

APPENDIX 11

FORMS FOR USE IN CHECKING DOSSIERS FOR COMPLETENESS

**Part 1 Evaluation Form 1 -
for use in checking that the required
supporting documentation has been provided**

Active substance: micro-organisms

Applicant:

Date:

Document	Description of the document - circumstances in which required	Document provided Y/N [#]	Official use only Data Gap Y/N [#]
A	Statement of the context in which the dossier is submitted - always required	—	—
B	Task Force Information, where relevant, to include - * Member ship of the task force and a contact point for the task force * Contact point for each member of the task force * List of test and study reports generated by the task force - and details of task force members rights of access to the test and study reports generated by the task force - required where relevant	— — —	— — —
C	Existing or proposed labels, and where relevant leaflets for each preparation for which a dossier is submitted - required where requested Existing or proposed labels relevant to the uses on the basis of which existing MRLs or import tolerances are supported or new MRLs or import tolerances are proposed - required where requested	— —	— —
D-1	Details of intended uses (supported by the applicant and for which data are provided or are to be provided) and the conditions of use, on food and feed crops, and on non food and feed crops, in the territory of the country to which application is made, presented using the appropriate form - <i>always required</i>	—	—
D-2	A list of the registered uses in the country to which application is made, an indication of whether actually used and of the extent of use, presented using the appropriate form - required for existing active substances	—	—

Y = yes; N = no

Appendix 11 Forms for use in checking dossiers for completeness

Part 1 Evaluation Form 1 Supporting Documentation

Active substance: Applicant: Date:

Document	Description of the document - circumstances in which required	Document provided Y/N	Official use only Data Gap Y/N
F	A copy of each statement of intent to submit in due course , a dossier or dossiers - required for existing active substances in countries in which such a requirement exists.	—	—
G	Whether permitted in food, animal feeding stuffs, medicines or cosmetics in accordance with the legislation of the country to which application is made - required for each formulant unless a dossier is provided for the formulant	—	—
H	Safety data sheet - required for each formulant	—	—
I	Other available toxicological and environmental data on the formulant - required if requested	—	—
J	Confidential data and information, to include - * A listing of the data and information for which confidentiality is requested, cross referenced to the relevant test and study reports, dossier summaries and supporting documentation - <i>always required</i> * A justification for the claim to confidentiality for each item for which confidentiality is requested - <i>always required</i> * Highlighting of information contained in relevant study reports, dossier summaries and supporting documentation - required where the information concerned is provided in those documents * File containing confidential data and information - optional requirement	— — — — —	— — — — —

Appendix 11 Forms for use in checking dossiers for completeness

Part 2 Evaluation Form 2 Dossier Summaries and Overall Assessment

**Part 2 Evaluation Form 2 -
for use in checking that the required
MPCA and MPCP
dossier summaries and an overall
assessment, have been provided**

Active substance: micro-organisms
Applicant:
Date:

Document	Description of the document - circumstances in which required	Document provided Y/N [#]	Official use only Data Gap Y/N [#]
L (active substance)	<i>Tier I</i> reports as to the quality of individual active substance test and study reports - <i>always required</i>	—	—
L (Reference List)	Listing of test and study reports, test guidelines and published papers relevant to the active substance dossier:- - papers and reports submitted listed by test and study type - papers and reports submitted listed by alphabetically by author - list of papers and reports not submitted, arranged alphabetically by author <i>- always required</i>	— — —	— — —
M (active substance)	<i>Tier II</i> active substance dossier summary and overall assessment - always required	—	—
L (formulation)	<i>Tier I</i> reports as to the quality of individual test and study reports for each formulated product for which a dossier was submitted - always required * First preparation * Second preparation * Third preparation * Fourth preparation	— — — —	— — — —
L (Reference List)	Listing of test and study reports, test guidelines and published papers relevant to each formulated product dossier - <i>always required</i> * First preparation - papers and reports submitted listed by Annex point - papers and reports submitted listed by alphabetically by author - list of papers and reports not submitted, arranged alphabetically by author * Second preparation - papers and reports submitted listed by Annex point - papers and reports submitted listed by alphabetically by author - list of papers and reports not submitted, arranged alphabetically by author	— — — — — — —	— — — — — — —

