Control Agent							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIB point number	US EPA Guideline / Requirement number ⁹	Canadian Data Code (DACO) ¹⁰	Japanese data requirement Yes / No ¹¹	Australian data requirement
IIM 1.1	Applicant (name, address, contact, telephone and telefax numbers)	R	1.1	Forms 40CFR 152.50	2.1	Yes	2-4.2
IIM 1.2	Producer (name, address, contact, telephone and telefax numbers)	R	1.2	40CFR 167.20	2.2 2.3	Yes	2-4.2 2-4.3(d) GRBAP s5 p1
IIM 1.3	Scientific information	R	1.3				
IIM 1.3.1	Scientific name of micro-organism to species level or a level sufficient to show taxonomic relation to known micro-organisms, especially pathogens;	R	1.3	885.1100 885.2100	2.4 2.5 2.71	Yes	GRBAP s5 p2
IIM 1.3.2	- accession no. of sample in a recognised culture collection						
IIM 1.3.3	- test procedures and criteria, using best available technology, to characterise the strain or serotype;						
IIM 1.3.4	- for mutant or genetically-modified strains, indicate all known differences between the modified micro-organism and the parent wild strain(s)						
IIM 1.3.5	- include any trade names, common names, developmental code names						
IIM 1.3.6	- indigenous or non-indigenous at the species level to the intended area of application.						
IIM 1.4	Composition of Technical Grade of MPCA/ Active Substance	R	1.4				
IIM 1.4.1	Concentration of micro-organism (and metabolite, if appropriate) in terms of g/kg or g/L (for US and Canada, also in % w/w) and cfu's/mL or appropriate potency units; include acceptable range for each term. Potency should be expressed in recognised units of potency or an appropriate expression of biological activity per unit weight/volume	R	1.4.1	885.11	2.9.2	Yes	2-4.3 GRBAP s5 p2

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IIM 1.4.2	Composition of microbial material used for manufacture of end use products in terms of g/kg or g/L (for US and Canada also in % w/w) for each active ingredient including:	R	1.4.2	885.1100 885.1300	2.9.1	Yes	2-4.3 GRBAP s5 p2, 4.1
IIM 1.4.2.1	- the MPCA. This information is not required if Technical Grade of MPCA is a hypothetical stage in a continuous production process of an end-use product.						
IIM 1.4.2.2	- additives (preservatives, stabilisers, diluents). This information is not required if Technical Grade of MPCA is a hypothetical stage in a continuous production process of an end-use product.						
IIM 1.4.2.3	- microbial impurities, classified/identified to a taxonomic level required by quality criteria to support the hygienic state of the production process. This information is not required if Technical Grade of MPCA is a hypothetical stage in a continuous production process of an end-use product.						
IIM 1.4.2.4	- non-microbial impurities (e.g. metabolic products, impurities in starting materials, fermentation residues, extraneous host residues). This information is not required if Technical Grade of MPCA is a hypothetical stage in a continuous production process of an end-use product.						
IIM 1.4.2.5	Composition in terms of g/kg or g/L, (for US and Canada also in % w/w), for each ingredient: The identity and maximum content of all microbial impurities must be reported, if possible and appropriate, as outlined in point 1.3, and expressed in appropriate units (in terms of cfu's/mL or appropriate expression of biological activity/viability).		1.4.2	885.13			

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IIM 1.4.3	Methods of production and quality criteria for the production and storage of the active micro-organism, including:	R	3.4	885.1300 885.1500	2.8 2.9.1 2.10.2	Yes	2-4.3(f) GRBAP s5 p7
IIM 1.4.3.1	- criteria for consistency and integrity of the master and working seed stock, typically, measures of biological activity and phenotypic or genotypic properties:						
IIM 1.4.3.2	- acceptable range for content of MPCA, in appropriate terms;						
IIM 1.4.3.3	- presence of human/mammalian pathogens;						
IIM 1.4.3.4	- presence or maximum accepted level of known mammalian toxins, if their presence is suspected at any stage in process, or if MPCA is closely related to a toxigenic human pathogen;						
IIM 1.4.3.5	- maximum accepted level for microbial impurities, using suitable indicators of an unhygienic process.						
IIM 1.4.4	Quality control data (measures of quality criteria) from 3 - 5 production batches, including storage stability data. If the Technical Grade of MPCA is a stage in a continuous production process of an end-use product, this information should be provided for the entire production process.	R	1.4.3	885.1300 885.1400 885.1500	2.8 2.9.1 2.10.2	Yes	2-4.3(f) GRBAP s5 p2
IIM 1.4.5	The formation, presence and/or impact of unintentional ingredients	R		885.13	2.9.3		2-4.3(e) GRBAP s5 p2
IIM 1.4.5.1	A theoretical discussion regarding the formation and/or presence of unintentional ingredients, including impurities of toxicological concern, likely to occur in the Technical Grade of the MPCA.						
IIM 1.4.5.2	A theoretical discussion regarding the impact of these ingredients on product quality.						

