

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. 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.

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

8. Member countries may require additional information on a proposed product to address potential hazards and 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.

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

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Point 1 Identity of the Microbial Pest Control Product

OECD data point number	Information, test or study	R or CR	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 1.2.1	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(s) (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 1.5	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		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	1.6 3.1	40CFR 152.50	1.2	Yes	GRBAP s5 pl

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IIIM 1.7	Other/special studies	CR			3.7 10.6	No	GRBAP S5 P1
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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
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Also indicate:

- scientific name and strain/serotype of MPCA, its accession number in a recognized culture collection,
- development phase (eg. spore) of MPCA in MPCP

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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

- Technical Grade of MPCA
- 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 MPCP
- 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, eg. cfu's/ml.
- non-microbial impurities (eg. metabolic products, impurities in starting materials, fermentation residues, extraneous host residues)

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IIIM 1.7.3	Quality criteria for the production and storage of the MPCP, including: <ul style="list-style-type: none"> • acceptable range for content of MPCA, in appropriate terms; • presence of human or non-target animal 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 contamination 	R	5	885.1300 885.1500	2.8 2.9.1 2.10.2	Yes	2-5.2 (h) GRBAP s5 p2
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

Point 1 Identity of the Microbial Pest Control Product

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IIIM 1.7.5	<p>A theoretical discussion regarding</p> <ul style="list-style-type: none"> • the formation and/or presence of unintentional ingredients, including impurities of toxicological concern, likely to occur in MPCP, • the impact of these ingredients on product quality, and • appropriate quality criteria. <p>For metabolically-active MPCP, consider degradation or metabolic production during storage.</p>	R	1.4	885.1300	2.9.3	Yes	2-5.2(I) 2-5.2(I) 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	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 MPCP, include QC data for hazardous contaminants originating from degradation or metabolic production during storage	R	2.2	885.2400	2.11	Yes	2-5.2(j)\ 2-5.2 (k) GRBAP s5 p2
IIIM 2.3	Explosivity, oxidizing properties, flash point, flammability, spontaneous ignition, acidity, alkalinity, pH, viscosity, surface tension: as appropriate	R	2.3 2.4 2.5 2.6		2.12	Yes	2-5.2 (e) GRBAP s5p2
IIIM 2.4	Technical characteristics as appropriate: wettability, persistent foaming, suspensibility, suspension stability, dry/wet sieve test, particle size distribution, content of dust/fines, emulsifiability, emulsion stability, flowability, pourability, dustability	R	2.7		2.12	Yes	2-5.2(e) GRBAP s5p2
	Density	R			2.12		
	Summary and evaluation of data on properties of the MPCP	R	2.10				

Points 3 & 4 Application Instructions, Precautions, Cleaning for the Microbial Pest Control Product

OECD data point number	Information, test or study	R or CR	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 microorganism transmitted or translocated to another part of plant?)	R	3.2	40CFR	1.1	Yes	1-3.4
			3.3	152.50(e)	1.2		8-3.3 GRBAP s5 p8
IIIM 3.2	Available information on the development of resistance in target pest and appropriate mitigation strategy	R			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	40CFR	1.1	Yes	1-3.5
			3.5	152.50(e)	1.2		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 and timing of applications, related to: host/pest phenology, duration of protection, application of other pesticides, preharvest interval	R	3.3	40CFR	1.1	Yes	8-3.3
			3.7	152.50(e)	1.2		GRBAP s5 p8
			4.3				

Points 3 & 4 Application Instructions, Precautions, Cleaning for the Microbial Pest Control Product

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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
	Proposed instructions for use as printed, or to be printed, on labels	R	3.9				

Points 3 & 4 Application Instructions, Precautions, Cleaning for the Microbial Pest Control Product

OECD data point number	Information, test or study	R or CR	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 re: 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 Re: safe handling and storage	R	4.4		1.1	Yes	1-3.5 GRBAP s5p6
IIIM 4.7	Recommendations Re: handling, storage, transport, fire: specify risks, specify procedures to minimize hazards and the generation of waste	R	4.4			Yes	6-1 GRBAP s5 p6
IIIM 4.8	Label instructions re: cleanup of spills	R	4.5		1.1	Yes	1-3.5 GRBAP 25p6

Points 3 & 4 Application Instructions, Precautions, Cleaning for the Microbial Pest Control Product

OECD data point number	Information, test or study	R or CR	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 4.9	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 (eg. detailed instructions for controlled incineration)	R	4.6			Yes	1-3.5

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	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: <ul style="list-style-type: none"> • 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 identify contaminant microorganisms in MPCP • 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. 	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

Point 5 Methods of Analysis, Manufacturing, Quality Control and Post-Registration Monitoring of the Microbial Pest Control Product

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OECD data point number	Information, test or study	R or CR	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 5.2	Storage stability test and determination of shelf life	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	5.1	885.1200 885.1300	2.8 2.9.3	Yes	2-5.2 (g)
	Method for determination of residues: required if information provided for MPCA in Part 4 is insufficient, for MPCP	CR	5.2				

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	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 6.1	Performance assessment: lab or growth chamber studies	R	2.9 see also Commission Directive 93/71	(conditionally required)	10.2.1	Yes	8-4 GRBAP s5 p8
	Adherence and distribution to seeds, for seed treatment products	R					
IIIM 6.2	Performance assessment: field studies	R	see Commission Directive 93/71	(conditionally required)	10.2.2	Yes	8-4 GRBAP s5 p8
IIIM 6.3	Toxic or pathogenic effects on the crop or host which is to be protected	R	see Commission Directive 93/71		10.3.1	Yes	8-5 GRBAP s5 p8
IIIM 6.4	Compatibility with products in authorized tank mixes and with other products that are applied under expected conditions of use. Recommended interval between application of MPCP and chemical pesticide, to avoid loss of efficacy	R	2.8		10.3.2 10.2.2 xi		8-4.3(b) GRBAP s5 p8
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

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	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 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 sensitization	R	7.2.3		label 'potential sensitizing agent'	Yes	3-4.2
				label 'potential sensitizing agent'			
IIIM 7.2	Operator and bystander 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	7.3		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 ©)

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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	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 7.6	Summary and evaluation of health effects R		7.6		4.1		3-4.10

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Points 8 & 9 Residues in/on Food and Feed Products and Fate and Behaviour in the Environment for the Microbial Pest Control Product

OECD data point number	Information, test or study	R or CR	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	Rationale to waive residue studies on MPCP	CR	8		7	Yes	GRBAP s5 p5
IIIM 9	Rationale to waive testing, based on adequacy of information provided for MPCA, to permit an assessment of the fate and behaviour of MPCA in the environment	CR	9				GRBAP s5 p7

Point 10 Effects of the Microbial Pest Control Product on Non-Target Organisms

OECD data point number	Information, test or study	R or CR	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

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	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 11	<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 MPCP • 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	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