[#] Y = yes; N = no

Appendix 11 Forms for use in checking dossiers for completeness

Part 2 Evaluation Form 2 Dossier Summaries and Overall Assessment

Active substance:

Applicant:

Date:

Document	Description of the document - circumstances in which required	Document provided Y/N	Official use only Data Gap Y/N
	* Third preparation		
	- papers and reports submitted listed by Annex point	—	—
	- papers and reports submitted listed by alphabetically by author	—	—
	- list of papers and reports not submitted, arranged alphabetically by author	—	—
	* Fourth preparation		
	- papers and reports submitted listed by Annex point	—	—
	- papers and reports submitted listed by alphabetically by author	—	—
	- list of papers and reports not submitted, arranged alphabetically by author	—	—
M (formulation)	Tier II dossier summary and overall assessment for each formulated product for which a dossier was submitted - <i>always required</i>		
	* First preparation	—	—
	* Second preparation	—	—
	* Third preparation	—	—
	* Fourth preparation	—	—
N	An overall summary and assessment of the application - <i>always required</i>	—	—

Part 3 Evaluation Form 3 -
for use in checking that all test and study reports relating to the MPCA which are required, have been provided; **

Active substance: micro-organisms
Applicant:
Date:

MPCA means Microbial Pest Control Agent

OECD data point number	Description of the document - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only* Data Gap Y/N [#]
IIM 1.1	Applicant (name, address, contact, telephone and telefax numbers)	—	—	—	—
IIM 1.2	Producer (name, address of each plant where active organism is produced)	—	—	—	—
IIM 1.3.1	Scientific name of micro-organism to species level or a level sufficient to show taxonomic relation to known micro-organisms, especially pathogens;				
	- accession no. of sample in a recognised culture collection	—	—	—	—
	- test procedures and criteria, using best available technology, to characterise the strain or serotype;	—	—	—	—
	- for mutant or genetically-modified strains, indicate all known differences between the modified micro-organism 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	—	—	—	—
II M 1.4.1	Concentration of micro-organism (and metabolite, if appropriate) in terms of g/kg or g/L (for US and Canada, also in % w/w) and cfu's/mL or appropriate potency units in the material used for manufacturing of formulated products; include acceptable range for each term. Potency should be expressed in recognised units of potency or an appropriate expression of biological activity per unit weight/ volume	—	—	—	—
	- <i>always required</i>				

* To be completed by the Competent Authority of the Member State to which application is made

[#] Y = yes; P = in part; N = no; L = location (volume and page) where justification can be found; Date = date report to be submitted

** Refer to Appendix 6 - Part 4 for requirements

Appendix 11

Forms for use in checking dossiers
for completeness

Part 3 Evaluation Form 3
Dossier Summaries and Overall Assessment

OECD data point number	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only* Data Gap Y/N [#]
IIM 1.4.2	<p>Composition of microbial material used for manufacture of end use products in terms of g/kg or g/L (for US and Canada also in % w/w) for each ingredient including:</p> <ul style="list-style-type: none"> - the MPCA - additives (preservatives, stabilisers, 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 (e.g. metabolic products, impurities in starting materials, fermentation residues, extraneous host residues). - <i>always required</i> unless the Technical Grade of the MPCA is a hypothetical stage in a continuous production process of an end-use product. <p>Composition in terms of g/kg or g/L, (for US and Canada also in % w/w), for each ingredient:</p> <p>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)</p>	<p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p>	<p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p>	<p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p>	<p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p>
IIM 1.4.3	<p>Quality criteria for the production and storage of the active micro-organism, including:</p> <p>criteria for consistency and integrity of the master and working seed stock, typically, measures of biological activity and phenotypic or genotypic properties:</p> <ul style="list-style-type: none"> - acceptable range for content of the active micro-organism, 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 the active micro-organism is closely related to a toxigenic human pathogen; - maximum accepted level for microbial impurities, using suitable indicators of an unhygienic process 	<p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p>	<p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p>	<p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p>	<p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p> <p>—</p>

