

Comparison list for
dossier submission in CADDY-Format
(OECD vs. EC)

rev. 15 final CADDY (05.12.2007)/La

OECD code (CADDY-Format)	OECD code text	EC code (CADDY-Format)	EC code text	Remarks (Explanations see end of table)	Line
KIIM 1	Identity of the Microbial Pest Control Agent	KIIB 1	Identity of the Micro-organism	OECD point corresponds with EC point.	2
KIIM 1.1	Applicant (name, address, contact, telephone and telefax numbers)	KIIB 1.1	Applicant	OECD point corresponds with EC point.	3
KIIM 1.2	Producer (name, address, contact, telephone and telefax numbers)	KIIB 1.2	Producer	OECD point corresponds with EC point.	4
KIIM 1.3	Scientific information	KIIB 1.3	Name and species description, strain characterisation	OECD point does not exist; new OECD point (header) inserted. OECD point corresponds with EC point.	5
KIIM 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;	KIIB 1.3	Name and species description, strain characterisation	OECD code text has been changed as new subpoints were inserted. OECD point corresponds with EC point.	6
<i>KIIM 1.3.1 new number: KIIM 1.3.2</i>	- accession no. of sample in a recognised culture collection	KIIB 1.3	Name and species description, strain characterisation	New OECD number inserted. OECD point corresponds with EC point.	7
<i>KIIM 1.3.1 new number: KIIM 1.3.3</i>	- test procedures and criteria, using best available technology, to characterise the strain or serotype;	KIIB 1.3	Name and species description, strain characterisation	New OECD number inserted. OECD point corresponds with EC point.	8
<i>KIIM 1.3.1 new number: KIIM 1.3.4</i>	- for mutant or genetically-modified strains, indicate all known differences between the modified micro-organism and the parent wild strain(s)	KIIB 1.3	Name and species description, strain characterisation	New OECD number inserted. OECD point corresponds with EC point.	9
<i>KIIM 1.3.1 new number: KIIM 1.3.5</i>	- include any trade names, common names, developmental code names	KIIB 1.3	Name and species description, strain characterisation	New OECD number inserted. OECD point corresponds with EC point.	10
<i>KIIM 1.3.1 new number: KIIM 1.3.6</i>	- indigenous or non-indigenous at the species level to the intended area of application	KIIB 1.3	Name and species description, strain characterisation	New OECD number inserted. OECD point corresponds with EC point.	11
KIIM 1.4	Composition of Technical Grade of MPCA/Active Substance	KIIB 1.4	Specification of the material used for manufacturing of formulated products	OECD point corresponds with EC point.	12
KIIM 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; 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	KIIB 1.4.1	Content of the micro-organism	OECD point corresponds with EC point.	13
KIIM 1.4.2	Composition of microbial material used for manufacture of end use products in terms of g/kg or g/L (for US and Canada also in % w/w) for each active ingredient including:	KIIB 1.4.2	Identity and content of impurities, additives, contaminating micro-organisms	OECD code text has been changed as new subpoints were inserted. OECD point corresponds with EC point.	14
<i>KIIM 1.4.2 new number: KIIM 1.4.2.1</i>	- the MPCA. This information is not required if Technical Grade of MPCA is a hypothetical stage in a continuous production process of an end-use product	KIIB 1.4.2	Identity and content of impurities, additives, contaminating micro-organisms	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	15
<i>KIIM 1.4.2 new number: KIIM 1.4.2.2</i>	- additives (preservatives, stabilisers, diluents). This information is not required if Technical Grade of MPCA is a hypothetical stage in a continuous production process of an end-use product	KIIB 1.4.2	Identity and content of impurities, additives, contaminating micro-organisms	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	16
<i>KIIM 1.4.2 new number: KIIM 1.4.2.3</i>	- microbial impurities, classified/identified to a taxonomic level required by quality criteria to support the hygienic state of the production process. This information is not required if Technical Grade of MPCA is a hypothetical stage in a continuous production process of an end-use product	KIIB 1.4.2	Identity and content of impurities, additives, contaminating micro-organisms	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	17
<i>KIIM 1.4.2 new number: KIIM 1.4.2.4</i>	- non-microbial impurities (e.g. metabolic products, impurities in starting materials, fermentation residues, extraneous host residues). This information is not required if Technical Grade of MPCA is a hypothetical stage in a continuous production process of an end-use product	KIIB 1.4.2	Identity and content of impurities, additives, contaminating micro-organisms	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	18
<i>KIIM 1.4.2 new number: KIIM 1.4.2.5</i>	Composition in terms of % g/kg or g/L, (for US and Canada also in % 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 (in terms of cfu's/mL or appropriate expression of biological activity/viability). <i>new wording:</i> Composition in terms of g/kg or g/L, (for US and Canada also in % w/w), for each ingredient: The identity and maximum content of all microbial impurities must be reported, if possible and appropriate, as outlined in point 1.3, and expressed in appropriate units (in terms of cfu's/mL or appropriate expression of biological activity/viability)	KIIB 1.4.2	Identity and content of impurities, additives, contaminating micro-organisms	OECD subpoint does not exist; new OECD number inserted. The OECD code text has been changed. OECD point corresponds with EC point.	19
KIIM 1.4.3	Methods of production and quality criteria for the production and storage of the active micro-organism, including:	KIIB 3.4	Method of production and quality control	OECD code text has been changed as new subpoints were inserted. OECD point corresponds with EC point.	20

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<i>KIIM 1.4.3</i> new number: <i>KIIM 1.4.3.1</i>	- criteria for consistency and integrity of the master and working seed stock, typically, measures of biological activity and phenotypic or genotypic properties;	KIIB 3.4	Method of production and quality control	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	21
<i>KIIM 1.4.3</i> new number: <i>KIIM 1.4.3.2</i>	- acceptable range for content of MPCA, in appropriate terms;	KIIB 3.4	Method of production and quality control	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	22
<i>KIIM 1.4.3</i> new number: <i>KIIM 1.4.3.3</i>	- presence of human/mammalian pathogens;	KIIB 3.4	Method of production and quality control	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	23
<i>KIIM 1.4.3</i> new number: <i>KIIM 1.4.3.4</i>	- 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;	KIIB 3.4	Method of production and quality control	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	24
<i>KIIM 1.4.3</i> new number: <i>KIIM 1.4.3.5</i>	- maximum accepted level for microbial impurities, using suitable indicators of an unhygienic process	KIIB 3.4	Method of production and quality control	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	25
KIIM 1.4.4	Quality control data (measures of quality criteria) from 3 - 5 production batches, including storage stability data. If the Technical Grade of MPCA is a stage in a continuous production process of an end-use product, this information should be provided for the entire production process	KIIB 1.4.3	Analytical profile of batches	OECD point corresponds with EC point.	26
KIIM 1.4.5	The formation, presence and/or impact of unintentional ingredients			OECD code text has been changed as new subpoints were inserted. No EC data requirement.	27
<i>KIIM 1.4.5</i> new number: <i>KIIM 1.4.5.1</i>	A theoretical discussion regarding the formation and/or presence of unintentional ingredients, including impurities of toxicological concern, likely to occur in the Technical Grade of the MPCA			OECD subpoint does not exist; new OECD number inserted. No EC data requirement.	28
<i>KIIM 1.4.5</i> new number: <i>KIIM 1.4.5.2</i>	A theoretical discussion regarding the impact of these ingredients on product quality			OECD subpoint does not exist; new OECD number inserted. No EC data requirement.	29
<i>KIIM 1.4.5</i> new number: <i>KIIM 1.4.5.3</i>	A theoretical discussion regarding appropriate quality criteria			OECD subpoint does not exist; new OECD number inserted. No EC data requirement.	30
<i>KIIM 1.4.5</i> new number: <i>KIIM 1.4.6</i>	Physical and chemical properties, if MPCA is produced as a manufacturing product that is stored prior to formulation of end-use products: physical state; density; viscosity or surface tension; explosivity, corrosive character, oxidising properties; technical characteristics as appropriate			OECD subpoint does not exist; new OECD number inserted. No EC data requirement.	31
<i>KIIM 1.4.5</i> new number: <i>KIIM 1.4.7</i>	International regulatory status of micro-organism			OECD subpoint does not exist; new OECD number inserted. No EC data requirement.	32
KIIM 1.4.5 (continued)	Comprehensive Data Summary / Tier II summaries in OECD format: "Guidelines and Criteria for Industry for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for Plant Protection Products and their 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.			This point has been deleted as purpose in the document is unclear.	33
<i>KIIM 1.4.5 (continued)</i> new number: <i>KIIM 1.4.8</i>	Sample of MPCA and analytical standard of metabolite	KIIB 4	Analytical methods	New OECD number inserted. OECD point partly covered by EC point KIIB 4; EC subpoint does not exist.	34
<i>KIIM 1.4.5 (continued)</i> new number: <i>KIIM 1.4.8.1</i>	Sample of MPCA; if requested	KIIB 4	Analytical methods	OECD subpoint does not exist; new OECD number inserted. OECD point partly covered by EC point KIIB 4; EC subpoint does not exist.	35
<i>KIIM 1.4.5 (continued)</i> new number: <i>KIIM 1.4.8.2</i>	Analytical standard of metabolite; if requested	KIIB 4	Analytical methods	OECD subpoint does not exist; new OECD number inserted. OECD point partly covered by EC point KIIB 4; EC subpoint does not exist.	36
<i>KIIM 1.4.5 (continued)</i> new number: <i>KIIM 1.4.8.3</i>	Reference substances for the relevant impurities; if requested	KIIB 4	Analytical methods	OECD subpoint does not exist; new OECD number inserted. OECD point partly covered by EC point KIIB 4; EC subpoint does not exist.	37
<i>KIIM 1.5.3</i> new number: <i>KIIM 1.5</i>	Patent status			New OECD number inserted. No EC data requirement.	38