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IIM 1.4.5.3	A theoretical discussion regarding appropriate quality criteria.						
IIM 1.4.6	Physical and chemical properties, if MPCA is produced as a manufacturing product that is stored prior to formulation of end-use products: physical state; density; viscosity or surface tension; explosivity, corrosive character, oxidising properties; technical characteristics as appropriate	R		40CFR 158.740(a)	2.12	Yes	2-4.3(b) GRBAP s5 p2
IIM 1.4.7	International regulatory status of micro-organism	R			1.3		2-4.3(a) GRBAP s5 p2
IIM 1.4.8	Sample of MPCA and analytical standard of metabolite	R	4	830.19			2-4.3(l)
IIM 1.4.8.1	Sample of MPCA: if requested						
IIM 1.4.8.2	Analytical standard of metabolite: if requested						
IIM 1.4.8.3	Reference substances for the relevant impurities: if requested	R	4				
IIM 1.5	Patent status	R			2.6		-

Appendix 6 documentation	Format for the listing of test and study reports and other	Part 4 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Agents
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Point 2 Biological Properties of the Microbial Pest Control Agent							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIB point number	US EPA Guideline / Requirement number ⁹	Canadian Data Code (DACO) ¹⁰	Japanese data requirement Yes / No ¹¹	Australian data requirement
IIM 2.1	Origin of the isolate; method of isolation; preservation and maintenance of strain during development; historical information on testing and use of the strain; history of use of closely related strains or species; Description of any unusual morphological, physiological, pesticidal or resistance characteristics of the MPCA which differ from classical description of the species	R	2.1 2.1.1 2.1.2	885.11	2.7.1 2.7.2 vii 2.7.2 viii	Yes	2-4.3(e) GRBAP s5 p2
IIM 2.2	Natural occurrence of the micro-organism including geographic distribution, hosts, habitat, ecological niche, level of natural occurrence	R	2.1.2	885.11	2.7.2 i	Yes	GRBAP s5 p1&2
IIM 2.3	Information on target organism(s)	R	2.2	885.11	2.7.2 ii	Yes	1-2 GRBAP s5 p2
IIM 2.3.1	Description of the target organism(s)		2.2.1				
IIM 2.3.2	Information on mode of action, kind of antagonism to target host, infective/toxic dose, transmissibility		2.2.2				
IIM 2.4	Available information on host specificity; possible effects on species closely related to the target pest. Any experience of toxic effect of the active substance or its metabolic products on human or animals, of whether the organism is capable of colonising or invading humans or animals and whether it is pathogenic shall be stated. Any experience of whether the active substance or its products may irritate skin, eyes or respiratory organs of humans or animals and whether it is allergenic in contact with skin or when inhaled.	R	2.3	885.11	2.7.2 iii	Yes	1-2 GRBAP s5 p2
IIM 2.5	Life cycle of the micro-organism including various forms that may occur, differences in pathogenic/ toxigenic character of	R	2.4	885.11	2.7.2 iv	Yes	1-2 GRBAP s5 p2