Appendix 11 Forms for use in checking dossiers for completeness

Part 3 Evaluation Form 3 Dossier Summaries and Overall Assessment

OECD data point number	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only* Data Gap Y/N [#]
IIM 1.4.4	<p>Quality control data (measures of quality criteria) from 3-5 production batches, including storage stability data.</p> <p><i>-always required</i> unless 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.</p>	—	—	—	—
IIM 1.4.5	<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 the Technical Grade of the MPCA, - the impact of these ingredients on product quality, and - appropriate quality criteria. <p>Physical and chemical properties, if the active micro-organism is produced as a manufacturing product that is stored prior to formulation of end-use products: physical state; density; viscosity or surface tension; explosivity, corrosive character, oxidising properties; technical characteristics as appropriate</p> <p>International regulatory status of micro-organism</p> <p>Comprehensive Data Summary / Tier II summaries in OECD format: "Guidelines and Criteria for Industry for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for Plant Protection Products and their 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.</p> <ul style="list-style-type: none"> - Sample of MPCA - required where requested - Analytical standards of relevant metabolites and all other components include in the residue definition - required where requested - Samples of reference substances for relevant impurities – if available, required where requested 	—	—	—	—
IIM 1.5.3	Patent status information	—	—	—	—

Appendix 11

Forms for use in checking dossiers
for completeness

Part 3 Evaluation Form 3
Dossier Summaries and Overall Assessment

OECD data point number	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only* Data Gap Y/N [#]
IIM 2.1	Origin of the isolate; method of isolation; preservation and maintenance of strain during development; historical information on testing and use of the strain; history of use of closely related strains or species; Description of any unusual morphological, physiological, pesticidal or resistance characteristics of the MPCA which differ from classical description of the species	—	—	—	
IIM 2.2	Natural occurrence of the micro-organism including geographic distribution, hosts, habitat, ecological niche, level of natural occurrence	—	—	—	
IIM 2.3	Description of the target organism(s); Information on mode of action, kind of antagonism to target host, infective/toxic dose, transmissibility	—	—	—	
IIM 2.4	Available information on host specificity; possible effects on species closely related to the target species or being especially exposed.	—	—	—	
	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.	—	—	—	
IIM 2.5	Life cycle of the micro-organism including various forms that may occur, differences in pathogenic/toxigenic character of various forms, virulence and survival time of resting stages, interactions with other species (vector, parasitism, competition)	—	—	—	
	Potential of the micro-organism to produce metabolites that are of concern for human health and/or the environment	—	—	—	
IIM 2.6	Among closely related species, provide available information on: - pathogenicity to plants, animals or humans - formation of toxic metabolites: structure, stability, conditions under which they are formed, mode of action	—	—	—	

Appendix 11 Forms for use in checking dossiers for completeness

Part 3 Evaluation Form 3 Dossier Summaries and Overall Assessment

OECD data point number	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only* Data Gap Y/N [#]
IIM 2.6 (continued)	Physiological properties, especially effect of environmental parameters on growth, infectivity, dispersal and colonisation ability: temperature, pH, redox potential, humidity, light, nutritional requirements	—	—	—	—
	Description of any plasmids or other extra chromosomal genetic elements involved in pesticidal activity, pathogenicity, toxicity, etc.	—	—	—	—
	Genetic stability (mutation rate of traits related to the mode of action), factors affecting genetic stability; micro-organism's capacity to transfer genetic information to another population	—	—	—	—
	Detailed discussion of relationship of micro-organism to any known human dermatophyte (see point 5.2)	—	—	—	—
	Information on Resistance/sensitivity to antibiotics / anti-microbial agents used in human or veterinary medicine	—	—	—	—
IIM 3.1	Function, e.g. fungicide	—	—	—	—
IIM 3.3	Field of use, e.g. forestry	—	—	—	—
IIM 3.4.1	Details of existing and intended uses (crops, groups of crops, plants or plant products treated or protected)	—	—	—	—
IIM 3.4.2	Details of harmful organisms against which protection is afforded	—	—	—	—
IIM 3.4.3	Effects achieved e.g. sprout suppression	—	—	—	—
IIM 3.5.1	Statement of the mode of action of the active substance in terms of biochemical and physiological mechanism(s) and biochemical pathway(s) involved	—	—	—	—