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KIIM 2	Biological Properties of the Microbial Pest Control Agent	KIIB 2	Biological properties of the micro-organism	OECD point corresponds with EC point.	39
KIIM 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	KIIB 2.1 KIIB 2.1.1 KIIB 2.1.2	History of the micro-organism and its uses. Natural occurrence and geographical distribution Historical background Origin and natural occurrence	OECD point corresponds with three EC points.	40
KIIM 2.2	Natural occurrence of the micro-organism including geographic distribution, hosts, habitat, ecological niche, level of natural occurrence	KIIB 2.1.2	Origin and natural occurrence	OECD point allocation depending on study title. OECD point KIIM 2.2 ist part of EC point KIIB 2.1.2.	41
KIIM 2.3	Information on target organism(s)	KIIB 2.2	Information on target organism(s)	OECD code text has been changed as new subpoints were inserted. OECD point corresponds with EC point.	42
<i>KIIM 2.3 new number: KIIM 2.3.1</i>	Description of the target organism(s)	KIIB 2.2.1	Description of the target organism(s)	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	43
<i>KIIM 2.3 new number: KIIM 2.3.2</i>	Information on mode of action, kind of antagonism to target host, infective/toxic dose, transmissibility	KIIB 2.2.2	Mode of action	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	44
KIIM 2.4	Available information on host specificity; possible effects on species closely related to the target pest. Any experience of toxic effect of the active substance or its metabolic products on human or animals, of whether the organism is capable of colonising or invading humans or animals and whether it is pathogenic shall be stated. Any experience of whether the active substance or its products may irritate skin, eyes or respiratory organs of humans or animals and whether it is allergenic in contact with skin or when inhaled	KIIB 2.3	Host specificity range and effects on species other than the target harmful organism	OECD point corresponds with EC point.	45
KIIM 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)	KIIB 2.4	Development stages/life cycle of the micro-organism	OECD point corresponds with EC point.	46
<i>KIIM 2.6</i>	<i>Potential of the micro-organism to produce metabolites that are of concern for human health and/or the environment</i>	KIIB 2.8	Information on the production of metabolites (especially toxins)	This second paragraph of OECD point KIIM 2.5 appears only in the check of completeness and not in the OECD Dossier guidance document Appendix 6 part 4. It has been added to the Dossier guidance document and a separate number has been allocated to this point.	47
<i>KIIM 2.6 new number: KIIM 2.7</i>	Information regarding closely related species	KIIB 2.6 KIIB 2.8	Relationships to known plant or animal or human pathogens Information on the production of metabolites (especially toxins)	OECD code text has been changed as new subpoints were inserted. OECD point corresponds with two EC points.	48
<i>KIIM 2.6 new number: KIIM 2.7.1</i>	Among closely related species, provide information on pathogenicity to plants, animals or humans	KIIB 2.6	Relationships to known plant or animal or human pathogens	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	49
<i>KIIM 2.6 new number: KIIM 2.7.2</i>	Among closely related species, provide information on formation of toxic metabolites: structure, stability, conditions under which they are formed, mode of action	KIIB 2.8	Information on the production of metabolites (especially toxins)	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	50
<i>KIIM 2.6 new number: KIIM 2.8</i>	Physiological properties, especially effect of environmental parameters on growth, infectivity, dispersal and colonisation ability: temperature, pH, redox potential, humidity, light, nutritional requirements	KIIB 2.5	Infectiveness, dispersal and colonization ability	New OECD number inserted. OECD point corresponds with EC point.	51
<i>KIIM 2.6 new number: KIIM 2.9</i>	Description of any plasmids or other extra chromosomal genetic elements involved in pesticidal activity, pathogenicity, toxicity, etc.			New OECD number inserted. No EC data requirement.	52
<i>KIIM 2.6 new number: KIIM 2.10</i>	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	KIIB 2.7	Genetic stability and factors affecting it	New OECD number inserted. OECD point corresponds with EC point.	53
<i>KIIM 2.6 new number: KIIM 2.11</i>	Detailed discussion of relationship of micro-organism to any known human dermatophyte (see point 5.2)			New OECD number inserted. No EC data requirement.	54

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<i>KIIM 2.6</i> new number: <i>KIIM 2.12</i>	Resistance/sensitivity to antibiotics/anti-microbial agents used in human or veterinary medicine	KIIB 2.9	Antibiotics and other anti-microbial agents	New OECD number inserted. OECD point corresponds with EC point.	55
KIIM 3	Further information on the Microbial Pest Control Agent (Function, Mode of Action, Handling)	KIIB 3	Further information on the micro-organism	OECD point corresponds with EC point.	56
KIIM 3.1	Function, e.g. fungicide	KIIB 3.1	Function	OECD point corresponds with EC point.	57
<i>KIIM 3.2</i>	<i>placeholder</i>			OECD point does not exist; new OECD point (placeholder) inserted. No EC data requirement.	58
KIIM 3.3	Field of use, e.g. forestry	KIIB 3.2	Field of use envisaged	OECD point corresponds with EC point.	59
<i>KIIM 3.4</i>	<i>Information on target crop and target organism(s)</i>	KIIB 3.3 KIIB 2.2.1	Crops or products protected or treated Description of the target organism(s)	OECD point does not exist; new OECD point (header) inserted. OECD point corresponds with two EC points.	60
KIIM 3.4.1	Details of existing and intended uses (crops, groups of crops, plants or plant products treated or protected)	KIIB 3.3	Crops or products protected or treated	OECD point corresponds with EC point.	61
KIIM 3.4.2	Details of harmful organisms against which protection is afforded	KIIB 2.2.1	Description of the target organism(s)	OECD point corresponds with EC point.	62
KIIM 3.4.3	Effects achieved e.g. sprout suppression			no EC data requirement.	63
<i>KIIM 3.5</i>	<i>Information on mode of action and metabolites</i>	KIIB 2.2.2 KIIB 2.8	Mode of action Information on the production of metabolites (especially toxins)	OECD point does not exist; new OECD point (header) inserted. OECD point corresponds with two EC points.	64
KIIM 3.5.1	Statement of the mode of action of the Microbial Pest Control Agent in terms of biochemical and physiological mechanism(s) and biochemical pathway(s) involved. (see IIM 2.3.2)	KIIB 2.2.2	Mode of action	OECD point corresponds with EC point.	65
KIIM 3.5.2	Details of active metabolites (especially toxins) and degradation products, cross referenced to the toxicological and residues data provided, to include:	KIIB 2.8	Information on the production of metabolites (especially toxins)	OECD code text has been changed as new subpoints were inserted. OECD point covers more than the corresponding EC point. EC point corresponds partly with OECD point.	66
<i>KIIM 3.5.2</i> new number: <i>KIIM 3.5.2.1</i>	- IUPAC and CA names	KIIB 2.8	Information on the production of metabolites (especially toxins)	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds partly with EC point.	67
<i>KIIM 3.5.2</i> new number: <i>KIIM 3.5.2.2</i>	- ISO common name proposed or accepted	KIIB 2.8	Information on the production of metabolites (especially toxins)	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds partly with EC point.	68
<i>KIIM 3.5.2</i> new number: <i>KIIM 3.5.2.3</i>	- CAS, CIPAC, EINECS and ELINCS numbers	KIIB 2.8	Information on the production of metabolites (especially toxins)	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds partly with EC point.	69
<i>KIIM 3.5.2</i> new number: <i>KIIM 3.5.2.4</i>	- molecular and structural formula	KIIB 2.8	Information on the production of metabolites (especially toxins)	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds partly with EC point.	70
<i>KIIM 3.5.2</i> new number: <i>KIIM 3.5.2.5</i>	- molecular mass	KIIB 2.8	Information on the production of metabolites (especially toxins)	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds partly with EC point.	71
KIIM 3.5.3	Information relative to the formation of active metabolites (especially toxins) and degradation products, to include:	KIIB 2.8	Information on the production of metabolites (especially toxins)	OECD code text has been changed as new subpoints were inserted. OECD point covers more than the corresponding EC point. EC point corresponds partly with OECD point.	72
<i>KIIM 3.5.3</i> new number: <i>KIIM 3.5.3.1</i>	- the processes, mechanisms and reactions involved	KIIB 2.8	Information on the production of metabolites (especially toxins)	OECD subpoint does not exist; new OECD number inserted. OECD point covers more than the corresponding EC point.	73
<i>KIIM 3.5.3</i> new number: <i>KIIM 3.5.3.2</i>	- kinetic and other data concerning the rate of conversion and if known the rate limiting step	KIIB 2.8	Information on the production of metabolites (especially toxins)	OECD subpoint does not exist; new OECD number inserted. OECD point covers more than the corresponding EC point.	74
<i>KIIM 3.5.3</i> new number: <i>KIIM 3.5.3.3</i>	- environmental and other factors effecting the rate and extent of conversion	KIIB 2.8	Information on the production of metabolites (especially toxins)	OECD subpoint does not exist; new OECD number inserted. OECD point covers more than the corresponding EC point.	75