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	various forms, virulence and survival time of resting stages, interactions with other species (vector, parasitism, competition)						
IIM 2.6	Potential of the micro-organism to produce metabolites that are of concern for human health and/or the environment.	R	2.8	850.4000	2.7.2 xi		GRBAP s5 p2
IIM 2.7	Information regarding closely related species	R	2.6 2.8	885.1100 850.4000	2.7.2 ix 2.7.2 xi		GRBAP s5 p2
IIM 2.7.1	Among closely related species, provide information on pathogenicity to plants, animals or humans	R	2.6	885.1100	2.7.2 ix		GRBAP s5 p2
IIM 2.7.2	Among closely related species, provide information on formation of toxic metabolites: structure, stability, conditions under which they are formed, mode of action	R	2.8	850.4000	2.7.2 xi		GRBAP s5 p2
IIM 2.8	Physiological properties, especially effect of environmental parameters on growth, infectivity, dispersal and colonisation ability: temperature, pH, redox potential, humidity, light, nutritional requirements	R	2.5		2.7.2 vi		
IIM 2.9	Description of any plasmids or other extra chromosomal genetic elements involved in pesticidal activity, pathogenicity, toxicity, etc.	R		885.11	2.7.2 v		
IIM 2.10	Genetic stability (mutation rate of traits related to the mode of action), factors affecting genetic stability; micro-organism's capacity to transfer genetic information to another population	R	2.7		2.7.1		
IIM 2.11	Detailed discussion of relationship of micro-organism to any known human dermatophyte (see point 5.2)	R			2.7.2 x		
IIM 2.12	Information on resistance/sensitivity to antibiotics/anti-microbial agents used in human or veterinary medicine	R	2.9		2.7.2vi		10

Appendix 6 Format for the listing of test and study reports and other documentation		Part 4 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Agents
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Point 3 Further Information on the Microbial Pest Control Agent (Function, Mode of Action, Handling)							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIB point number	US EPA Guideline / Requirement number ⁹	Canadian Data Code (DACO) ¹⁰	Japanese data requirement Yes / No ¹¹	Australian data requirement
IIM 3.1	Function, e.g. fungicide	R	3.1		1.2	Yes	36892
IIM 3.2	placeholder						
IIM 3.3	Field of use, e.g. forestry	R	3.2		1.2	Yes	36892
IIM 3.4	Information on target crop and target organism(s)	R	3.3				
			2.2.1				
IIM 3.4.1	Details of existing and intended uses (crops, groups of crops, plants or plant products treated or protected)	R	3.2	860.1200 40CFR 152.50(e)	1	No	1-3.7 1-3.8 1-3.9
IIM 3.4.2	Details of harmful organisms against which protection is afforded	R	2.2.1	860.1200 40CFR 152.50(e)	10.2.2	Yes	1-2 GRBAP s5 p2
IIM 3.4.3	Effects achieved e.g. sprout suppression	R	3.3		10.2.3	Yes	1-2 GRBAP s5 p2
IIM 3.5	Information on mode of action and metabolites	R	2.2.2				
			2.8				
IIM 3.5.1	Statement of the mode of action of the Microbial Pest Control Agent in terms of biochemical and physiological mechanism(s) and biochemical pathway(s) involved. (see IIM 2.3.2)	R	2.2.2		10.2.1	Yes	1-2 GRBAP s5 p2
IIM 3.5.2	Details of active metabolites (especially toxins) and degradation products, cross referenced to the toxicological and residues data provided, to include:	R	2.8	885.13	10.2.1	Yes	GRBAP s5 p2
IIM 3.5.2.1	- IUPAC and CA names						
IIM 3.5.2.2	- ISO common name proposed or accepted						
IIM 3.5.2.3	- CAS, CIPAC, EINECS and ELINCS numbers						
IIM 3.5.2.4	- molecular and structural formula						
IIM 3.5.2.5	- molecular mass						
IIM 3.5.3	Information relative to the formation of active metabolites (especially toxins) and degradation products, to include:	R	2.8	885.13	10.2.1	No	GRBAP s5 p2
IIM 3.5.3.1	- the processes, mechanisms and reactions involved						

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Appendix 6 documentation		Format for the listing of test and study reports and other		Part 4 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Agents			
Point 3 Further Information on the Microbial Pest Control Agent (Function, Mode of Action, Handling)							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIB point number	US EPA Guideline / Requirement number ⁹	Canadian Data Code (DACO) ¹⁰	Japanese data requirement Yes / No ¹¹	Australian data requirement
IIM 3.5.3.2	- kinetic and other data concerning the rate of conversion and if known the rate limiting step						
IIM 3.5.3.3	- environmental and other factors effecting the rate and extent of conversion						
IIM 3.6	Information on the possible occurrence of the development of resistance or cross-resistance	R	3.5				GRBAP s5 p2
IIM 3.7	A material safety data sheet for the Microbial Active Substance	R	3.7		2.11.2	No	-
IIM 3.8	Detailed instructions for safe disposal	R	3.8	40 CFR 165.9 (a) - (d)	8.4.1	No	-
IIM 3.9	Procedures for the decontamination of water in case of an accident	R	3.9		8.4	No	-
IIM 3.10	Other/special studies	CR	3		2.16 8.6 10.6	No	GRBAP s5
IIM 3.11	Crops or products to be protected or treated (see IIM 3.4.1)	R	3.3	885.125	1.2	R	-
IIM 3.12	Measures to render micro-organism harmless, in case of an accident	R	3.9				-