Appendix 11 Forms for use in checking dossiers for completeness

Part 3 Evaluation Form 3 Dossier Summaries and Overall Assessment

OECD data point number	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only* Data Gap Y/N [#]
IIM 3.5.2	Details of active metabolites (especially toxins) and degradation products, cross referenced to the toxicological and residues data provided, to include:				
	-IUPAC and CA names	—	—	—	—
	-ISO common name proposed or accepted	—	—	—	—
	-CAS, CIPAC, EINECS and ELINCS numbers	—	—	—	—
	-molecular and structural formula	—	—	—	—
	-molecular mass	—	—	—	—
IIM 3.5.3	Information relative to the formation of active metabolites (especially toxins) and degradation products, to include:				
	-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	—	—	—	—
IIM 3.6	Information on the occurrence or possible occurrence of the development of resistance	—	—	—	—
IIM 3.7	A material safety data sheet for the Microbial Active Substance	—	—	—	—
IIM 3.8.1.2	Detailed instructions for safe disposal	—	—	—	—
IIM 3.9	Procedures for the decontamination of water in case of an accident	—	—	—	—
IIM 3.10	Other/special studies	—	—	—	—
IIM 3.11	Crops or products to be protected or treated	—	—	—	—
IIM 3.12	Measures to render micro-organism harmless, in case of an accident	—	—	—	—
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	—	—	—	—

Appendix 11

Forms for use in checking dossiers for completeness

Part 3

Evaluation Form 3
Dossier Summaries and Overall Assessment

OECD data point number	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only* Data Gap Y/N [#]
IIM 4.2.8	Description of the production process for Technical Grade of the 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.	—	—	—	—
IIM 4.3	Quality control and post-registration monitoring methods: <ul style="list-style-type: none"> <li data-bbox="337 785 829 833">- to detect, isolate, and enumerate the micro-organism <li data-bbox="337 833 829 882">- to differentiate a mutant or genetically-modified micro-organism from the parent strain. <li data-bbox="337 882 829 930">- to detect spontaneous change in major characteristics of micro-organism. <li data-bbox="337 930 829 1066">- to define content of micro-organism in appropriate terms (same as 1.4.1), incl. standardisation, sensitivity, reproducibility, statistical validity, and representative data to validate the bioassay. <li data-bbox="337 1066 829 1224">- 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. <li data-bbox="337 1224 829 1283">- to show presence of any human and mammalian pathogens 	—	—	—	—
IIM 4.4	Storage stability test, data and determination of shelf life, if MPCA is stored	—	—	—	—
IIM 4.5	Post-registration monitoring methods to determine and quantify residues of viable or non-viable micro-organism and metabolites (especially toxins) on food, feed, animal tissue, in soil, water or air Analytical methods for amount or activity of proteinaceous products	—	—	—	—