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KIIM 3.6	Information on the possible occurrence of the development of resistance or cross-resistance	KIIB 3.5	Information on the occurrence or possible occurrence of the development of resistance of the target organism(s)	OECD point corresponds with EC point.	76
KIIM 3.7	A material safety data sheet for the Microbial Active Substance	KIIB 3.7	Recommended methods and precautions concerning handling, storage, transport or fire	OECD point corresponds with EC point.	77
<i>KIIM 3.8.1.2</i> new number: <i>KIIM 3.8</i>	Detailed instructions for safe disposal	KIIB 3.8	Procedures for destruction or decontamination	OECD number follows no numerical scheme in this section; new OECD number inserted. OECD point corresponds with EC point.	78
KIIM 3.9	Procedures for the decontamination of water in case of an accident	KIIB 3.9	Measures in case of an accident	OECD point allocation depending on information.	79
KIIM 3.10	Other/special studies	KIIB 3	Further information on the micro-organism	EC subpoint does not exist.	80
KIIM 3.11	Crops or products to be protected or treated (see IIM 3.4.1)	KIIB 3.3	Crops or products protected or treated	OECD point corresponds with EC point.	81
KIIM 3.12	Measures to render micro-organism harmless, in case of an accident	KIIB 3.9	Measures in case of an accident	OECD point corresponds with EC point.	82
KIIM 4	Analytical Methods	KIIB 4	Analytical methods	OECD point corresponds with EC point.	83
<i>KIIM 4.1.5</i> new number: <i>KIIM 4.1</i>	Method to preserve and maintain the master seed stock; criteria for an acceptable level of consistency and integrity of seed stock	KIIB 3.6	Methods to prevent loss of virulence of seed stock of the micro-organism	OECD number follows no numerical scheme in this section; new OECD number inserted. OECD point corresponds with EC point.	84
<i>KIIM 4.2.8</i> new number: <i>KIIM 4.2</i>	Production process for Technical Grade of MPCA, describing techniques used to ensure a uniform product and procedures when hazardous contamination is detected in a batch List starting and intermediate materials, with source and purity of each	KIIB 3.4	Method of production and quality control	OECD number follows no numerical scheme in this section; new OECD number inserted. OECD point corresponds with EC point.	85
KIIM 4.3	Quality control and post-registration monitoring methods	KIIB 3.4 KIIB 4.1	Method of production and quality control Methods for the analysis of the micro-organism as manufactured	OECD code text has been changed as new subpoints were inserted. OECD point corresponds with two EC points.	86
<i>KIIM 4.3</i> new number: <i>KIIM 4.3.1</i>	Methods to detect, isolate, and enumerate the micro-organism	KIIB 3.4 KIIB 4.1	Method of production and quality control Methods for the analysis of the micro-organism as manufactured	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with two EC points.	87
<i>KIIM 4.3</i> new number: <i>KIIM 4.3.2</i>	Methods to differentiate a mutant or genetically-modified micro-organism from the parent strain	KIIB 3.4 KIIB 4.1	Method of production and quality control Methods for the analysis of the micro-organism as manufactured	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with two EC points.	88
<i>KIIM 4.3</i> new number: <i>KIIM 4.3.3</i>	Methods to detect spontaneous change in major characteristics of micro-organism	KIIB 3.4 KIIB 4.1	Method of production and quality control Methods for the analysis of the micro-organism as manufactured	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with two EC points.	89
<i>KIIM 4.3</i> new number: <i>KIIM 4.3.4</i>	Methods to define content of micro-organism in appropriate terms (same as IIM 1.4.1), incl. standardisation, sensitivity, reproducibility, statistical validity, and representative data to validate the bioassay	KIIB 3.4 KIIB 4.1	Method of production and quality control Methods for the analysis of the micro-organism as manufactured	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with two EC points.	90
<i>KIIM 4.3</i> new number: <i>KIIM 4.3.5</i>	Methods to show control to a specified and acceptable level, of microbial impurities and of any other impurities of toxicological concern, including toxic metabolites, which are known or suspected to be present at any stage of the manufacturing process	KIIB 3.4 KIIB 4.1	Method of production and quality control Methods for the analysis of the micro-organism as manufactured	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with two EC points.	91
<i>KIIM 4.3</i> new number: <i>KIIM 4.3.6</i>	Methods to show presence of any human and mammalian pathogens	KIIB 3.4 KIIB 4.1	Method of production and quality control Methods for the analysis of the micro-organism as manufactured	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with two EC points.	92
KIIM 4.4	Storage stability test, data and determination of shelf life, if MPCA is stored			no EC data requirement.	93
KIIM 4.5	Post-registration monitoring methods to determine and quantify residues of viable or non-viable micro-organism and metabolites (especially toxins)	KIIB 4.2	Methods to determine and quantify residues (viable or non-viable)	OECD code text has been changed as new subpoints were inserted. OECD point corresponds with EC point.	94
<i>KIIM 4.5</i> new number: <i>KIIM 4.5.1</i>	Food (where relevant)	KIIB 4.2	Methods to determine and quantify residues (viable or non-viable)	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	95
<i>KIIM 4.5</i> new number: <i>KIIM 4.5.2</i>	Feed (where relevant)	KIIB 4.2	Methods to determine and quantify residues (viable or non-viable)	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	96
<i>KIIM 4.5</i> new number: <i>KIIM 4.5.3</i>	Animal tissue (where relevant)	KIIB 4.2	Methods to determine and quantify residues (viable or non-viable)	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	97