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Appendix 6 Format for the listing of test and study reports and other documentation		Part 4 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Agents

Point 4 Analytical Methods							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIB point number	US EPA Guideline / Requirement number ⁹	Canadian Data Code (DACO) ¹⁰	Japanese data requirement Yes / No ¹¹	Australian data requirement
IIM 4.1	Method to preserve and maintain the master seed stock; criteria for an acceptable level of consistency and integrity of seed stock	R	3.6	885.12	2.8	Yes	GRBAP s5 p2
IIM 4.2	Production process for Technical Grade of MPCA, describing techniques used to ensure a uniform product and procedures when hazardous contamination is detected in a batch. List starting and intermediate materials, with source and purity of each.	R	3.4	885.1200 885.1300	2.8	Yes	2-4.3(e) GRBAP s5 p2
IIM 4.3	Quality control and post-registration monitoring methods	R	3.4 4.1	885.1200 885.1300 885.1500	2.7.2xi 2.8 2.9.3 2.10.1		2-4.3(f) GRBAP s5 p2
IIM 4.3.1	Methods to detect, isolate, and enumerate the micro-organism						
IIM 4.3.2	Methods to differentiate a mutant or genetically-modified micro-organism from the parent strain.						
IIM 4.3.3	Methods to detect spontaneous change in major characteristics of micro-organism.						
IIM 4.3.4	Methods to define content of micro-organism in appropriate terms (same as IIM 1.4.1), incl. standardisation, sensitivity, reproducibility, statistical validity, and representative data to validate the bioassay.						
IIM 4.3.5	Methods to show control to a specified and acceptable level, of microbial impurities and of any other impurities of toxicological concern, including toxic metabolites, which are known or suspected to be present at any stage of the manufacturing process.						
IIM 4.3.6	Methods to show presence of any human and mammalian pathogens.						
IIM 4.4	Storage stability test, data and determination of shelf life, if MPCA is stored	R		885.24	2.11	R	2-4.3©)

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Point 4 Analytical Methods							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIB point number	US EPA Guideline / Requirement number ⁹	Canadian Data Code (DACO) ¹⁰	Japanese data requirement Yes / No ¹¹	Australian data requirement
IIM 4.5	Post-registration monitoring methods to determine and quantify residues of viable or non-viable micro-organism and metabolites (especially toxins)	CR	4.2				-
IIM 4.5.1	Food (where relevant)						
IIM 4.5.2	Feed (where relevant)						
IIM 4.5.3	Animal tissue (where relevant)						
IIM 4.5.4	Soil (where relevant)						
IIM 4.5.5	Water (where relevant)						
IIM 4.5.6	Air (where relevant)						
IIM 4.5.7	Analytical methods for amount or activity of proteinaceous products (where relevant)						