Appendix 11

Forms for use in checking dossiers
for completeness

Part 3 Evaluation Form 3
Dossier Summaries and Overall Assessment

OECD data point number	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only* Data Gap Y/N [#]
IIM 5.1	Summary: potential of microbial pest control agent to be hazardous to humans with consideration of its pathogenic potential, its ability to infect and pattern of clearance, and its toxicological effects	—	—	—	
IIM 5.2	Occupational health surveillance report on workers during production and testing of MPCA, including information on: - the sensitisation and allergenic response of workers - details on any occurrence of hypersensitivity and chronic sensitisation - any significant clinical findings related to exposure, with special attention to those whose susceptibility may be affected	—	—	—	
IIM 5.3	Acute oral infectivity and toxicity	—	—	—	
IIM 5.4	Acute intra tracheal/ inhalation infectivity and toxicity	—	—	—	
IIM 5.5	Acute intravenous/ intraperitoneal infectivity	—	—	—	
IIM 5.6	Cell culture study, for viruses and viroids or specific bacteria and protozoa with intracellular replication - <i>always required</i> , unless it is clearly demonstrated that the micro-organisms do not replicate in warm-blooded hosts	—	—	—	
IIM 5.7	Genotoxic potential	—	—	—	
IIM 5.8	Toxicity studies on metabolites (especially toxins)	—	—	—	
IIM 5.9	Published reports of adverse effects, especially reports of clinical cases and follow-up studies; list databases and key words used in a literature search.	—	—	—	
IIM 5.9.1	Proposed first aid measures and medical treatment	—	—	—	
IIM 5.10	Other/special studies	—	—	—	
IIM 5.10.1	Short-term toxicity, pathogenicity, infectivity (28-day minimum)	—	—	—	

Appendix 11 **Forms for use in checking dossiers
for completeness**

Part 3 **Evaluation Form 3
Dossier Summaries and Overall Assessment**

OECD data point number	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only* Data Gap Y/N [#]
IIM 5.11	Summary of mammalian toxicity and overall evaluation	—	—	—	—
IIM 6.1	Rationale for waiver of residue data based on information showing that MPCA is not hazardous to mammals, i.e. lack of potential for a known mammalian toxin and negative result from the acute oral toxicity test.	—	—	—	—
	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.	—	—	—	—
	Summary of residue behaviour and overall evaluation	—	—	—	—
IIM 7	Sufficient information on the origin, properties, survival and residual metabolites of the micro-organism to assess its fate and behaviour in the environment. Information provided in parts 2 - 6 may suffice.	—	—	—	—
	Viability/population dynamics, persistence, multiplication and mobility of the micro-organism	—	—	—	—
IIM 7.13	Other /special studies	—	—	—	—
IIM 8	Effects on non-target organisms	—	—	—	—
IIM 8.1	Effects on birds	—	—	—	—
IIM 8.2	Effects on fish	—	—	—	—
IIM 8.3	Effects on aquatic invertebrates	—	—	—	—
IIM 8.4	Effects on algal growth and growth rate	—	—	—	—
IIM 8.6	Effects on aquatic / terrestrial plants	—	—	—	—
IIM 8.7	Effects on bees	—	—	—	—
IIM 8.8	Effects on non-target terrestrial arthropods	—	—	—	—

Appendix 11 **Forms for use in checking dossiers
for completeness**

Part 3 **Evaluation Form 3
Dossier Summaries and Overall Assessment**

OECD data point number	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only* Data Gap Y/N [#]
IIM 8.9	Effects on other terrestrial invertebrates	—	—	—	—
IIM 8.9.1	Effects on earthworms				
IIM 8.10	Effects on non-target soil micro-organisms	—	—	—	—
IIM 8.11	Other/special studies	—	—	—	—
IIM 9	Summary and evaluation of environmental impact: summarise all data relevant to environmental impact and assess environmental risk by: - addressing distribution and fate of MPCA, - identifying non-target species at risk and the extent of their exposure - identifying precautions necessary to minimise environmental contamination and to protect non-target species.	—	—	—	—
		—	—	—	—
		—	—	—	—

Appendix 11

Forms for use in checking dossiers for completeness

Part 4

Evaluation Form 4
Dossier Summaries and Overall Assessment

Part 4 **Evaluation Form 4 -**

for use in checking that all test and study reports relating to the MPCP which are required, have been provided; **