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OECD code (CADDY-Format)	OECD code text	EC code (CADDY-Format)	EC code text	Remarks (Explanations see end of table)	Line
<i>KIIM 4.5</i> <i>new number:</i> <i>KIIM 4.5.4</i>	Soil (where relevant)	KIIB 4.2	Methods to determine and quantify residues (viable or non-viable)	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	98
<i>KIIM 4.5</i> <i>new number:</i> <i>KIIM 4.5.5</i>	Water (where relevant)	KIIB 4.2	Methods to determine and quantify residues (viable or non-viable)	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	99
<i>KIIM 4.5</i> <i>new number:</i> <i>KIIM 4.5.6</i>	Air (where relevant)	KIIB 4.2	Methods to determine and quantify residues (viable or non-viable)	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	100
<i>KIIM 4.5</i> <i>new number:</i> <i>KIIM 4.5.7</i>	Analytical methods for amount or activity of proteinaceous products (where relevant)	KIIB 4.2	Methods to determine and quantify residues (viable or non-viable)	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	101
KIIM 5	Toxicological and Exposure Data and Information on the Microbial Pest Control Agent	KIIB 5	Effects on human health	OECD point corresponds with EC point.	102
		KIIB 5.1	Basic information	OECD point (heading) does not exist; additional OECD point not necessary.	103
KIIM 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	KIIB 5.1.1	Medical data	OECD point corresponds with EC point.	104
KIIM 5.2	Occupational health surveillance report on workers during production and testing of MPCA, including information on: see IIM 5.2.1 to 5.2.4. Published reports of adverse effects, especially reports of clinical cases and followup studies. Proposed first aid measures and medical treatment	KIIB 5.1.2 KIIB 5.1.3 KIIB 5.1.4 KIIB 5.2.6	Medical surveillance on manufacturing plant personnel Sensitisation/allergenicity observations, if appropriate Direct observation, e.g. clinical cases Proposed treatment: first aid measures, medical treatment	OECD code text has been changed as new subpoints were inserted, and OECD point KIIM 5.9 as well as KIIM 5.9.1 were moved to this point to summarize all observations on humans. OECD point corresponds with four EC points.	105
<i>KIIM 5.2</i> <i>new number:</i> <i>KIIM 5.2.1</i>	The sensitisation and allergenic response of workers	KIIB 5.1.2 KIIB 5.1.3 KIIB 5.1.4	Medical surveillance on manufacturing plant personnel Sensitisation/allergenicity observations, if appropriate Direct observation, e.g. clinical cases	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	106
<i>KIIM 5.2</i> <i>new number:</i> <i>KIIM 5.2.2</i>	Details on any occurrence of hypersensitivity and chronic sensitisation	KIIB 5.1.2 KIIB 5.1.3 KIIB 5.1.4	Medical surveillance on manufacturing plant personnel Sensitisation/allergenicity observations, if appropriate Direct observation, e.g. clinical cases	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	107
<i>KIIM 5.2</i> <i>new number:</i> <i>KIIM 5.2.3</i>	Any significant clinical findings related to exposure, with special attention to those whose susceptibility may be affected	KIIB 5.1.2 KIIB 5.1.3 KIIB 5.1.4	Medical surveillance on manufacturing plant personnel Sensitisation/allergenicity observations, if appropriate Direct observation, e.g. clinical cases	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	108
<i>KIIM 5.9</i> <i>new number:</i> <i>KIIM 5.2.4</i>	Published reports of adverse effects, especially reports of clinical cases and followup studies; list databases and key words used in a literature search	KIIB 5.1.4	Direct observation, e.g. clinical cases	This OECD point has been moved from further below to here; new OECD number inserted. OECD point corresponds with EC point.	109
<i>KIIM 5.9.1</i> <i>new number:</i> <i>KIIM 5.2.5</i>	Proposed first aid measures and medical treatment	KIIB 5.2.6	Proposed treatment: first aid measures, medical treatment	This OECD point has been moved from further below to here; new OECD number inserted. OECD point corresponds with EC point.	110
<i>KIIM 5.3</i>	<i>Basic studies</i>	KIIB 5.2	Basic studies	OECD point does not exist; new OECD point inserted. OECD point corresponds with EC point.	111
<i>KIIM 5.3.1</i>	<i>Sensitisation properties</i>	KIIB 5.2.1	Sensitisation	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	112
		KIIB 5.2.2	Acute toxicity, pathogenicity and infectiveness	OECD point (heading) does not exist; additional OECD point not necessary.	113
<i>KIIM 5.3</i> <i>new number:</i> <i>KIIM 5.3.2</i>	Acute oral infectivity and toxicity <i>new wording:</i> Acute oral infectivity, toxicity and pathogenicity	KIIB 5.2.2.1	Acute oral toxicity, pathogenicity and infectiveness	New OECD number inserted. The OECD code text has been changed. OECD point corresponds with EC point.	114
<i>KIIM 5.4</i> <i>new number:</i> <i>KIIM 5.3.3</i>	Acute intratracheal/inhalation infectivity and toxicity <i>new wording:</i> Acute intratracheal/inhalation infectivity, toxicity and pathogenicity	KIIB 5.2.2.2	Acute inhalation toxicity, pathogenicity and infectiveness	New OECD number inserted. The OECD code text has been changed. OECD point corresponds with EC point.	115
<i>KIIM 5.5</i> <i>new number:</i> <i>KIIM 5.3.4</i>	Acute intravenous/intraperitoneal infectivity	KIIB 5.2.2.3	Intraperitoneal/subcutaneous single dose	New OECD number inserted. OECD point corresponds with EC point.	116

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OECD code (CADDY-Format)	OECD code text	EC code (CADDY-Format)	EC code text	Remarks (Explanations see end of table)	Line
<i>KIIM 5.7</i> new number: <i>KIIM 5.3.5</i>	Genotoxic potential, especially for fungi and actinomycetes: a discussion of the potential for genotoxin production based on the relationship of the micro-organism 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)	KIIB 5.2.3.1	In vitro studies	This OECD point has been moved from further below to here; new OECD number inserted. OECD point corresponds with EC point.	117
<i>KIIM 5.6</i> new number: <i>KIIM 5.3.6</i>	Cell culture study, for viruses and viroids or specific bacteria and protozoa with intracellular replication	KIIB 5.2.4	Cell culture study	New OECD number inserted. OECD point corresponds with EC point.	118
<i>KIIM 5.10.1</i> new number: <i>KIIM 5.3.7</i>	Short-term toxicity (including inhalatory short-term toxicity), pathogenicity, infectivity	KIIB 5.2.5 KIIB 5.2.5.1	Information on short-term toxicity and pathogenicity Health effects after repeated inhalatory exposure	This OECD point has been moved from further below to here; new OECD number inserted. OECD point corresponds with two EC points.	119
<i>KIIM 5.10.1</i> new number: <i>KIIM 5.3.7.1</i>	Short-term toxicity, pathogenicity, infectivity (28-day minimum)	KIIB 5.2.5	Information on short-term toxicity and pathogenicity	This OECD point has been moved from further below to here; new OECD number inserted. OECD point corresponds with EC point.	120
<i>KIIM 5.3.7.2</i>	<i>Inhalatory short-term toxicity</i>	KIIB 5.2.5.1	Health effects after repeated inhalatory exposure	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	121
		KIIB 5.2.3	Genotoxicity testing	Heading not available in OECD, not necessary to propose new heading.	122
<i>KIIM 5.7</i>	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).	KIIB 5.2.3.1	In vitro studies	This OECD point has been moved to (become a subpoint of) OECD point KIIM 5.3, see above.	123
<i>KIIM 5.8</i> new number: <i>KIIM 5.4</i>	Toxicity studies on metabolites (especially toxins)	KIIB 5.2.3	Genotoxicity testing	New OECD number inserted. OECD point partly covered by EC point. On this point, see also introduction paragraph (VIII) to Commission Directive 2001/36/EC: "If the plant protection action is known to be due to the residual effect of a toxin or if significant residues of toxins are to be expected not related to the effect of the active substance, a dossier for the toxin has to be submitted in accordance with the requirements of Annex II, part A".	124
<i>KIIM 5.9</i>	Published reports of adverse effects, especially reports of clinical cases and follow-up studies; list databases and key words used in a literature search.	KIIB 5.1.4	Direct observation, e.g. clinical cases	This OECD point has been moved to (become a subpoint of) OECD point KIIM 5.2, see above. OECD point corresponds with EC point.	125
<i>KIIM 5.9.1</i>	Proposed first aid measures and medical treatment	KIIB 5.2.6	Proposed treatment: first aid measures, medical treatment	This OECD point has been moved to (become a subpoint of) OECD point KIIM 5.2, see above. OECD point corresponds with EC point.	126
<i>KIIM 5.10</i> new number: <i>KIIM 5.5</i>	Other/special studies	KIIB 5.3 KIIB 5.4 KIIB 5.5	Specific toxicity, pathogenicity and infectiveness studies In vivo studies in somatic cells Genotoxicity - In vivo studies in germ cells	New OECD number inserted. OECD point corresponds with three EC points. EC point allocation depending on information.	127
<i>KIIM 5.5.1</i>	<i>Specific toxicity, pathogenicity and infectiveness studies</i>	KIIB 5.3	Specific toxicity, pathogenicity and infectiveness studies	OECD subpoint does not exist; New OECD number inserted. OECD point corresponds with EC point.	128
<i>KIIM 5.5.2</i>	<i>In vivo studies in somatic cells</i>	KIIB 5.4	In vivo studies in somatic cells	OECD subpoint does not exist; New OECD number inserted. OECD point corresponds with EC point.	129
<i>KIIM 5.5.3</i>	<i>Genotoxicity - In vivo studies in germ cells</i>	KIIB 5.5	Genotoxicity - In vivo studies in germ cells	OECD subpoint does not exist; New OECD number inserted. OECD point corresponds with EC point.	130
<i>KIIM 5.10.1</i>	Short-term toxicity, pathogenicity, infectivity (28-day minimum)	KIIB 5.2.5	Information on short-term toxicity and pathogenicity	This OECD point has been moved to (become a subpoint of) OECD point KIIM 5.3, see above. OECD point corresponds with EC point.	131
<i>KIIM 5.11</i> new number: <i>KIIM 5.6</i>	Summary of mammalian toxicity and overall evaluation	KIIB 5.6	Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation	New OECD number inserted. OECD point corresponds with EC point.	132