Appendix 6 Format for the listing of test and study reports and other documentation		Part 4 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Agents
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Point 5 Toxicological and Exposure Data and Information on the Microbial Pest Control Agent							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIB point number	US EPA Guideline / Requirement number ⁹	Canadian Data Code (DACO) ¹⁰	Japanese data requirement Yes / No ¹¹	Australian data requirement
IIM 5.1	Summary: potential of microbial pest control agent to be hazardous to humans with consideration of its pathogenic potential, its ability to infect and pattern of clearance, and its toxicological effects	R	5.1.1		4.1		3-4.10
IIM 5.2	Occupational health surveillance report on workers during production and testing of MPCA, including information on: see IIM 5.2.1 to 5.2.4. Published reports of adverse effects, especially reports of clinical cases and followup studies. Proposed first aid measures and medical treatment.	R	5.1.2 5.1.3 5.1.4 5.2.6	40CFR 152.50f(3) or post reg. 40CFR 152.125 2.7.2 xiii	4.6 5.0 1.1	Yes	GRBAP s5 p6 36956 3-4.9
IIM 5.2.1	The sensitisation and allergenic response of workers	R	5.1.2 5.1.3 5.1.4	40CFR 152.50f(3) or post reg. 40CFR 152.125	4.6 5.0	Yes	GRBAP s5 p6
IIM 5.2.2	Details on any occurrence of hypersensitivity and chronic sensitisation	R	5.1.2 5.1.3 5.1.4	40CFR 152.50f(3) or post reg. 40CFR 152.125	4.6 5.0	Yes	GRBAP s5 p6
IIM 5.2.3	Any significant clinical findings related to exposure, with special attention to those whose susceptibility may be affected.	R	5.1.2 5.1.3 5.1.4	40CFR 152.50f(3) or post reg. 40CFR 152.125	4.6 5.0	Yes	GRBAP s5 p6
IIM 5.2.4	Published reports of adverse effects, especially reports of clinical cases and followup studies; list databases and key words used in a literature search.	R	5.1.4	40CFR 152.50f(3) or post reg. 40CFR 152.125	4.6 5.0	Yes	GRBAP s5 p6
IIM 5.2.5	Proposed first aid measures and medical treatment	R	5.2.6	40CFR 152.50f(3) or post reg. 40CFR 152.125	4.6 5.0	Yes	GRBAP s5 p6
IIM 5.3	Basic studies	R	5.2				
IIM 5.3.1	Sensitisation properties	R	5.2.1				

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IIM 5.3.2	Acute oral infectivity, toxicity and pathogenicity	R	5.2.2.1	885.305	4.2.2	Yes	3-4.2 GRBAP s5 p3
IIM 5.3.3	Acute intratracheal/inhalation infectivity, toxicity and pathogenicity	R	5.2.2.2	885.315	4.2.3	Yes	3-4.2 GRBAP s5 p3
IIM 5.3.4	Acute intravenous/intraperitoneal infectivity	R	5.2.2.3	885.32	4.3	Yes	3-4.2 GRBAP s5 p3
IIM 5.3.5	Genotoxic potential, especially for fungi and actinomycetes: a discussion of the potential for genotoxin production based on the relationship of the micro-organism to a genus/species known to produce genotoxins. If a related fungus/actinomycete produces a genotoxin, either an appropriate and sensitive analytical test (e.g. HPLC) must be done to detect its presence in the MPCA (for Canada), or genotoxicity testing is required (for EC).	R	5.1 5.2.3		2.7.2 xii 4.8		3-4.8 GRBAP s5 p3
IIM 5.3.6	Cell culture study, for viruses and viroids or specific bacteria and protozoa with intracellular replication	R	5.2.4	885.35	4.7	Yes	GRBAP s5 p3
IIM 5.3.7	Short-term toxicity (including inhalatory short-term toxicity), pathogenicity, infectivity	R	5.2.5 5.2.5.1				
IIM 5.3.7.1	Short-term toxicity, pathogenicity, infectivity (28-day minimum)	R	5.2.5				
IIM 5.3.7.2	Inhalatory short-term toxicity	R	5.2.5.1				
IIM 5.4	Toxicity studies on metabolites (especially toxins)	CR	5.2.3	885.335		Yes	3-4.9 GRBAP s5 p3
IIM 5.5	Other/special studies	CR	5.3 5.4 5.5		4.2.9 4.3.8 4.4.5 4.5.8 4.5.12 4.8 5.1.4 10.3.2	Yes	GRBAP s5 p3
IIM 5.5.1	Specific toxicity, pathogenicity and infectiveness studies	CR	5.3				

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IIM 5.5.2	<i>In vivo</i> studies in somatic cells	R	5.4				
IIM 5.5.3	Genotoxicity - <i>In vivo</i> studies in germ cells	R	5.5				
IIM 5.6	Summary of mammalian toxicity and overall evaluation	R	5.6			Yes	3-2.2

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Point 6 Metabolism and Residues Studies on the Microbial Pest Control Agent							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIB point number	US EPA Guideline / Requirement number ⁹	Canadian Data Code (DACO) ¹⁰	Japanese data requirement Yes / No ¹¹	Australian data requirement
IIM 6.1	Rationale for waiver of residue data based on information showing that MPCA is not hazardous to mammals, i.e. lack of potential for a known mammalian toxin and negative result from the acute oral toxicity test.	R	6	40CFR 158.740(b)	7	Yes	GRBAP s5 p5
IIM 6.2	Rationale for waiver based on a substantiated estimation that MPCA is unlikely to occur on treated food/feed stuffs in concentrations considerably higher than under natural conditions.	CR					
IIM 6.3	Persistence and likelihood of multiplication in or on crops, feedingstuffs or foodstuffs	CR	6.1				
IIM 6.4	Further information required	CR	6.2				
IIM 6.4.1	Non-viable residues	CR	6.2.1				
IIM 6.4.2	Viable residues	CR	6.2.2				
IIM 6.5	Summary of residue behaviour and overall evaluation	CR	6.3				