<p>Active substance: micro-organisms</p> <p>Applicant:</p> <p>Date:</p>
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OECD data point number	Description of the document - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only* Data Gap Y/N [#]
IIIM 1.1	Applicant (name, address, contact, telephone and telefax numbers)	—	—	—	—
IIIM 1.2.1	Producer(s) of the preparation (name, address, contact telephone and telefax numbers of each plant where MPCP is manufactured)	—	—	—	—
IIIM 1.2.2	Producer of MPCA used in MPCP. If different from above, provide name and address of each plant where MPCA is produced.	—	—	—	—
IIIM 1.3	Trade name or proposed trade name and producers code number(s), for the preparation and similar preparations (differences to be specified)	—	—	—	—
IIIM 1.5	Physical state of MPCP (Crop Life formulation type)	—	—	—	—
IIIM 1.6	Function (herbicide, insecticide, etc.)	—	—	—	—
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”	—	—	—	—
IIIM 1.7	Other /special studies	—	—	—	—
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. Also indicate: - scientific name and strain/serotype of MPCA, its accession number in a recognised culture collection, - development phase (e.g. spore) of MPCA in MPCP	— —	— —	— —	— —

** Refer to Appendix 6 - Part 5 for requirements

Appendix 11 Forms for use in checking dossiers for completeness Part 4 Evaluation Form 4 Dossier Summaries and Overall Assessment

OECD data point number	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only Data Gap* Y/N [#]
IIIM 1.7.2	Composition in terms of g/kg or g/L (for US and Canada, also provide figures in % w/w) for 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 the 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, e.g. cfu's/ml. - non-microbial impurities (e.g. metabolic products, impurities in starting materials, fermentation residues, extraneous host residues) 	—	—	—	—
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 an unhygienic process 	—	—	—	—
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 enduse product, this information should be provided for the entire production process.	—	—	—	—
IIIM 1.7.5	A theoretical discussion regarding <ul style="list-style-type: none"> - the formation and/or presence of unintentional ingredients, including impurities of toxicological concern, likely to occur in the MPCP, - the impact of these ingredients on product quality, and - appropriate quality criteria. For metabolically-active MPCP, consider degradation or metabolic production during storage.	—	—	—	—
IIIM 2.1	Appearance (colour, odour, physical state)	—	—	—	—

Appendix 11 Forms for use in checking dossiers for completeness Part 4 Evaluation Form 4 Dossier Summaries and Overall Assessment

OECD data point number	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N#	Justification provided L/N#	Undertaking provided Date/N#	Official use only Data Gap* Y/N#
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.	—	—	—	—
IIIM 2.3	Explosivity, oxidising properties, flash point, flammability, spontaneous ignition, acidity, alkalinity, pH, viscosity, surface tension: as appropriate	—	—	—	—
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	—	—	—	—
	Density	—	—	—	—
	Summary and evaluation of data on properties of the MPCP	—	—	—	—
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?)	—	—	—	—
IIIM 3.2	Available information on the development of resistance in target pest and appropriate mitigation strategy.	—	—	—	—
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).	—	—	—	—
IIIM 3.4	Application rate in terms of units of micro-organism per unit area/volume	—	—	—	—
IIIM 3.5	Method of application (incl. type of equipment and volume of diluent)	—	—	—	—
IIIM 3.6	Number and timing of applications, related to: host/pest phenology, duration of protection, application of other pesticides, pre-harvest interval	—	—	—	—
IIIM 3.7	Precautions to avoid phytotoxic/ phytopathogenic effects on protected crop or on succeeding crops, if appropriate	—	—	—	—