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KIIM 6	Metabolism and Residues Studies on the Microbial Pest Control Agent	KIIB 6	Residues in or on treated products, food and feed	OECD point corresponds with EC point.	133
KIIM 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	KIIB 6	Residues in or on treated products, food and feed	OECD point corresponds with EC point; especially paragraph (III) of the introduction.	134
<i>KIIM 6.1 new number: KIIM 6.2</i>	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			New OECD number inserted. No EC data requirement.	135
<i>KIIM 6.3</i>	<i>Persistence and likelihood of multiplication in or on crops, feedingstuffs or foodstuffs</i>	KIIB 6.1	Persistence and likelihood of multiplication in or on crops, feedingstuffs or foodstuffs	OECD point does not exist; new OECD point inserted. OECD point corresponds with EC point.	136
<i>KIIM 6.4</i>	<i>Further information required</i>	KIIB 6.2	Further information required	OECD point does not exist; new OECD point inserted. OECD point corresponds with EC point.	137
<i>KIIM 6.4.1</i>	<i>Non-viable residues</i>	KIIB 6.2.1	Non-viable residues	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	138
<i>KIIM 6.4.2</i>	<i>Viable residues</i>	KIIB 6.2.2	Viable residues	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	139
<i>KIIM 6.1 new number: KIIM 6.5</i>	Summary of residue behaviour and overall evaluation	KIIB 6.3	Summary and evaluation of residue behaviour resulting from data submitted under points 6.1 to 6.2	New OECD number inserted. OECD point corresponds with EC point.	140
KIIM 7	Fate and Behaviour Studies on the Microbial Pest Control Agent in the Environment	KIIB 7	Fate and behaviour in the environment	OECD point corresponds with EC point.	141
<i>KIIM 7 new number: KIIM 7.1</i>	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	KIIB 7.1	Persistence and multiplication	New OECD number inserted. OECD point corresponds with EC point.	142
<i>KIIM 7.1.1</i>	<i>Persistence and mobility in soil</i>	KIIB 7.1.1	Soil	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with two EC points.	143
<i>KIIM 7.1.2</i>	<i>Water</i>	KIIB 7.2	Mobility		
<i>KIIM 7.1.2</i>	<i>Water</i>	KIIB 7.1.2	Water	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	144
<i>KIIM 7.1.3</i>	<i>Air</i>	KIIB 7.1.3	Air	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	145
<i>KIIM 7.13 new number: KIIM 7.2</i>	Other/special studies	KIIB 7	Fate and behaviour in the environment	OECD number follows no numerical scheme in this section; new OECD number inserted. EC subpoint does not exist.	146
KIIM 8	Ecotoxicological Studies on the Microbial Pest Control Agent (Effects on non-target organisms)	KIIB 8	Effects on non-target organisms	OECD point corresponds with EC point.	147
KIIM 8.1	Birds <i>new wording: Effects on birds</i>	KIIB 8.1	Effects on birds	OECD code text has been changed. OECD point corresponds with EC point.	148
		KIIB 8.2	Effects on aquatic organisms	Heading not available in OECD, not necessary to propose new heading.	149
KIIM 8.2	Fish <i>new wording: Effects on fish</i>	KIIB 8.2.1	Effects on fish	OECD code text has been changed. OECD point corresponds with EC point.	150
KIIM 8.3	Aquatic invertebrates <i>new wording: Effects on aquatic invertebrates</i>	KIIB 8.2.2	Effects on freshwater invertebrates	OECD code text has been changed. OECD point corresponds with EC point.	151
KIIM 8.4	Effects on algal growth and growth rate (2 species) <i>new wording: Effects on algal growth and growth rate</i>	KIIB 8.2.3	Effects on algae growth	OECD code text has been changed. OECD point corresponds with EC point.	152
<i>KIIM 8.5</i>	<i>Effects on aquatic plants</i>	KIIB 8.2.4	Effects on plants other than algae	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	153
<i>KIIM 8.6</i>	<i>Effects on aquatic or terrestrial plants. new wording: Effects on terrestrial plants</i>			OECD code text has been changed as a new OECD point (KIIM 8.5) which covers aquatic plants was inserted. No EC data requirement.	154
KIIM 8.7	Bees <i>new wording: Effects on bees</i>	KIIB 8.3	Effects on bees	OECD code text has been changed. OECD point corresponds with EC point.	155

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KIIM 8.8	Non-target terrestrial arthropods <i>new wording:</i> Effects on terrestrial arthropods other than bees	KIIB 8.4	Effects on arthropods other than bees	OECD code text has been changed as the header of this section. KIIM 8 specifies already that it deals with non-target organisms. OECD point corresponds with EC point.	156
KIIM 8.9	Other terrestrial invertebrates <i>new wording:</i> Effects on other terrestrial invertebrates			OECD code text has been changed. No EC data requirement.	157
KIIM 8.9.1	Effects on earthworms	KIIB 8.5	Effects on earthworms	OECD point corresponds with EC point.	158
<i>KIIM 8.9.2</i>	<i>Effects on other terrestrial invertebrates</i>			OECD subpoint does not exist; new OECD number inserted. No EC data requirement.	159
KIIM 8.10	Effects on non-target soil micro-organisms <i>new wording:</i> Effects on soil micro-organisms	KIIB 8.6	Effects on non-target soil micro-organisms	OECD code text has been changed as the header of this section. KIIM 8 specifies already that it deals with non-target organisms. OECD point corresponds with EC point.	160
KIIM 8.11	Other/special studies	KIIB 8.7	Additional studies	OECD point corresponds with EC point.	161
KIIM 9	Summary and evaluation of environmental impact: summarise all data relevant to environmental impact and assess environmental risk by:	KIIB 9	Summary and evaluation of environmental impact	OECD code text has been changed as new subpoints were inserted. OECD point corresponds with EC point.	162
<i>KIIM 9 new number: KIIM 9.1</i>	- addressing distribution and fate of MPCA	KIIB 9	Summary and evaluation of environmental impact	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	163
<i>KIIM 9 new number: KIIM 9.2</i>	- identifying non-target species at risk and the extent of their exposure	KIIB 9	Summary and evaluation of environmental impact	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	164
<i>KIIM 9 new number: KIIM 9.3</i>	- identifying precautions necessary to minimise environmental contamination and to protect non-target species	KIIB 9	Summary and evaluation of environmental impact	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	165
					166
KIIM1 1	Identity of the Microbial Pest Control Product	KIIB1 1	Identity of the plant protection product	OECD point corresponds with EC point.	167
KIIM1 1.1	Applicant (name, address, contact, telephone and telefax numbers)	KIIB1 1.1	Applicant	OECD point corresponds with EC point.	168
<i>KIIM1 1.2</i>	<i>Manufacturer(s) of the preparation and producer of the microbial pest control agent</i>	<i>KIIB1 1.2</i>	<i>Manufacturer of the preparation and the micro-organism(s)</i>	<i>OECD point does not exist; new OECD point (header) inserted. OECD point corresponds with EC point.</i>	169
KIIM1 1.2.1	Manufacturer(s) of the preparation (name, address, contact, telephone and telefax numbers)	KIIB1 1.2	Manufacturer of the preparation and the micro-organism(s)	EC subpoint does not exist.	170
KIIM1 1.2.2	Producer of the microbial pest control agent (name, address, contact, telephone and telefax numbers)	KIIB1 1.2	Manufacturer of the preparation and the micro-organism(s)	EC subpoint does not exist.	171
KIIM1 1.3	Trade name or proposed trade name and manufacturers code number(s), for the preparation and similar preparations (differences to be specified)	KIIB1 1.3	Trade name or proposed trade name, and manufacturer's development code number of the preparation if appropriate	OECD point corresponds with EC point.	172
<i>KIIM1 1.4</i>	<i>placeholder</i>			<i>OECD number does not exist; new OECD number inserted (placeholder). No EC data requirement.</i>	173
KIIM1 1.5	Physical state of MPCP (Crop Life formulation type)	KIIB1 1.5	Physical state and nature of the preparation	OECD point corresponds with EC point.	174
KIIM1 1.6	Function (herbicide, insecticide, etc.)	KIIB1 1.6	Function	OECD point corresponds with EC point.	175
KIIM1 1.6.1	Biological function category and field of use category, using terms defined by each country, e.g. "control of weeds" for "forestry"	KIIB1 3.1	Field of use envisaged	OECD point corresponds with EC point.	176
KIIM1 1.7	Other/special studies	KIIB1 1	Identity of the plant protection product	EC subpoint does not exist.	177
KIIM1 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	KIIB1 1.4	Detailed quantitative and qualitative information on the composition of the preparation	OECD code text has been changed as new subpoints were inserted. EC subpoint does not exist.	178

