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Guidance for Registration Requirements for Microbial Pesticides

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Guidance for Registration Requirements for Microbial Pesticides

**Environment Directorate
Organisation for Economic Co-operation and Development
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No. 17, *OECD Guidance for Country Data Review Reports for Pheromones and Other Semiochemicals and their Active Substances (Monograph Guidance for Pheromones and other Semiochemicals), (2003)*

Published separately:

OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances - Monograph Guidance (1998, revised 2001)

OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances - Dossier Guidance (1998, revised 2001)

Report of the Pesticide Aquatic Risk Indicators Expert Group (2000)

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ABOUT THE OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation composed of 30 industrialised countries in North America, Europe and the Pacific. The OECD works to co-ordinate and harmonise government policies, address issues of mutual concern, and respond to international problems.

The Pesticide Programme was created in 1992 within the OECD's Environmental Health and Safety Division to help OECD countries:

- harmonise their pesticide review procedures,
- share the work of evaluating pesticides, and
- reduce risks associated with pesticide use.

The Pesticide Programme is directed by the Working Group on Pesticides, composed primarily of delegates from OECD Member countries, but also including representatives from the European Commission and other international organisations (e.g. United Nations Food and Agriculture Organization, United Nations Environment Programme, World Health Organization, Council of Europe), and observers from the pesticide industry and public interest organisations (NGOs).

In addition to the **Series on Pesticides**, the Environment, Health and Safety (EHS) Division publishes documents in five other series: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Risk Management**; **Harmonization of Regulatory Oversight in Biotechnology**; and **Chemical Accidents**. More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (see next page).

This publication was produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC). It was approved for derestriction by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, the governing body of the Environment, Health and Safety Division.

The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO and the OECD (the Participating Organizations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. UNITAR joined the IOMC in 1997 to become the seventh Participating Organization. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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or contact:

**OECD Environment Directorate,
Environment, Health and Safety Division**

**2, rue André-Pascal
75775 Paris Cedex 16
France**

Fax: (33-1) 45 24 16 75

E-mail: ehscont@oecd.org

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1. Introduction and Background

The development of harmonized data requirements for microbial pesticides has been a goal of the OECD Working Group on Pesticides for several years. A guidance for registration requirements would facilitate access to a wider range of new, reduced risk, IPM compatible pest management tools, by making it easier for companies to submit registration applications to many countries and for regulatory agencies to benefit from each other's reviews. A 1996 report of the European Crop Protection Association (ECPA) supported harmonization, as a means to encourage the development of environmentally-friendly pest control products for sustainable agriculture.

At the June 1997 meeting of the Working Group on Pesticides, countries expressed interest in developing guidance for registration requirements for microbial pesticides. The European Commission (EC) invited comment on a draft document outlining European Union (EU) data requirements for microbial pesticides. Progress of the United States and Canada toward harmonization was also noted, particularly in the areas of health and product chemistry. The OECD Secretariat subsequently distributed for comment, the proposed EU data requirements as well as information provided by Canada, Switzerland and the U.S. on their own data requirements.

Canada prepared a comparative summary of the data requirements of the EU, Canada, Switzerland and the United States, which was distributed at the February 1998 meeting of the Working Group on Pesticides. The EC indicated that the proposed EU data requirements would be amended to take into account these comments. An OECD Microbial Steering Group was established with a workplan to facilitate input from non-EU countries to the EC activity as the basis for developing an 'OECD' guidance for registration requirements for microbial pesticides.

An EU workshop on "The Scientific Basis for Risk Assessment" of microbial pesticides was held in Stockholm in October 1998, with the invited participation of several non-EU countries. Sweden was tasked with drafting an EC Guidance Document on microbial data requirements, which was circulated for comment to EU Member States and the OECD Microbial Steering Group, in spring 1999.

At the June 1999 meeting of the OECD Working Group on Pesticides, Canada provided a table comparing data requirements of Canada, the U.S. and the EC draft Guidance Document, indicating substantial similarities in regulatory approach. Canada agreed to draft a proposal for 'OECD' basic data requirements for microbial pesticides, which would provide guidance for registration requirements and flag areas of difference.