Appendix 11 Forms for use in checking dossiers for completeness

Part 4 Evaluation Form 4 Dossier Summaries and Overall Assessment

OECD data point number	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only Data Gap* Y/N [#]
IIIM 3.7 (continued)	Proposed instructions for use as printed, out to be printed, on labels	—	—	—	—
IIIM 4.1	Packaging: description	—	—	—	—
IIIM 4.2	Specifications of packaging and measures of its suitability	—	—	—	—
IIIM 4.3	Label instructions re: cleaning equipment and protective clothing	—	—	—	—
IIIM 4.4	Procedures to clean equipment and protective clothing; measures of their effectiveness	—	—	—	—
IIIM 4.5	Necessary waiting periods for re-entry; recommended protective measures to reduce occupational exposure	—	—	—	—
IIIM 4.6	Label instructions regarding: safe handling and storage	—	—	—	—
IIIM 4.7	Recommendations regarding: handling, storage, transport, fire: specify risks, specify procedures to minimise hazards and the generation of waste.	—	—	—	—
IIIM 4.8	Label instructions regarding: cleanup of spills	—	—	—	—
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.	—	—	—	—
IIIM 4.10	Procedures for destruction/disposal of MPCP and its packaging (e. g. detailed instructions for controlled incineration)	—	—	—	—

Appendix 11

Forms for use in checking dossiers for completeness

Part 4 Evaluation Form 4
Dossier Summaries and Overall Assessment

OECD data point number	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only Data Gap* Y/N [#]
IIIM 5.1	Quality control and post-registration monitoring methods: <ul style="list-style-type: none"> - to differentiate a mutant or genetically-modified micro-organism from the parent strain. - to detect spontaneous change in major characteristics of micro-organism. - to define content of micro-organism in appropriate terms (same as 1.4.1), incl. standardisation, sensitivity, reproducibility, statistical validity, and representative data to validate the bioassay. - to identify contaminant micro-organisms 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. 	—	—	—	—
IIIM 5.2	Storage stability test and determination of shelf life	—	—	—	—
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. Method for determination of residues: required if information provided for MPCP in Part 4 is insufficient, for MPCP.	—	—	—	—
IIIM 6.1	Performance assessment: lab or growth chamber studies Adherence and distribution to seeds, for seed treatment products	—	—	—	—
IIIM 6.2	Performance assessment: field studies	—	—	—	—
IIIM 6.3	Toxic or pathogenic effects on the crop or host which is to be protected.	—	—	—	—
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 MPPP and chemical pesticide, to avoid loss of efficacy.	—	—	—	—

Appendix 11 Forms for use in checking dossiers for completeness

Part 4 Evaluation Form 4 Dossier Summaries and Overall Assessment

OECD data point number	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only Data Gap* Y/N [#]
IIIM 6.5	Contribution to risk reduction and integrated pest management strategies, for the targeted crop or resource.	—	—	—	—
IIIM 7.1.1	Acute oral toxicity	—	—	—	—
IIIM 7.1.2	Acute percutaneous (dermal) toxicity	—	—	—	—
IIIM 7.1.3	Acute inhalation toxicity to rats	—	—	—	—
IIIM 7.1.4	Skin irritation	—	—	—	—
IIIM 7.1.5	Eye irritation	—	—	—	—
IIIM 7.1.6	Skin sensitisation	—	—	—	—
IIIM 7.2	Operator, bystander and worker exposure: monitoring data	—	—	—	—
IIIM 7.3	Operator and bystander exposure: reporting of hypersensitivity incidents before and after registration	—	—	—	—
IIIM 7.4	Safety data sheet for each additive	—	—	—	—
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.	—	—	—	—
IIIM 7.6	Summary and evaluation of health effects	—	—	—	—
IIIM 8	Rationale to waive residue studies on MPCP	—	—	—	—
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.	—	—	—	—
IIIM 10	Rationale to waive additional testing, based on adequacy of information provided for MPCA, to permit an assessment of the impact of the MPCP on non-target organisms.	—	—	—	—

Appendix 11 **Forms for use in checking dossiers
for completeness**

Part 4 **Evaluation Form 4
Dossier Summaries and Overall Assessment**

OECD data point number	Information, test or study - circumstances in which required	Information, test or study provided Y/P/N [#]	Justification provided L/N [#]	Undertaking provided Date/N [#]	Official use only Data Gap* Y/N [#]
IIIM 11	Summary and evaluation of environmental impact: summarise 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 minimise environmental contamination and to protect non-target species	—	—	—	—
		—	—	—	—
		—	—	—	—