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<i>KIIM1 1.7.1</i> new number: <i>KIIM1 1.7.1.1</i>	Also indicate: scientific name and strain/serotype of MPCA, its accession number in a recognised culture collection	KIIB1 1.4	Detailed quantitative and qualitative information on the composition of the preparation	OECD subpoint does not exist; new OECD number inserted. EC subpoint does not exist.	179
<i>KIIM1 1.7.1</i> new number: <i>KIIM1 1.7.1.2</i>	Also indicate: development phase (e.g. spore) of MPCA in MPCP	KIIB1 1.4	Detailed quantitative and qualitative information on the composition of the preparation	OECD subpoint does not exist; new OECD number inserted. EC subpoint does not exist.	180
KIIM1 1.7.2	Composition in terms of g/kg or g/L and % w/w of each ingredient in MPCP, including:	KIIB1 1.4	Detailed quantitative and qualitative information on the composition of the preparation	OECD code text has been changed as new subpoints were inserted. EC subpoint does not exist.	181
<i>KIIM1 1.7.2</i> new number: <i>KIIM1 1.7.2.1</i>	- technical Grade of MPCA	KIIB1 1.4	Detailed quantitative and qualitative information on the composition of the preparation	OECD subpoint does not exist; new OECD number inserted. EC subpoint does not exist.	182
<i>KIIM1 1.7.2</i> new number: <i>KIIM1 1.7.2.2</i>	- 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	KIIB1 1.4	Detailed quantitative and qualitative information on the composition of the preparation	OECD subpoint does not exist; new OECD number inserted. EC subpoint does not exist.	183
<i>KIIM1 1.7.2</i> new number: <i>KIIM1 1.7.2.3</i>	- 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	KIIB1 1.4	Detailed quantitative and qualitative information on the composition of the preparation	OECD subpoint does not exist; new OECD number inserted. EC subpoint does not exist.	184
<i>KIIM1 1.7.2</i> new number: <i>KIIM1 1.7.2.4</i>	- non-microbial impurities (e.g. metabolic products, impurities in starting materials, fermentation residues, extraneous host residues)	KIIB1 1.4	Detailed quantitative and qualitative information on the composition of the preparation	OECD subpoint does not exist; new OECD number inserted. EC subpoint does not exist.	185
KIIM1 1.7.3	Quality criteria for the production and storage of the MPCP, including:	KIIB1 1.4	Detailed quantitative and qualitative information on the composition of the preparation	OECD code text has been changed as new subpoints were inserted. OECD point corresponds partly with EC point (part of EC point KIIB1 1.4 (ii), first indent is part of OECD point KIIM1 1.7.3).	186
<i>KIIM1 1.7.3</i> new number: <i>KIIM1 1.7.3.1</i>	- acceptable range for content of MPCA, in appropriate terms;	KIIB1 1.4	Detailed quantitative and qualitative information on the composition of the preparation	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds partly with EC point (part of EC point KIIB1 1.4 (ii), first indent is part of OECD point KIIM1 1.7.3).	187
<i>KIIM1 1.7.3</i> new number: <i>KIIM1 1.7.3.2</i>	- presence of human or non-target animal pathogens;	KIIB1 1.4	Detailed quantitative and qualitative information on the composition of the preparation	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds partly with EC point (part of EC point KIIB1 1.4 (ii), first indent is part of OECD point KIIM1 1.7.3).	188
<i>KIIM1 1.7.3</i> new number: <i>KIIM1 1.7.3.3</i>	- 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	KIIB1 1.4	Detailed quantitative and qualitative information on the composition of the preparation	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds partly with EC point (part of EC point KIIB1 1.4 (ii), first indent is part of OECD point KIIM1 1.7.3).	189
<i>KIIM1 1.7.3</i> new number: <i>KIIM1 1.7.3.4</i>	- maximum accepted level for microbial impurities, using suitable indicators of contamination	KIIB1 1.4	Detailed quantitative and qualitative information on the composition of the preparation	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds partly with EC point (part of EC point KIIB1 1.4 (ii), first indent is part of OECD point KIIM1 1.7.3).	190
KIIM1 1.7.4	Quality control data (measures of quality criteria) from 3 - 5 production batches, including product stored for duration of shelf life if it is metabolically active. If the Technical Grade of MPCA is a stage in a continuous production process of an end use product, this information should be provided for the entire production process			no EC data requirement.	191
KIIM1 1.7.5	The formation, presence and/or impact of unintentional ingredients			OECD code text has been changed as new subpoints were inserted. No EC data requirement.	192
<i>KIIM1 1.7.5</i> new number: <i>KIIM1 1.7.5.1</i>	A theoretical discussion regarding the formation and/or presence of unintentional ingredients, including impurities of toxicological concern, likely to occur in the MPCP			OECD subpoint does not exist; new OECD number inserted. No EC data requirement.	193
<i>KIIM1 1.7.5</i> new number: <i>KIIM1 1.7.5.2</i>	A theoretical discussion regarding the impact of these ingredients on product quality			OECD subpoint does not exist; new OECD number inserted. No EC data requirement.	194
<i>KIIM1 1.7.5</i> new number: <i>KIIM1 1.7.5.3</i>	A theoretical discussion regarding appropriate quality criteria			OECD subpoint does not exist; new OECD number inserted. No EC data requirement.	195

