

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. 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.
4. 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.
5. 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.
6. In the table that follows, CR means that the information is conditionally required.
7. 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.
8. Member countries may require additional information on a proposed product to address potential hazards and

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exposure scenarios specific to the proposal.

9. If a microbial pesticide does not meet the above criteria, member countries may require additional information or refuse registration.

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Point 1 **Identity 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 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 1.3.1	Scientific name of microorganism to species level or a level sufficient to show taxonomic relation to known microorganisms, especially pathogens; <ul style="list-style-type: none"> • accession no. of sample in a recognized culture collection • test procedures and criteria, using best available technology, to characterize the strain or serotype; • for mutant or genetically-modified strains, indicate all known differences between the modified microorganism and the parent wild strain(s) • include any trade names, common names, developmental code names • indigenous or non-indigenous at the species level to the intended area of application (required in the EU) 	R	1.3	885.1100 885.2100	2.4 2.5 2.71	Yes	GRBAP s5 p2
IIM 1.4	Composition of Technical Grade of MPCA/ Active Substance						2-4.2

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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) ¹¹	Japanese data requirement Yes / No ¹¹	Australian data requirement
IIM 1.4.1	Concentration of microorganism (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 recognized 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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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) ¹¹	Japanese data requirement Yes / No ¹¹	Australian data requirement
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IIM 1.4.2	<p>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:</p> <ul style="list-style-type: none"> • the MPCA • additives (preservatives, stabilizers, diluents) • microbial impurities, classified/ identified to a taxonomic level required by quality criteria to support the hygienic state of the production process • non-microbial impurities (eg. metabolic products, impurities in starting materials, fermentation residues, extraneous host residues) <p>This information is not required if Technical Grade of MPCA is a hypothetical stage in a continuous production process of an end-use product.</p>	R	1.4.2	885.1100 885.1300	2.9.1	Yes	2-4.3 GRBAP s5 p2, 4.1
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Point 1 Identity 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 1.4.2 (continued)	Composition in terms of % g/kg or g/L, w/w for each ingredient: The identity and maximum content of all microbial impurities must be reported, if possible and appropriate, expressed in appropriate units, as outlined in point 1.3.1 (in terms of cfu`s/mL or appropriate expression of biological activity / viability)		1.4.2	885.13			
IIM 1.4.3	Quality criteria for the production and storage of the MPCA, including: criteria for consistency and integrity of the master and working seed stock, typically, measures of biological activity and phenotypic or genotypic properties: <ul style="list-style-type: none"> • acceptable range for content of MPCA, in appropriate terms; • presence of human/ mammalian pathogens; • 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 • maximum accepted level for microbial impurities, using suitable indicators of an unhygienic process 	R	3.4	885.1300 885.1500	2.8 2.9.1 2.10.2	Yes	2-4.3(f) GRBAP s5 p7

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Point 1 Identity 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 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	A theoretical discussion regarding <ul style="list-style-type: none"> • formation and/or presence of unintentional ingredients, including impurities of toxicological concern, likely to occur in the Technical Grade of the MPCA, • the impact of these ingredients on product quality, and • appropriate quality criteria. 	R		885.13	2.9.3		2-4.3(e) GRBAP s5 p2
	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, oxidizing properties; technical characteristics as appropriate	R		40CFR 158.740(a)	2.12	Yes	2-4.3(b) GRBAP s5 p2
	International regulatory status of microorganism	R			1.3		2-4.3(a) GRBAP s5 p2

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Point 1 **Identity 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 1.4.5 (continued)	Comprehensive Data Summary / Tier II summaries in OECD format: "Guidelines and Criteria for Industry for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for Plant Protection Products and their Microbial Active Substances in Support of Regulatory Decisions in OECD Countries, Appendix 7 and 8 / Tier II format required by Annex IIB of 91/414/EEC.	R			12.7	Yes	-
	Sample of MPCA, analytical standard of metabolite (and reference substances for the relevant impurities - EU only): if requested	R	4	830.19			2-4.3(I)
IIM 1.5.3	Patent Status	R			2.6		-

Point 2 Biological Properties 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 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; describe any unusual morphological, physiological, pesticidal or resistance characteristics of MPCA which differ from classical description of species	R	2.1	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 microorganism including geographic distribution, hosts, habitat, ecological niche, level of natural occurrence	R	2.1	885.11	2.7.2 i	Yes	GRBAP s5 p1&2
IIM 2.3	Description of target organism(s); information on mode of action, kind of antagonism to target host, infective/toxic dose, transmissibility	R	2.2	885.11	2.7.2 ii	Yes	1-2 GRBAP s5 p2