This document proposes guidance for registration requirements for microbial plant protection products, as well as indicating where there are differences among countries. Some differences include:

- requirement by Canada, U.S. and Japan, but not EU, for additional quality control data
- requirement by Canada and U.S. but not EU or Japan for theoretical discussion of unintentional ingredients in technical grade active substances and in end-use products,
- requirement by EU but not Canada, U.S. or Japan, for short-term toxicity/pathogenicity data,
- requirement by EU and U.S. but not Canada or Japan for acute oral and inhalation data on end-use products, as well as different approaches to potential skin sensitization,
- requirement by EU, U.S. and Japan but not Canada for eye irritation data
- requirement by EU but not Canada, U.S. and Japan, for operator/bystander exposure monitoring data,
- requirement by EU, Canada and Japan but not U.S., for efficacy data.

2. Definitions

Additive: an ingredient, other than the MPCA, intentionally added to a formulation.

Microbial impurity (= microbial contaminant): a microorganism present in product, other than the specified microorganism of the MPCA; an alternate/mutant form of the MPCA is considered to be a microbial impurity.

Other impurities of toxicological concern: unintentional ingredients of the product, other than microbial impurities, which are toxic or sensitizing to mammals.

Microbial pest control agent (MPCA)(= active substance): a microorganism (bacterium, alga, fungus, protozoan, virus, mycoplasma, rickettsia) and any associated metabolites, to which the effects of pest control are attributed.

Microbial pest control product (MPCP) (= microbial plant protection product): a product containing an MPCA that is registered or labelled with instructions for direct use or application for pest control purposes.

Technical grade of MPCA: microbial material used for manufacture of microbial pest control products. It is the purest preparation of the MPCA resulting from a typical production process, and contains no additives except for purposes of MPCA growth or replication, or typical purification. It may be commercially distributed to manufacturers of microbial pest control products either in its pure form or augmented with preservatives, stabilizers, and diluents; or it may be a hypothetical stage in the manufacture of the microbial pest control product.

Infectivity: the ability of a microorganism to invade and persist in a viable state or to multiply within or on an organism, with or without disease manifestation.

Pathogenicity: the ability of a microorganism to inflict injury and damage in the host after infection, and depends on host resistance or susceptibility.

Toxicity: the injury or damage in a host caused by a poison or toxin; infection, replication or viability of the microorganism is not necessarily required.

Maximum hazard testing: a testing scheme that is designed to maximize any toxic or pathogenic effects of the test substance on the test (nontarget) organism. The following concentrations of MPCA are typically employed:

- for topical application to arthropods, 100x maximum rate of application on label
- for spray to terrestrial plants, maximum rate of application on label
- for application to a medium, 10^6 active units/gram of soil or water; or 1000x the expected environmental concentration of the MPCA immediately following direct application at the maximum label rate to a 15 cm layer of soil or water, whichever is greater or achievable.

3. Rationale

Regulatory authorities generally require sufficient information on a microbial pesticide to characterize it, to assess its potential risks to people and to the environment, and to confirm its effectiveness for pest control. Unlike chemical pesticides, microbial agents may infect or cause disease in other living organisms. Potential adverse effects of microbial pesticides include displacement of nontarget microorganisms and allergenic, toxic, and pathogenic effects on humans and other nontarget organisms. However, microbial agents typically have narrow host ranges and occur naturally in the environment to which they are applied. Such factors reduce the likelihood of harm should a microorganism be used for pest control. Consequently, the risk assessment of microbial products rests heavily on the biological and ecological profile of the microorganism and a set of short term toxicity/pathogenicity tests, with the expectation that negative test results will allow a high degree of confidence in the safety of the microorganism.

4. Explanation of the tables

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.

The first table provides guidance for registration requirements for microbial pest control agents, the 'active substances'; the second table lists requirements for microbial products used for pest control. For reference, the right-hand columns provide the data-part or guideline numbers of the registration guidance published by the EC, Canada, and USA, which describe the information requirement listed in the left-hand column. In the column for Japan, "R" means that the data submission is in principle necessary in Japan; "CR" means that the data submission is necessary when the microbial pesticide meets a certain criteria. Each table includes information requirements common to the European Union, United States, Japan and Canada, as well as the requirements (underlined) of several but not all of these authorities.

Member countries may require additional information on a proposed product to address potential hazards and exposure scenarios specific to the proposal.