Active Substance:

Applicant:

Date:

Test or Study Title:

Data Point:

**Part 3 Evaluation Form 5 -
for use in checking that the Tier I
quality checks for individual tests and
studies are of acceptable quality³¹**

Micro-organisms

Applicant:

Date:

Test or Study Point	Description of the requirement	Provided Y/N [#]
1.1	The data point addressed	—
1.2	A descriptive title of the type of test or study	—
2	Reference point (location) of the report in the dossier (<i>e.g.</i> volume, section and point)	—
3.1	The names of the authors	—
3.2	The title of the report	—
3.3	The owner of test or study the report	—
3.4	An indication as to whether it is a published or unpublished report	—
3.5	The report number	—
3.6	The date of the report	—
4.1	The name and address of the testing facility involved	—
4.2	The laboratory report/project number	—
5.1	The dates of commencement and completion of experimental work	—
5.1	A statement of the objectives of the test or study	—
6.1	The identity of the test substance or material (ISO common name, batch number and degree of purity)	—
6.2	An explicit reference to the relevant specification of composition of the test substance or material	—

³¹ Relevant for tests and studies for which the test methods used were not those currently specified (*e.g.* certain older studies)

Active Substance:

Applicant:

Date:

Test or Study Title:

Data Point:

Test or Study Point	Description of the requirement	Provided Y/N [#]
6.3	Where available, data relevant to the storage stability of the test substance or material	—
6.4	Where relevant and available, data as to the stability of the test substance or material in the dosing vehicle	—
6.5	Where relevant and available, data as to the homogeneity of the test substance or material in the dosing or testing vehicle	—
6.6	Where data relating to the stability or homogeneity of the test substance is not available (e.g. certain older studies), a justification of the scientific validity of the study	—
6.7	Where relevant, information as to the physical form of the test substance or material	—
6.8	Full details of the composition of any dosing vehicles or solvents used	—
7.1	The identity of the test method used	—
7.2	Where not a method specified, a reasoned justification for the choice of method used in terms of its scientific validity and comparability with the method currently specified	—
7.3	On request, a copy of the method - full details of methods used which are unlikely to be accessible to the regulatory authority of the country to which the dossier is submitted, should be attached to the study or test report	—
7.4	Where test guidelines provide choice as to the method to be used, a reasoned justification for the choice made	—
7.5	Where deviations from the test guidelines specified, or from other methods used, are employed, a description of and reasoned justification for the deviations	—
8.1	Where relevant, an indication as to whether, or not, the test or study has been conducted by a laboratory certified as to its competence to conduct the test or study in compliance with the principles of GLP	—
8.2	Where relevant, the certifying authority	—
8.3	Where applicable, an indication as to whether, or not, the principles of GLP have been complied with	—
8.4	Where relevant, a justification for non compliance with the principles of GLP	—
9.1	Where relevant, a clear statement that the requirements relating to compliance with the principles of Good Experimental Practice (GEP) have been complied with	—
9.2	Where the requirements relating to compliance with the principles of GEP apply, whether conducted by an official or an officially recognised testing facility or organisation	—
9.3	Where relevant, a justification for non compliance with the principles of GEP	—

Active Substance:

Applicant:

Date:

Test or Study Title:

Data Point:

Test or Study Point	Description of the requirement	Provided Y/N [#]
10	A description of the test system	-
11	The identity of any statistical and other techniques applied to the data to aid interpretation, together with adequate documentation thereof and a justification for the use of the technique selected where non standard techniques are used	-
12.1	Where reference to published papers is made in <i>Tier I</i> checks as to the quality of individual test and study reports, the bibliographic references concerned	-
12.2	On request, copies of the papers concerned	-
12	Where reference to unpublished data is made in <i>Tier I</i> checks as to the quality of individual test and study reports (<i>e.g.</i> historical control data on strains of test animals) a summary of such data	-

Assessment of the Acceptability of the Quality of the Report

Report of acceptable quality

Yes

No

Comments:

Signature: