

PART 5

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

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 active substances and Microbial Pest Control Products 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 active substances and Microbial Pest Control Products 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 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products
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Point 1 Identity of the Microbial Pest Control Product							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No	Australian data requirement
IIIM 1.1	Applicant (name, address, contact, telephone and telefax numbers)	R	1.1	40CFR 152.50	2.1	Yes	1.2
IIIM 1.2	Manufacturer(s) of the preparation and producer of the microbial pest control agent	R	1.2	40CFR 167.20	2.2 2.3	Yes	GRBAP s5 pl 2-4.2 2-4.3(d) 2-5.2(f)
IIIM 1.2.1	Manufacturer(s) of the preparation (name, address, contact, telephone and telefax numbers)	R	1.2	40CFR 167.20	2.3	Yes	GRBAP s5 pl 2-5.2(f)
IIIM 1.2.2	Producer of the microbial pest control agent (name, address, contact, telephone and telefax numbers)	R	1.2	40CFR 167.20	2.2	Yes	2-4.2 2-4.3(d) GRBAP s5 pl
IIIM 1.3	Trade name or proposed trade name and manufacturers code number(s), for the preparation and similar preparations (differences to be specified)	R	1.3	885.1100	2.4	Yes	2-5.2(a) GRBAP s5 p2
IIIM 1.4	Placeholder						
IIIM 1.5	Physical state of MPCP (Crop Life formulation type)	R	1.5	885.1600	1.2 2.9.1	Yes	2-5.2(b) GRBAP s5 p2
IIIM 1.6	Function (herbicide, insecticide, etc.)	R	1.6	Form 8570-4(15)	10.2.1	Yes	1.2
IIIM 1.6.1	Biological function category and field of use category, using terms defined by each country, e.g. "control of weeds" for "forestry"	R	3.1	40CFR 152.50	1.2	Yes	GRBAP s5 pl

	- A6/5 -	
Appendix 6 Format for the listing of test and study reports and other documentation		Part 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products

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IIIM 1.7	Other/special studies	CR	1		3.7 10.6	No	GRBAP S5 P1
IIIM 1.7.1	Concentration of MPCA in MPCP, measured in terms of g/kg or g/L of the MPCP (for US and Canada, also provide figures in % w/w) and in cfu's or other appropriate potency units; provide content of MPCA in Technical Grade of MPCA, in the same terms.	R	1.4	885.1100	2.9.2	Yes	2-5.2 ©) GRBAP s5 p2
IIIM 1.7.1.1	Also indicate: scientific name and strain/serotype of MPCA, its accession number in a recognised culture collection						
IIIM 1.7.1.2	Also indicate: development phase (e.g. spore) of MPCA in MPCP						
IIIM 1.7.2	Composition in terms of g/kg or g/L and % w/w of each ingredient in MPCP, including:	R	1.4	885.1100 885.1300 885.1500	2.9.2 2.9.3	Yes	2-5.2(d) GRBAP s5 p2
IIIM 1.7.2.1	- technical Grade of MPCA						
IIIM 1.7.2.2	- each additive: include chemical name and structure; CAS and EEC numbers of components of additive if they exist or an appropriate specification; trade name; function in the MPCP						
IIIM 1.7.2.3	- microbial impurities: taxonomic identification as required by quality criteria to support the hygienic state of the production process; express content of microbial impurities in appropriate units, e.g. cfu's/ml.						
IIIM 1.7.2.4	- non-microbial impurities (e.g. metabolic products, impurities in starting materials, fermentation residues, extraneous host residues)						

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OECD data point number	Information, test or study	R or CR	Former EU Annex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No	Australian data requirement
IIIM 1.7.3	Quality criteria for the production and storage of the MPCP, including:	R	1.4	885.1300 885.1500	2.8 2.9.1 2.10.2	Yes	2-5.2 (h) GRBAP s5 p2
IIIM 1.7.3.1	- acceptable range for content of MPCA, in appropriate terms;						
IIIM 1.7.3.2	- presence of human or non-target animal pathogens;						
IIIM 1.7.3.3	- 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						
IIIM 1.7.3.4	- maximum accepted level for microbial impurities, using suitable indicators of contamination						
IIIM 1.7.4	Quality control data (measures of quality criteria) from 3 - 5 production batches, including product stored for duration of shelf life if it is metabolically active. 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		885.1300 885.1400 885.1500	2.8 2.9.1 2.10.2	Yes	2-5.2 (I) 2-5.2 (k) 2-5.2 (j) GRBAP s5p2
IIIM 1.7.5	The formation, presence and/or impact of unintentional ingredients	R		885.1300	2.9.3	Yes	2-5.2(I) 2-5.2(l) GRBAP s5p2
IIIM 1.7.5.1	A theoretical discussion regarding the formation and/or presence of unintentional ingredients, including impurities of toxicological concern, likely to occur in the MPCP						
IIIM 1.7.5.2	A theoretical discussion regarding the impact of these ingredients on product quality						
IIIM 1.7.5.3	A theoretical discussion regarding appropriate quality criteria.						

	- A6/7 -	
Appendix 6 Format for the listing of test and study reports and other documentation		Part 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products

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OECD data point number	Information, test or study	R or CR	Former EU Annex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No	Australian data requirement
IIIM 1.7.5.4	For metabolically-active MPCP, consider degradation or metabolic production during storage in the theoretical discussion.						

	- A6/8 -	
Appendix 6 Format for the listing of test and study reports and other documentation		Part 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products

Point 2 Physical, Chemical and Technical Properties of the Microbial Pest Control Product							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
IIIM 2.1	Appearance (colour, odour, physical state)	R	2.1	830.6302 830.6303 830.6304	3.3.2	Yes	2-5.2(e) GRBAP s5 p2
IIIM 2.2	Storage stability and shelf-life for MPCP which must contain metabolically active MPCA, include QC data for hazardous contaminants originating from degradation or metabolic production during storage.	R	2.2 2.2.1 2.2.2	885.2400	2.11	Yes	2-5.2(j)\ 2-5.2 (k) GRBAP s5 p2
IIIM 2.3	Explosivity, oxidising properties, flash point, flammability, spontaneous ignition, acidity, alkalinity, pH, viscosity, surface tension	R	2.3 2.4 2.5 2.6		2.12	Yes	2-5.2 (e) GRBAP s5p2
IIIM 2.3.1	Explosivity, oxidising properties: as appropriate	R	2.3		2.12	Yes	2-5.2 (e) GRBAP s5p2
IIIM 2.3.2	Flash point, flammability, spontaneous ignition: as appropriate	R	2.4		2.12	Yes	2-5.2 (e) GRBAP s5p2
IIIM 2.3.3	Acidity, alkalinity, pH: as appropriate	R	2.5		2.12	Yes	2-5.2 (e) GRBAP s5p2
IIIM 2.3.4	Viscosity, surface tension: as appropriate	R	2.6		2.12	Yes	2-5.2 (e) GRBAP s5p2
IIIM 2.4	Technical characteristics as appropriate:	R	2.7		2.12	Yes	2-5.2(e) GRBAP s5p2
IIIM 2.4.1	Wettability	R	2.7.1		2.12	Yes	2-5.2(e) GRBAP s5p2
IIIM 2.4.2	Persistent foaming	R	2.7.2		2.12	Yes	2-5.2(e) GRBAP s5p2
IIIM 2.4.3	Suspensibility, suspension stability	R	2.7.3		2.12	Yes	2-5.2(e) GRBAP s5p2
IIIM 2.4.4	dry sieve test and wet sieve test	R	2.7.4		2.12	Yes	2-5.2(e) GRBAP s5p2
IIIM 2.4.5	particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and	R	2.7.5		2.12	Yes	2-5.2(e) GRBAP s5p2

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Point 2 Physical, Chemical and Technical Properties of the Microbial Pest Control Product							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
	friability (granules)						
IIIM 2.4.6	emulsifiability, re-emulsifiability, emulsion stability	R	2.7.6		2.12	Yes	2-5.2(e) GRBAP s5p2
IIIM 2.4.7	flowability, pourability (rinsability), dustability	R	2.7.7		2.12	Yes	2-5.2(e) GRBAP s5p2
IIIM 2.5	Density	R			2.12		
IIIM 2.6	Adherence and distribution to seeds, for seed treatment products		2.9				
IIIM 2.7	Summary and evaluation of data on properties of the MPCP	R	2.10				

	- A6/10 -	
Appendix 6 Format for the listing of test and study reports and other documentation		Part 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products

Point 3 Data on Application of the Microbial Pest Control Product							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
IIIM 3.1	Pest to be controlled, crop to be protected, available information on mode of action (site of uptake, toxic/competitive effect, is micro-organism transmitted or translocated to another part of plant?)	R	3.2 3.3	40CFR 152.50(e)	1.1 1.2	Yes	1-3.4 8-3.3 GRBAP s5 p8
IIIM 3.2	Available information on the development of resistance in target pest and appropriate mitigation strategy.	R	6.3		10.4.4		8-4.4 GRBAP s5p8
IIIM 3.3	Application rate in terms of mass/vol of MPCP per unit area/volume (e.g. kg/ha). Content of micro-organism in material used (diluted spray, bait, treated seed).	R	3.4 3.5	40CFR 152.50(e)	1.1 1.2	Yes	1-3.5 8-4.3 (b) GRBAP s5 p8
IIIM 3.4	Application rate in terms of units of micro-organism per unit area/volume	R	3.4			Yes	8-3.3 GRBAP s5 p8
IIIM 3.5	Method of application (incl. type of equipment and volume of diluent)	R	3.6	40CFR 152.50(e)	1.1 1.2	Yes	8-3.3 GRBAP s5 p8
IIIM 3.6	Number, timing and conditions of applications, related to: host/pest phenology, duration of protection, application of other pesticides, pre-harvest interval	R	3.7 4.3	40CFR 152.50(e)	1.1 1.2	Yes	8-3.3 GRBAP s5 p8
IIIM 3.6.1	Number, timing and conditions of applications, related to: host/pest phenology, duration of protection, application of other pesticides.						
IIIM 3.6.2	Pre-harvest interval.						
IIIM 3.7	Precautions to avoid phytotoxic/phytopathogenic effects on protected crop or on succeeding crops, if appropriate	R	3.8	40CFR 152.50(e)	1.1	Yes	8-5 GRBAP s5p8

	- A6/11 -	
Appendix 6 Format for the listing of test and study reports and other documentation		Part 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products

Point 3 Data on Application of the Microbial Pest Control Product							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
IIIM 3.8	Proposed instructions for use as printed, or to be printed, on labels	R	3.9				

	- A6/12 -	
Appendix 6 Format for the listing of test and study reports and other documentation		Part 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products

Point 4 Further information on the Microbial Pest Control Product							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
IIIM 4.1	Packaging: description	R	4.1		3.3.2	Yes	2-5.2(m)
IIIM 4.2	Specifications of packaging and measures of its suitability	R	4.1			Yes	2-5.2 (m)
IIIM 4.3	Label instructions regarding cleaning equipment and protective clothing	R	4.2		1.1	Yes	1-3.5 GRBAP s5p6
IIIM 4.4	Procedures to clean equipment and protective clothing; measures of their effectiveness	R	4.2			Yes	6-1 GRBAP s5 p6
IIIM 4.5	Necessary waiting periods for re-entry; recommended protective measures to reduce occupational exposure	R	4.3		1.1 1.2	Yes	6-1 GRBAP s5p6
IIIM 4.6	Label instructions regarding: safe handling and storage	R	4.4		1.1	Yes	1-3.5 GRBAP s5p6
IIIM 4.7	Recommendations regarding: handling, storage, transport, fire: specify risks, specify procedures to minimise hazards and the generation of waste.	R	4.4			Yes	6-1 GRBAP s5 p6
IIIM 4.8	Label instructions regarding: cleanup of spills	R	4.5		1.1	Yes	1-3.5 GRBAP 25p6
IIIM 4.9	Detailed procedures in case of accident to: contain a spill, decontaminate an area or vehicle, dispose of adsorbents and packaging, protect workers and bystanders, first aid.	R	4.5			Yes	6-1
IIIM 4.10	Procedures for destruction/disposal of MPCP and its packaging	R	4.6			Yes	1-3.5
IIIM 4.10.1	Controlled incineration						
IIIM 4.10.2	Methods other than controlled incineration						

	- A6/13 -	
Appendix 6 Format for the listing of test and study reports and other documentation		Part 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products

Point 5 Methods of Analysis, Manufacturing, Quality Control and Post-Registration Monitoring of the Microbial Pest Control Product							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
IIIM 5.1	Quality control and post-registration monitoring methods	R	5.1	885.1200 885.1300 885.1500	2.7.2 xi 2.8 2.9.3 2.10.2 2.10.3	Yes	GRBAP s5 p6 & 7
IIIM 5.1.1	Methods to differentiate a mutant or genetically-modified micro-organism from the parent strain.						
IIIM 5.1.2	Methods to detect spontaneous change in major characteristics of micro-organism.						
IIIM 5.1.3	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.						
IIIM 5.1.4	Methods to identify contaminant micro-organisms in MPCP						
IIIM 5.1.5	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.						
IIIM 5.1.6	Methods to show presence of any human and mammalian pathogens.						
IIIM 5.2	Storage stability test and determination of shelf life (methods of analysis)	R	5.1	885.2400	2.11	Yes	2-5.2 (k)
IIIM 5.3	Production process for MPCP, 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		885.1200 885.1300	2.8 2.9.3	Yes	2-5.2 (g)

	- A6/14 -	
Appendix 6 Format for the listing of test and study reports and other documentation		Part 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products

Point 5 Methods of Analysis, Manufacturing, Quality Control and Post-Registration Monitoring of the Microbial Pest Control Product							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
IIIM 5.4	Method for determination of residues: required if information provided for MPCA in Annex II Part 4 is insufficient, for MPCP.	CR	5.2				

	- A6/15 -	
Appendix 6 Format for the listing of test and study reports and other documentation		Part 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products

Point 6 Efficacy Data and Information (Including Value Data) for the Microbial Pest Control Product							
OECD data point number	Information, test or study	R or CR	Former IIB EU Annex point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
IIIM 6.1	Preliminary range finding tests	R	6.1	(conditionally required)	10.2.1	Yes	8-4 GRBAP s5 p8
IIIM 6.2	Performance assessment: field studies	R	6.2	(conditionally required)	10.2.2	Yes	8-4 GRBAP s5 p8
IIIM 6.2.1	Efficacy tests						
IIIM 6.2.2	Minimum effective dose tests						
IIIM 6.3	Toxic or pathogenic effects on the crop or host which is to be protected.	R	6.5		10.3.1	Yes	8-5 GRBAP s5 p8
IIIM 6.4	Compatibility with products in authorised tank mixes and with other products that are applied under expected conditions of use. Recommended interval between application of MPCP and any other products, to avoid loss of efficacy.	R	2.8 2.8.1 2.8.2 2.8.3		10.3.2 10.2.2 xi		8-4.3(b) GRBAP s5 p8
IIIM 6.4.1	Physical compatibility						
IIIM 6.4.2	Chemical compatibility						
IIIM 6.4.3	Biological compatibility						
IIIM 6.5	Contribution to risk reduction and integrated pest management strategies, for the targeted crop or resource.	R			10.4.4		8-4.3 (d) 8-4.5 GRBAP s5 p8
IIIM 6.6	Effects on yield and quality	R	6.4				
IIIM 6.6.1	Impact on the quality of plants and plant products	R	6.4.1				
IIIM 6.6.2	Effects on the processing procedure	R	6.4.2				
IIIM 6.6.3	Effects on the the yield of treated plants and plant products	R	6.4.3				
IIIM 6.7	Adverse effects	R	6.6				
IIIM 6.7.1	Impact on succeeding crops	R	6.6.1				
IIIM 6.7.2	Impact on other plants including adjacent crops	R	6.6.2				
IIIM 6.7.3	Adverse effects on parts of plants used for propagating purposes (e.g. seeds,	R	6.6.3				

	- A6/16 -	
Appendix 6 Format for the listing of test and study reports and other documentation		Part 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products

Point 6 Efficacy Data and Information (Including Value Data) for the Microbial Pest Control Product							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
	cuttings, runners)						
IIIM 6.7.4	Adverse effects on beneficial and other organisms apart from target organisms	R	6.6.4				
IIIM 6.8	Summary and assessment of data according to points 6.1 to 6.7.4	R	6.7				

	- A6/17 -	
Appendix 6 Format for the listing of test and study reports and other documentation		Part 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products

Point 7 Toxicological Studies and Exposure Data and Information for the Microbial Pest Control Product							
OECD data point number	Information, test or study	R or CR	Former IIB EU Annex point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
IIIM 7.1	Acute toxicity studies	R	7.1				
IIIM 7.1.1	Acute oral toxicity	R	7.1.1	870.1100			3-4.2
IIIM 7.1.2	Acute percutaneous (dermal) toxicity	R	7.1.3	870.1200	4.4	Yes	3-4.2
IIIM 7.1.3	Acute inhalation toxicity to rats	R	7.1.2	870.1300			3-4.2
IIIM 7.1.4	Skin irritation	R	7.2.1	870.2500	4.5	Yes	3-4.2
IIIM 7.1.5	Eye irritation	R	7.2.2	870.2400	label as irritant	Yes	3-4.2
IIIM 7.1.6	Skin sensitisation	R	7.2.3		label 'potential sensitizing agent'	Yes	3-4.2
			label 'potential sensitizing agent'				
IIIM 7.2	Operator, bystander and worker exposure: monitoring data	CR	7.3				6-6.2
IIIM 7.3	Operator and bystander exposure: reporting of hypersensitivity incidents before and after registration	R			4.6		6-6.2
IIIM 7.4	Safety data sheet for each additive	R	7.4		2.9.1	Yes	--
IIIM 7.5	Supplementary information on all data points in part 7: Effects on Human Health, if it is recommended that MPCP be tank-mixed with an adjuvant or another pest control product.	R	7.5				3-4.9 ©)
IIIM 7.6	Summary and evaluation of health effects	R	7.6		4.1		3-4.10

	- A6/18 -	
Appendix 6 Format for the listing of test and study reports and other documentation		Part 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products

Point 8 Residues in/on Food and Feed Products for the Microbial Pest Control Product							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
IIIM 8	Residues in/on Food and Feed products for the Microbial Pest Control Product (Rationale to waive residue studies on MPCP)	CR	8		7	Yes	GRBAP s5 p5

	- A6/19 -	
Appendix 6 Format for the listing of test and study reports and other documentation		Part 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products

Point 9 Fate and Behaviour in the Environment for the Microbial Pest Control Product							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
IIIM 9	Fate and Behaviour in the environment for the Microbial Pest Control Product (Rationale to waive testing, based on adequacy of information provided for MPCA, to permit an assessment of the fate and behaviour of MPCP in the environment)	CR	9				GRBAP s5 p7

	- A6/20 -	
Appendix 6 Format for the listing of test and study reports and other documentation		Part 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products

Point 10 Effects of the Microbial Pest Control Product on Non-Target Organisms							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
IIIM 10	Rationale to waive additional testing, based on adequacy of information provided for MPCA, to permit an assesment of the impact of the MPCP on non-target organisms	CR	10		9.1		GRBAP s5p8
IIIM 10.1	Effects on birds	CR	10.1		9.1		GRBAP s5p8
IIIM 10.2	Effects on aquatic organisms	CR	10.2		9.1		GRBAP s5p8
IIIM 10.3	Effects on bees	CR	10.3		9.1		GRBAP s5p8
IIIM 10.4	Effects on terrestrial arthropods other than bees	CR	10.4		9.1		GRBAP s5p8
IIIM 10.5	Effects on earthworms	CR	10.5		9.1		GRBAP s5p8
IIIM 10.6	Effects on soil micro-organisms	CR	10.6		9.1		GRBAP s5p8
IIIM 10.7	Additional studies	CR	10.7		9.1		GRBAP s5p8

	- A6/21 -	
Appendix 6 Format for the listing of test and study reports and other documentation		Part 5 OECD, EU, US, Canadian, Japanese and Australian Numbering Systems for Data and Information on Microbial Pest Control Products

Point 11 Summary and Evaluation of Environmental Impact of the Microbial Pest Control Product							
OECD data point number	Information, test or study	R or CR	Former EU Annex IIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
IIIM 11	Summary and evaluation of environmental impact: summarise all data relevant to environmental impact and assess environmental risk by:	R	11		9.1 12.7		
IIIM 11.1	addressing distribution and fate of MPCP	R	11		9.1 12.7		
IIIM 11.2	identifying non-target species at risk and the extent of their exposure	R	11		9.1 12.7		
IIIM 11.3	identifying precautions necessary to minimise environmental contamination and to protect non-target species	R	11		9.1 12.7		

¹³ 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>

¹⁴ Data code used by the Canadian Pest Management Regulatory Agency

¹⁵ Data point numbering system being developed