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

5. Guidance for Registration Requirements for a Microbial Pest Control Agent

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, telephone and telefax numbers), contact, 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	<p>Scientific name of microorganism to R species level or a level sufficient to show taxonomic relation to known microorganisms, especially pathogens;</p> <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

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) ¹¹	Japanese data requirement Yes / No ¹¹	Australian data requirement
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IIM 1.4 Composition of Technical Grade of MPCA/
Active Substance

IIM 1.4.1

Concentration of microorganism (and R 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

1.4.1 885.11 2.9.2 Yes 2-4.3
GRBAP s5 p2

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) ¹¹	Japanese data requirement Yes / No ¹¹	Australian data requirement
IIM 1.4.2	Composition of microbial material used for R 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: <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) 	R	1.4.2	885.1100 885.1300	2.9.1	Yes	2-4.3 GRBAP s5 p2, 4.1

This information is not required if Technical Grade of MPCA is a hypothetical stage in a continuous production process of an end-use product.

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 R storage of the MPCAs, including: criteria for consistency and integrity of the master and working seed stock, typically, measures of biological activity and phenotypic or genotypic properties:		3.4	885.1300 885.1500	2.8 2.9.1 2.10.2	Yes	2-4.3(f) GRBAP s5 p7

- acceptable range for content of MPCAs, 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 MPCAs is closely related to a toxigenic human pathogen
- maximum accepted level for microbial impurities, using suitable indicators of an unhygienic process

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 MPCAs 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 MPCAs, · the impact of these ingredients on product quality, and · appropriate quality criteria. Physical and chemical properties, if MPCAs are 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		885.13 40CFR 158.740(a)	2.9.3 2.12	Yes	2-4.3(e) GRBAP s5 p2 2-4.3(b) GRBAP s5 p2
	International regulatory status of R microorganism				1.3		2-4.3(a) GRBAP s5 p2

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 R 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.		4	830.19	12.7	Yes	-
IIM 1.5.3	Sample of MPCA, analytical standard of R metabolite (and reference substances for the relevant impurities - EU only): if requested						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; R 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 MPCAs which differ from classical description of species		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 R including geographic distribution, hosts, habitat, ecological niche, level of natural occurrence		2.1	885.11	2.7.2 i	Yes	GRBAP s5 p1&2
IIM 2.3	Description of target organism(s); R information on mode of action, kind of antagonism to target host, infective/toxic dose, transmissibility		2.2	885.11	2.7.2 ii	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
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IIM 2.4	Available information on host specificity; R 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).		2.3	885.11	2.7.2 iii	Yes	1-2 GRBAP s5 p2
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IIM 2.5	Life cycle of micro-organism including R 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)		2.4	885.11	2.7.2 iv	Yes	1-2 GRBAP s5 p2
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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	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 R available information on:		2.6 2.8	885.1100 850.4000	2.7.2 ix 2.7.2 xi		GRBAP s5 p2

- 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 R of environmental parameters on growth, infectivity, dispersal, and colonization ability: temperature, pH, redox potential, humidity, light, nutritional requirements

2.5 2.7.2 vi

Description of any plasmids or other extra R chromosomal genetic elements involved in pesticidal activity, pathogenicity, toxicity, etc.

885.11 2.7.2 v

Genetic stability (mutation rate of traits R related to the mode of action), factors affecting genetic stability; microorganism's capacity to transfer genetic information to another population

2.7 2.7.1

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
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2.7.2 x

IIM 2.6 (continued)
 Detailed discussion of relationship of R microorganism to any known human dermatophyte (see point 5.2)

Resistance/sensitivity to antibiotics / anti- R microbial agents used in human or veterinary medicine

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 R 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 R 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 R 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 		2.8	885.13	10.2.1	Yes	GRBAP s5 p2
IIM 3.5.3	<p>Information relative to the formation of R 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 		2.8	885.13	10.2.1	No	GRBAP s5 p2
IIM 3.6	<p>Information on the possible occurrence of R the development of resistance or cross-resistance</p>		3.5				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 3.7	A material safety data sheet for the Microbial Active Substance	for the 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	of 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				-

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		4.1 3.6	885.12	2.8	Yes	GRBAP s5 p2
IIM 4.2.8	Production process for Technical Grade of R 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.		3.4	885.1200 885.1300	2.8	Yes	2-4.3(e) GRBAP s5 p2

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: <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 I.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. 	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