Point 2 Biological Properties of the Microbial Pest Control Agent

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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 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 - always required in the EU).	R	2.3	885.11	2.7.2 iii	Yes	1-2 GRBAP s5 p2
IIM 2.5	Life cycle of micro-organism including various forms that may occur, differences in pathogenic/ toxigenic character of various forms, virulence and survival time of resting stages, interactions with other species (vector, parasitism, competition)	R	2.4	885.11	2.7.2 iv	Yes	1-2 GRBAP s5 p2

Point 2 Biological Properties 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 2.6	Among closely related species, provide available information on:	R	2.6 2.8	885.1100 850.4000	2.7.2 ix 2.7.2 xi		GRBAP s5 p2
	<ul style="list-style-type: none"> pathogenicity to plants, animals or humans formation of toxic metabolites: structure, stability, conditions under which they are formed, mode of action. 						
	Physiological properties, especially effect of environmental parameters on growth, infectivity, dispersal, and colonization ability: temperature, pH, redox potential, humidity, light, nutritional requirements	R	2.5		2.7.2 vi		
	Description of any plasmids or other extra chromosomal genetic elements involved in pesticidal activity, pathogenicity, toxicity, etc.	R		885.11	2.7.2 v		
	Genetic stability (mutation rate of traits related to the mode of action), factors affecting genetic stability; microorganism's capacity to transfer genetic information to another population	R	2.7		2.7.1		

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IIM 2.6 (continued)	Detailed discussion of relationship of microorganism to any known human dermatophyte (see point 5.2)	R			2.7.2 x		
	Resistance/sensitivity to antibiotics / anti-microbial agents used in human or veterinary medicine	R	2.9		2.7.2vi		10

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	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 <i>e.g.</i> fungicide	R	3.1		1.2	Yes	36892
IIM 3.3	Fields of use <i>e.g.</i> forestry	R	3.2		1.2	Yes	36892
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 <i>e.g.</i> sprout suppression	R	3.3		10.2.3	Yes	1-2 GRBAP s5 p2
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	R	2.2.2		10.2.1	Yes	1-2 GRBAP s5 p2

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	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 3.5.2	<p>Details of active metabolites (especially toxins) and degradation products, cross referenced to the toxicological and residues data provided, to include:</p> <ul style="list-style-type: none"> • IUPAC and CA names • ISO common name proposed or accepted • CAS, CIPAC, EINECS and ELINCS numbers • molecular and structural formula • molecular mass 	R	2.8	885.13	10.2.1	Yes	GRBAP s5 p2
IIM 3.5.3	<p>Information relative to the formation of active metabolites (especially toxins) and degradation products, to include:</p> <ul style="list-style-type: none"> • the processes, mechanisms and reactions involved • kinetic and other data concerning the rate of conversion and if known the rate limiting step • environmental and other factors effecting the rate and extent of conversion 	R	2.8	885.13	10.2.1	No	GRBAP s5 p2
IIM 3.6	Information on the possible occurrence of the development of resistance or cross-resistance	R	3.5				GRBAP s5 p2

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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	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 3.7	A material safety data sheet for the Microbial Active Substance	R	3.7		2.11.2	No	-
IIM 3.8.1.2	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			2.16 8.6 10.6	No	GRBAP s5
IIM 3.11	Crops or products to be protected or treated	R	3.3	885.125	1.2	R	-
IIM 3.12	Measures to render microorganism harmless, in case of an accident	R	3.9				-

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Point 4 **Analytical Methods**

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 4.1.5	Method to preserve and maintain the master seed stock; criteria for an acceptable level of consistency and integrity of seed stock	R	4.1 3.6	885.12	2.8	Yes	GRBAP s5 p2
IIM 4.2.8	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

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Point 4 **Analytical Methods**

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 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
	<ul style="list-style-type: none"> • to detect, isolate, and enumerate the microorganism • to differentiate a mutant or genetically-modified microorganism from the parent strain. • to detect spontaneous change in major characteristics of microorganism. • to define content of micro-organism in appropriate terms (same as 1.4.1), incl. standardization, sensitivity, reproducibility, statistical validity, and representative data to validate the bioassay. • 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. • to show presence of any human and mammalian pathogens. 						

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Point 4 **Analytical Methods**

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 4.4	Storage stability test, data and determination of shelf life, if MPCA is stored	R	4.1	885.24	2.11	R	2-4.3©)
IIM 4.5	Post-registration monitoring methods to determine and quantify residues of viable or non-viable micro-organism and metabolites (especially toxins) on food, feed, animal tissue, in soil, water or air, where relevant. (Analytical methods for amount or activity of proteinaceous products - required in the EU, where relevant)	CR	4.2				-

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	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		4.1		3-4.10
IIM 5.2	Occupational health surveillance report on workers during production and testing of MPCA, including information on: <ul style="list-style-type: none"> the sensitization and allergenic response of workers details on any occurrence of hypersensitivity and chronic sensitization any significant clinical findings related to exposure, with special attention to those whose susceptibility may be affected 	R	5.1.2 5.1.3 5.2.1	40CFR 152.50f(3) or post reg. 40CFR 152.125	4.6 5.0	Yes	GRBAP s5 p6
IIM 5.3	Acute oral infectivity and toxicity	R	5.2.2.1	885.305	4.2.2	Yes	3-4.2 GRBAP s5 p3
IIM 5.4	Acute intra tracheal/ inhalation infectivity and toxicity	R	5.2.2.2	885.315	4.2.3	Yes	3-4.2 GRBAP s5 p3
IIM 5.5	Acute intravenous/ intra peritoneal infectivity	R	5.2.2.3	885.32	4.3	Yes	3-4.2 GRBAP s5 p3
IIM 5.6	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

Point 5 Toxicological and Exposure Data and Information on the Microbial Pest Control Agent

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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 5.7	Genotoxic potential, especially for fungi and actinomycetes: a discussion of the potential for genotoxin production based on the relationship of the microorganism 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 5.8	Toxicity studies on metabolites (especially toxins)	CR	5.1 5.2.3	885.335		Yes	3-4.9 GRBAP s5 p3
IIM 5.9	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	40CFR 152f(3) or 40CFR 152.125	2.7.2 xiii	No	3-4.9
IIM 5.9.1	Proposed first aid measures and medical treatment	R	5.2.6		1.1		36956

Point 5 **Toxicological and Exposure Data and Information on the Microbial Pest Control Agent**

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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 5.10	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 5.10.1	Short-term toxicity, pathogenicity, infectivity (28-day minimum) - for EU only	R	5.2.5				-
IIM 5.11	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	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
	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.		6.1				
	Summary of residue behaviour and overall evaluation		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	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	Sufficient information on the origin, properties, survival and residual metabolites of the microorganism 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	885.5200 885.5300 885.5400	8.3.2		-
IIM 7.13	Other/special studies	CR			8.2.3.6 8.2.4.6 8.5 8.6	No	-

Point 8 Ecotoxicological Studies on 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 8	Effects on non-target organisms	R	8	885.4050 850.4000 885.4100		Yes	-
IIM 8.1	Birds	R	8.1				-
IIM 8.2	Fish	R	8.2.1	885.4200 885.4280	9.4	Yes	-
IIM 8.3	Aquatic invertebrates	R	8.2.2	885.425	9.5.2	Yes	-
IIM 8.4	Effects on algal growth and growth rate (2 species)	R - EU only	8.2.3				-
IIM 8.6	Effects on aquatic or terrestrial plants	CR	8.2.4	850.4000 885.4300	9.8	Yes	-
IIM 8.7	Bees	R	8.3	885.438	9.5.1	Yes	-
IIM 8.8	Non-target terrestrial arthropods	R	8.4	885.4340	9.5.1	Yes	-
IIM 8.9	Other terrestrial invertebrates	CR	8.7		9.2.7	No	-
IIM 8.9.1	In EU effects on earthworms required	R	8.5		-		-
IIM 8.10	In EU Effects on non-target soil microorganisms required	R	8.6		-	Yes	-
IIM 8.11	Other/special studies	CR	8.7				-

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 9 **Summary Information for 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	<p>Summary and evaluation of environmental impact: summarize all data relevant to environmental impact and assess environmental risk by:</p> <ul style="list-style-type: none"> • addressing distribution and fate of MPCA • identifying non-target species at risk and the extent of their exposure • identifying precautions necessary to minimize environmental contamination and to protect non-target species. 	R	9		9.1 12.7		-

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