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Point 7 Fate and Behaviour Studies on the Microbial Pest Control Agent in the Environment							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIB point number	US EPA Guideline / Requirement number ⁹	Canadian Data Code (DACO) ¹⁰	Japanese data requirement Yes / No ¹¹	Australian data requirement
IIM 7.1	Sufficient information on the origin, properties, survival and residual metabolites of the micro-organism to assess its fate and behaviour in the environment. Information provided in parts 2 - 6 may suffice. Viability/population dynamics, persistence, multiplication and mobility	EU - R US - CR Japan - CR Canada - CR	7.1	885.5200 885.5300 885.5400	8.3.2		-
IIM 7.1.1	Persistence and mobility in soil	EU - R US - CR Japan - CR Canada - CR	7.1.1 7.2	885.5200 885.5300 885.5400	8.3.2		-
IIM 7.1.2	Water	EU - R US - CR Japan - CR Canada - CR	7.1.2	885.5200 885.5300 885.5400	8.3.2		-
IIM 7.1.3	Air	EU - R US - CR Japan - CR Canada - CR	7.1.3	885.5200 885.5300 885.5400	8.3.2		-
IIM 7.2	Other/special studies	CR	7		8.2.3.6 8.2.4.6 8.5 8.6	No	-

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Point 8 Ecotoxicological Studies on the Microbial Pest Control Agent							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIB point number	US EPA Guideline / Requirement number ⁹	Canadian Data Code (DACO) ¹⁰	Japanese data requirement Yes / No ¹¹	Australian data requirement
IIM 8	Effects on non-target organisms	R	8	885.4050 850.4000 885.4100		Yes	-
IIM 8.1	Effects on birds	R	8.1				-
IIM 8.2	Effects on fish	R	8.2.1	885.4200 885.4280	9.4	Yes	-
IIM 8.3	Effects on aquatic invertebrates	R	8.2.2	885.425	9.5.2	Yes	-
IIM 8.4	Effects on algal growth and growth rate	R - EU only	8.2.3				-
IIM 8.5	Effects on aquatic plants	CR	8.2.4	850.4000	9.8	Yes	-
IIM 8.6	Effects on terrestrial plants	CR		885.4300	9.8	Yes	-
IIM 8.7	Effects on bees	R	8.3	885.438	9.5.1	Yes	-
IIM 8.8	Effects on terrestrial arthropods other than bees	R	8.4	885.4340	9.5.1	Yes	-
IIM 8.9	Effects on other terrestrial invertebrates	CR			9.2.7	No	-
IIM 8.9.1	Effects on earthworms	R	8.5		-		-
IIM 8.9.2	Effects on other terrestrial invertebrates	R			-		-
IIM 8.10	Effects on soil micro-organisms	R	8.6		-	Yes	-
IIM 8.11	Other/special studies	CR	8.7				-

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Point 9 Summary and evaluation of environmental impact of the Microbial Pest Control Agent							
OECD data point number	Information, test or study	R or CR	EU Annex IIB point number	US EPA Guideline / Requirement number ⁹	Canadian Data Code (DACO) ¹⁰	Japanese data requirement Yes / No ¹¹	Australian data requirement
IIM 9	Summary and evaluation of environmental impact: summarise all data relevant to environmental impact and assess environmental risk by:	R	9		9.1 12.7		-
IIM 9.1	- addressing distribution and fate of MPCA						
IIM 9.2	- identifying non-target species at risk and the extent of their exposure						
IIM 9.3	- identifying precautions necessary to minimise environmental contamination and to protect non-target species.						

9 US Data Requirements are found in 40CFR 158.740/ The new US guidelines recommending how to perform the studies are in the 8xx.xxxx series and are available at <http://www.epa.gov/opptsfrs/home/testmeth.htm>

10 Data code used by the Canadian Pest Management Regulatory Agency

11 Data point numbering system being developed