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
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IIM 4.4	Storage stability test, data and R determination of shelf life, if MPCAs are stored		4.1	885.24	2.11	R	2-4.3(c)
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IIM 4.5 Post-registration monitoring methods to CR 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)

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 R 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		5.1		4.1		3-4.10
IIM 5.2	Occupational health surveillance report on R 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 		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 5.3.9	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 R and toxicity		5.2.2.2	885.315	4.2.3	Yes	3-4.2 GRBAP s5 p3
IIM 5.5	Acute intravenous/ intra peritoneal R infectivity		5.2.2.3	885.32	4.3	Yes	3-4.2 GRBAP s5 p3

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 5.6	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 5.7	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

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 5.8.1	Published reports of adverse effects, R especially reports of clinical cases and followup studies; list databases and key words used in a literature search.		5.1	40CFR 152f(3) or 40CFR 152.125	2.7.2 xiii	No	3-4.9
	Short-term toxicity, pathogenicity, R infectivity (28-day minimum) - for EU only		5.2.5				-
	Proposed first aid measures and medical R treatment		5.2.6		1.1		36956
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 5.11	Summary of mammalian toxicity and overall evaluation		5.6			Yes	3-2.2

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 R 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.		6	40CFR 158.740(b)	7	Yes	GRBAP s5 p5

6.1

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.

6.3

Summary of residue behaviour and overall evaluation

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, EU - R properties, survival and residual US - CR metabolites of the microorganism to assess Japan - CR its fate and behaviour in the environment. Canada - CR Information provided in parts 2 - 6 may suffice.		7	885.5200 885.5300 885.5400	8.3.2		-
IIM 7.13	Viability/population dynamics, persistence, multiplication and mobility.					No	-
	Other/special studies	CR			8.2.3.6 8.2.4.6 8.5 8.6		

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	885.439	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		-		-

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
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Yes

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8.6

In EU effects on non-target soil R microorganisms required

8.7

CR

Other/special studies

IIM 8.11

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
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IIM 9	Summary and evaluation of environmental R impact: summarize all data relevant to environmental impact and assess environmental risk by:		9		9.1 12.7	-	-
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- 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.

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

10 Data code used by the Canadian Pest Management Regulatory Agency

11 Data point numbering system being developed

Finalized for publication - June 17, 2002

6. Guidance for Registration Requirements for a Microbial Pest Control Product

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	885.11	2.4	Yes	2-5.2(a) GRBAP s5 p2
IIIM 1.5	Physical state of MPCP (GIFAP R formulation type)	R	1.5	885.16	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

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

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 ¹⁵	Australian data requirement
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IIIM 1.7.1 Concentration of MPCAs in MPCP, R 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 MPCAs in Technical Grade of MPCAs, in the same terms.

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

2.9.2 Yes 2-5.2 (c) GRBAP s5 p2

1.4 885.11

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 ¹⁵	Australian data requirement
IIIM 1.7.2	Composition in terms of g/kg or g/L and R % w/w of each ingredient in MPCP, including: <ul style="list-style-type: none"> · 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 hygienic 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) 		1.4	885.1100 885.1300 885.1500	2.9.2 2.9.3	Yes	2-5.2(d) GRBAP s5 p2

Point 1 Identity of the Microbial Pest Control Product

OECD data point number	Information, test or study	R or CR	EU Amex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
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IIIM 1.7.3 Quality criteria for the production and R storage of the MPCP, including:

- acceptable range for content of MPCAs, 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 MPCAs is closely related to a toxigenic human pathogen
- maximum accepted level for microbial impurities, using suitable indicators of contamination

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 R criteria) from 3 - 5 production batches, including product stored for duration of shelf life if it is metabolically active. If the Technical Grade of MPCAs is a stage in a continuous production process of an end use product, this information should be provided for the entire production process

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

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 1.7.5	A theoretical discussion regarding	R	1.4	885.13	2.9.3	Yes	2-5.2(i) 2-5.2(l)

- 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.

For metabolically-active MPCP, consider degradation or metabolic production during storage.

GRBAP s5p2

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 Amex 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	885.24	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	2.1				

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 Amex 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 R protected, available information on mode of action (site of uptake, toxic/competitive effect), is microorganism transmitted or translocated to another part of plant?)		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 R development of resistance in target pest and appropriate mitigation strategy				10.4.4		8-4.4 GRBAP s5p8
IIIM 3.3	Application rate in terms of mass/vol of R MPCP per unit area/volume (e.g. kg/ha). Content of micro-organism in material used (diluted spray, bait, treated seed).		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 R micro-organism per unit area/volume		3.4			Yes	8-3.3 GRBAP s5 p8
IIIM 3.5	Method of application (incl. type of R equipment and volume of diluent)		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, R related to: host/pest phenology, duration of protection, application of other pesticides, preharvest interval		3.3 3.7 4.3	40CFR 152.50(e)	1.1 1.2	Yes	8-3.3 GRBAP s5 p8
IIIM 3.7	Precautions to avoid phytotoxic/ R phytopathogenic effects on protected crop or on succeeding crops, if appropriate Proposed instructions for use as printed, R or to be printed, on labels		3.8 3.9	40CFR 152.50(e)	1.1	Yes	8-5 GRBAP s5p8
IIIM 4.1	Packaging: description	R	4.1		3.3.2	Yes	2-5.2(m)

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 Amex IIIB point number	US EPA Guideline/ Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
IIIM 4.2	Specifications of packaging and R measures of its suitability		4.1			Yes	2-5.2 (m)
IIIM 4.3	Label instructions re: cleaning equipment R and protective clothing	R	4.2		1.1	Yes	1-3.5 GRBAP s5p6
IIIM 4.4	Procedures to clean equipment and R protective clothing; measures of their effectiveness	R	4.2			Yes	6-1 GRBAP s5 p6
IIIM 4.5	Necessary waiting periods for re-entry; R 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 37042
IIIM 4.9	Detailed procedures in case of accident R to: contain a spill, decontaminate an area or vehicle, dispose of adsorbents and packaging, protect workers and bystanders, first aid	R	4.5			Yes	
IIIM 4.10	Procedures for destruction/disposal of R 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 Amex 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	<p>Quality control and post-registration R monitoring methods:</p> <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 microorganism 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. 		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 5.2	Storage stability test and determination R of shelf life		5.1	885.24	2.11	Yes	2-5.2 (k)

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 Amex IIIB point number	US EPA Guideline / Requirement number ¹³	Canadian Data Code (DACO) ¹⁴	Japanese data requirement Yes / No ¹⁵	Australian data requirement
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IIIM 5.3 Production process for MPCP, describing R 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

Method for determination of residues: CR required if information provided for MPCP in Part 4 is insufficient, for MPCP

5.1 885.1200 885.1300 2.8 2.9.3 Yes

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 Amex 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 Adherence and distribution to seeds, for R seed treatment products	R	2.9 see also Commission Directive 93/71	Conditionally required	10.2.1	Yes	8-4 GRBAP s5 p8
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 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 Amex 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	870.2900	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
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 (c)
IIIM 7.6	Summary and evaluation of health effects	R	7.6		4.1		3-4.10

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 Amex 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 CR MPCP		8		7	Yes	GRBAP s5 p5
IIIM 9	Rationale to waive testing, based on CR adequacy of information provided for MPCP, to permit an assessment of the fate and behaviour of MPCP in the environment		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 Amex 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. CR based on adequacy of information provided for MPCA, to permit an assessment of the impact of the MPCP on non-target organisms		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
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IIIM 11 Summary and evaluation of R environmental impact: summarize all data relevant to environmental impact and assess environmental risk by:

- 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.

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/opptisfrs/home/testmeth.htm>

¹⁴

Data code used by the Canadian Pest Management Regulatory Agency

¹⁵

Data point numbering system being developed

Finalized for publication - June 17, 2002

7. Sources and Web Sites

Canada PMRA Guidelines for the Registration of Microbial Pest Control Agents and Products, Pro98-01, at <http://www.hc-sc.gc.ca/pmra-arla/pro9801e.pdf>

Commission of the European Communities. Directive 2001/36/EC - Annexes I and II – Data requirements for micro-organisms: dated May 16, 2001.

U.S. EPA 40CFR 158.740 Microbial Pesticides Data Requirements, at <http://www.epa.gov/epacfr40/chapt-I.info/subch-E/40P0158.pdf>

U.S. EPA Microbial Pesticide Test Guidelines, at http://www.epa.gov/docs/OPPTS_Harmonized/885_Microbial_Pesticide_Test_Guidelines