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<i>KIIIM1 1.7.5</i> <i>new number:</i> <i>KIIIM1 1.7.5.4</i>	For metabolically-active MPCP, consider degradation or metabolic production during storage in the theoretical discussion			OECD subpoint does not exist; new OECD number inserted. No EC data requirement.	196
KIIIM1 2	Physical, Chemical and Technical Properties of the Microbial Pest Control Product	KIIIB1 2	Physical, chemical and technical properties of the plant protection product	OECD point corresponds with EC point.	197
KIIIM1 2.1	Appearance (colour, odour, physical state)	KIIIB1 2.1	Appearance (colour and odour)	OECD point corresponds with EC point.	198
KIIIM1 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	KIIIB1 2.2 KIIIB1 2.2.1 KIIIB1 2.2.2	Storage stability and shelf-life Effects of light, temperature and humidity on technical characteristics of the plant protection product Other factors affecting stability	OECD point corresponds with three EC points. EC point allocation depending on information.	199
KIIIM1 2.3	Explosivity, oxidising properties, flash point, flammability, spontaneous ignition, acidity, alkalinity, pH, viscosity, surface tension	KIIIB1 2.3 KIIIB1 2.4 KIIIB1 2.5 KIIIB1 2.6	Explosivity and oxidizing properties Flash point and other indications of flammability or spontaneous ignition Acidity, alkalinity and if necessary pH value Viscosity and surface tension	OECD point corresponds with four EC points. EC point allocation depending on information.	200
<i>KIIIM1 2.3</i> <i>new number:</i> <i>KIIIM1 2.3.1</i>	Explosivity, oxidising properties: as appropriate	KIIIB1 2.3	Explosivity and oxidizing properties	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	201
<i>KIIIM1 2.3</i> <i>new number:</i> <i>KIIIM1 2.3.2</i>	Flash point, flammability, spontaneous ignition: as appropriate	KIIIB1 2.4	Flash point and other indications of flammability or spontaneous ignition	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	202
<i>KIIIM1 2.3</i> <i>new number:</i> <i>KIIIM1 2.3.3</i>	Acidity, alkalinity, pH: as appropriate	KIIIB1 2.5	Acidity, alkalinity and if necessary pH value	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	203
<i>KIIIM1 2.3</i> <i>new number:</i> <i>KIIIM1 2.3.4</i>	Viscosity, surface tension: as appropriate	KIIIB1 2.6	Viscosity and surface tension	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	204
KIIIM1 2.4	Technical characteristics as appropriate:	KIIIB1 2.7	Technical characteristics of the plant protection product	OECD code text has been changed as new subpoints were inserted. OECD point corresponds with EC point.	205
<i>KIIIM1 2.4</i> <i>new number:</i> <i>KIIIM1 2.4.1</i>	Wettability	KIIIB1 2.7.1	Wettability	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	206
<i>KIIIM1 2.4</i> <i>new number:</i> <i>KIIIM1 2.4.2</i>	Persistent foaming	KIIIB1 2.7.2	Persistent foaming	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	207
<i>KIIIM1 2.4</i> <i>new number:</i> <i>KIIIM1 2.4.3</i>	Suspensibility, suspension stability	KIIIB1 2.7.3	Suspensibility, suspension stability	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	208
<i>KIIIM1 2.4</i> <i>new number:</i> <i>KIIIM1 2.4.4</i>	Dry/wet sieve test <i>new wording: Dry sieve test and wet sieve test</i>	KIIIB1 2.7.4	Dry sieve test and wet sieve test	OECD subpoint does not exist; new OECD number inserted. OECD code text has been changed, see EC point. OECD point corresponds with EC point.	209
<i>KIIIM1 2.4</i> <i>new number:</i> <i>KIIIM1 2.4.5</i>	Particle size distribution, content of dust/fines <i>new wording: Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)</i>	KIIIB1 2.7.5	Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)	OECD subpoint does not exist; new OECD number inserted. OECD code text has been changed, see EC point. OECD point corresponds with EC point.	210
<i>KIIIM1 2.4</i> <i>new number:</i> <i>KIIIM1 2.4.6</i>	Emulsifiability, emulsion stability <i>new wording: Emulsifiability, re-emulsifiability, emulsion stability</i>	KIIIB1 2.7.6	Emulsifiability, re-emulsifiability, emulsion stability	OECD subpoint does not exist; new OECD number inserted. OECD code text has been changed, see EC point. OECD point corresponds with EC point.	211
<i>KIIIM1 2.4</i> <i>new number:</i> <i>KIIIM1 2.4.7</i>	Flowability, pourability, dustability <i>new wording: Flowability, pourability (rinsability), dustability</i>	KIIIB1 2.7.7	Flowability, pourability (rinsability), dustability	OECD subpoint does not exist; new OECD number inserted. OECD code text has been changed, see EC point. OECD point corresponds with EC point.	212
<i>KIIIM1 2.4</i> <i>new number:</i> <i>KIIIM1 2.5</i>	Density			New OECD number inserted. No EC data requirement.	213

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KIIM1 6.1 new number: KIIM1 2.6	Adherence and distribution to seeds, for seed treatment products	KIIB1 2.9	Adherence and distribution to seeds	This OECD point has been moved from section 6 to this section; new OECD number inserted. OECD point corresponds with EC point.	214
KIIM1 2.4 new number: KIIM1 2.7	Summary and evaluation of data on properties of the MPCP	KIIB1 2.10	Summary and evaluation of data presented under points 2.1 to 2.9	New OECD number inserted. OECD point corresponds with EC point.	215
KIIM1 3 & 4 new number: KIIM1 3	Application Instructions, Precautions, Cleaning for the Microbial Pest Control Product new wording: Data on application	KIIB1 3	Data on application	OECD number and code text has been changed. OECD point corresponds with EC point.	216
KIIM1 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?)	KIIB1 3.2 KIIB1 3.3	Mode of action Details of intended use	OECD point corresponds with two EC points. EC point allocation depending on information.	217
KIIM1 3.2	Available information on the development of resistance in target pest and appropriate mitigation strategy	KIIB1 6.3	Information on the possible occurrence of the development of resistance	OECD point corresponds with EC point.	218
KIIM1 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)	KIIB1 3.4 KIIB1 3.5	Application rate Content of micro-organism in material used (e.g. in the diluted spray, baits or treated seed)	OECD point corresponds with two EC points. EC point allocation depending on information.	219
KIIM1 3.4	Application rate in terms of units of micro-organism per unit area/volume	KIIB1 3.4	Application rate	EC point allocation depending on study title.	220
KIIM1 3.5	Method of application (incl. type of equipment and volume of diluent)	KIIB1 3.6	Method of application	OECD point corresponds with EC point.	221
KIIM1 3.6	Number and timing of applications, related to: host/pest phenology, duration of protection, application of other pesticides, pre-harvest interval. new wording: Number, timing and conditions of applications, related to: host/pest phenology, duration of protection, application of other pesticides, pre-harvest interval	KIIB1 3.7 KIIB1 4.3	Number and timing of applications and duration of protection Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment	OECD code text has been changed. OECD point corresponds with two EC points.	222
KIIM1 3.6 new number: KIIM1 3.6.1	Number and timing of applications, related to: host/pest phenology, duration of protection, application of other pesticides, pre-harvest interval. new wording: Number, timing and conditions of applications, related to: host/pest phenology, duration of protection, application of other pesticides	KIIB1 3.7	Number and timing of applications and duration of protection	OECD subpoint does not exist; new OECD number inserted. OECD code text has been changed as a new OECD point (KIIM1 3.6.2) which covers preharvest interval was inserted. OECD point corresponds with EC point.	223
KIIM1 3.6 new number: KIIM1 3.6.2	Number and timing of applications, related to: host/pest phenology, duration of protection, application of other pesticides, pre-harvest interval. new wording: Pre-harvest interval	KIIB1 4.3	Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment	OECD subpoint does not exist; new OECD number inserted. OECD code text has been changed as a new OECD point (KIIM1 3.6.1) was inserted. OECD point corresponds with EC point.	224
KIIM1 3.7	Precautions to avoid phytotoxic/ phytopathogenic effects on protected crop or on succeeding crops, if appropriate	KIIB1 3.8	Necessary waiting periods or other precautions to avoid phytopathogenic effects on succeeding crops	OECD point corresponds with EC point.	225
KIIM1 3.7 new number: KIIM1 3.8	Proposed instructions for use as printed, or to be printed, on labels	KIIB1 3.9	Proposed instructions for use	New OECD number inserted. OECD point corresponds with EC point.	226
KIIM1 3 & 4 new number: KIIM1 4	Application Instructions, Precautions, Cleaning for the Microbial Pest Control Product new wording: Further information on the Microbial Pest Control Product	KIIB1 4	Further information on the plant protection product	OECD number and code text has been changed. OECD point corresponds with EC point.	227
KIIM1 4.1	Packaging: description	KIIB1 4.1	Packaging and compatibility of the preparation with proposed packaging materials	OECD point allocation depending on information.	228
KIIM1 4.2	Specifications of packaging and measures of its suitability	KIIB1 4.1	Packaging and compatibility of the preparation with proposed packaging materials	OECD point allocation depending on information.	229
KIIM1 4.3	Label instructions re: cleaning equipment and protective clothing new wording: Label instructions regarding cleaning equipment and protective clothing	KIIB1 4.2	Procedures for cleaning application equipment	OECD code text has been changed for reasons of clarification. OECD point allocation depending on information.	230
KIIM1 4.4	Procedures to clean equipment and protective clothing: measures of their effectiveness	KIIB1 4.2	Procedures for cleaning application equipment	OECD point allocation depending on information.	231
KIIM1 4.5	Necessary waiting periods for re-entry; recommended protective measures to reduce occupational exposure	KIIB1 4.3	Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment	OECD point corresponds with EC point.	232
KIIM1 4.6	Label instructions regarding: safe handling and storage	KIIB1 4.4	Recommended methods and precautions concerning: handling, storage, transport or fire	OECD point allocation depending on information.	233
KIIM1 4.7	Recommendations regarding: handling, storage, transport, fire: specify risks, specify procedures to minimise hazards and the generation of waste	KIIB1 4.4	Recommended methods and precautions concerning: handling, storage, transport or fire	OECD point allocation depending on information.	234

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KIIIM1 4.8	Label instructions regarding: cleanup of spills	KIIIB1 4.5	Measures in the case of an accident	OECD point allocation depending on information.	235
KIIIM1 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	KIIIB1 4.5	Measures in the case of an accident	OECD point allocation depending on information.	236
KIIIM1 4.10	Procedures for destruction/disposal of MPCP and its packaging (e.g. detailed instructions for controlled incineration) <i>new wording: Procedures for destruction/disposal of MPCP and its packaging</i>	KIIIB1 4.6	Procedures for destruction or decontamination of the plant protection product and its packaging	OECD code text has been changed as new subpoints were inserted. OECD point corresponds with EC point.	237
<i>KIIIM1 4.10.1</i>	<i>Controlled incineration</i>	KIIIB1 4.6.1	Controlled incineration	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	238
<i>KIIIM1 4.10.2</i>	<i>Methods other than controlled incineration</i>	KIIIB1 4.6.2	Others	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	239
KIIIM1 5	Methods of Analysis, Manufacturing, Quality Control and Post-Registration Monitoring of the Microbial Pest Control Product	KIIIB1 5	Analytical methods	OECD point corresponds with EC point.	240
KIIIM1 5.1	Quality control and post-registration monitoring methods	KIIIB1 5.1	Methods for the analysis of the preparation	OECD code text has been changed as new subpoints were inserted. OECD point allocation depending on information.	241
<i>KIIIM1 5.1</i> <i>new number:</i> <i>KIIIM1 5.1.1</i>	Methods to differentiate a mutant or genetically-modified micro-organism from the parent strain	KIIIB1 5.1	Methods for the analysis of the preparation	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	242
<i>KIIIM1 5.1</i> <i>new number:</i> <i>KIIIM1 5.1.2</i>	Methods to detect spontaneous change in major characteristics of micro-organism	KIIIB1 5.1	Methods for the analysis of the preparation	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	243
<i>KIIIM1 5.1</i> <i>new number:</i> <i>KIIIM1 5.1.3</i>	Methods to define content of micro-organism in appropriate terms (same as IIM 1.4.1), incl. standardisation, sensitivity, reproducibility, statistical validity, and representative data to validate the bioassay	KIIIB1 5.1	Methods for the analysis of the preparation	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	244
<i>KIIIM1 5.1</i> <i>new number:</i> <i>KIIIM1 5.1.4</i>	Methods to identify contaminant micro-organisms in MPCP	KIIIB1 5.1	Methods for the analysis of the preparation	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	245
<i>KIIIM1 5.1</i> <i>new number:</i> <i>KIIIM1 5.1.5</i>	Methods to show control to a specified and acceptable level, of microbial impurities and of any other impurities of toxicological concern, including toxic metabolites, which are known or suspected to be present at any stage of the manufacturing process	KIIIB1 5.1	Methods for the analysis of the preparation	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	246
<i>KIIIM1 5.1</i> <i>new number:</i> <i>KIIIM1 5.1.6</i>	Methods to show presence of any human and mammalian pathogens	KIIIB1 5.1	Methods for the analysis of the preparation	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	247
KIIIM1 5.2	Storage stability test and determination of shelf life <i>new wording: Storage stability test and determination of shelf life (methods of analysis)</i>	KIIIB1 5.1	Methods for the analysis of the preparation	OECD code text has been changed. OECD point allocation depending on information (last indent of EC point KIIIB1 5.1 corresponds to OECD point KIIIM1 5.2).	248
KIIIM1 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			no EC data requirement (only required for MPCA).	249
<i>KIIIM1 5.3</i> <i>new number:</i> <i>KIIIM1 5.4</i>	Method for determination of residues: required if information provided for MPCA in Part 4 is insufficient, for MPCP. <i>new wording: Method for determination of residues: required if information provided for MPCA in Annex II Part 4 is insufficient, for MPCP</i>	KIIIB1 5.2	Methods to determine and quantify residues	New OECD number inserted. OECD code text has been changed. OECD point corresponds with EC point.	250
KIIIM1 6	Efficacy Data and Information (including Value Data) for the Microbial Pest Control Product	KIIIB1 6	Efficacy data	OECD point corresponds with EC point.	251
KIIIM1 6.1	Performance assessment: lab or growth chamber studies <i>new wording: Preliminary range finding tests</i>	KIIIB1 6.1	Preliminary range finding tests	OECD code text has been changed. OECD point corresponds with EC point.	252
	<i>Adherence and distribution to seeds, for seed-treatment products</i>	<i>KIIIB1 2.9</i>	<i>Adherence and distribution to seeds</i>	This OECD point has been moved to section 2.	253
KIIIM1 6.2	Performance assessment: field studies	KIIIB1 6.2	Efficacy tests	OECD point corresponds with EC point.	254
<i>KIIIM1 6.2.1</i>	<i>Efficacy tests</i>	KIIIB1 6.2	Efficacy tests	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	255
<i>KIIIM1 6.2.2</i>	<i>Minimum effective dose tests</i>	KIIIB1 6.2	Minimum effective dose tests	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	256

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KIIIM1 6.3	Toxic or pathogenic effects on the crop or host which is to be protected.	KIIIB1 6.5	Phytotoxicity to target plants (including different cultivars), or to target plant products	OECD point corresponds with EC point.	257
KIIIM1 6.4	Compatibility with products in authorised tank mixes and with other products that are applied under expected conditions of use. Recommended interval between application of MPCP and chemical pesticide, to avoid loss of efficacy. <i>new wording. Compatibility with products in authorised tank mixes and with other products that are applied under expected conditions of use. Recommended interval between application of MPCP and any other products, to avoid loss of efficacy</i>	KIIIB1 2.8	Physical, chemical and biological compatibility with other products including plant protection products with which its use is to be authorized	OECD code text has been changed to cover also biological pesticides. OECD point corresponds with EC point.	258
KIIIM1 6.4.1	<i>Physical compatibility</i>	KIIIB1 2.8.1	Physical compatibility	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	259
KIIIM1 6.4.2	<i>Chemical compatibility</i>	KIIIB1 2.8.2	Chemical compatibility	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	260
KIIIM1 6.4.3	<i>Biological compatibility</i>	KIIIB1 2.8.3	Biological compatibility	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	261
KIIIM1 6.5	Contribution to risk reduction and integrated pest management strategies, for the targeted crop or resource			no EC data requirement.	262
KIIIM1 6.6	<i>Effects on yield and quality</i>	KIIIB1 6.4	Effects on the quality and where appropriate on the yield of treated plants or effects on the quality of treated plant products	OECD point does not exist; new OECD point inserted. OECD point corresponds with EC point.	263
KIIIM1 6.6.1	<i>Impact on the quality of plants and plant products</i>	KIIIB1 6.4.1	Impact on the quality of plants and plant products	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	264
KIIIM1 6.6.2	<i>Effects on the processing procedure</i>	KIIIB1 6.4.2	Effects on the processing procedure	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	265
KIIIM1 6.6.3	<i>Effects on the yield of treated plants and plant products</i>	KIIIB1 6.4.3	Effects on the yield of treated plants and plant products	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	266
KIIIM1 6.7	<i>Adverse effects</i>	KIIIB1 6.6	Observations concerning undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms, on succeeding crops, other plants or parts of treated plants used for propagating purposes (e.g. seeds, cuttings, runners)	OECD point does not exist; new OECD point inserted. OECD point corresponds with EC point.	267
KIIIM1 6.7.1	<i>Impact on succeeding crops</i>	KIIIB1 6.6.1	Impact on succeeding crops	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	268
KIIIM1 6.7.2	<i>Impact on other plants including adjacent crops</i>	KIIIB1 6.6.2	Impact on other plants including adjacent crops	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	269
KIIIM1 6.7.3	<i>Adverse effects on parts of plants used for propagating purposes (e.g. seeds, cuttings, runners)</i>	KIIIB1 6.6.3	Adverse effects on parts of plants used for propagating purposes (e.g. seeds, cuttings, runners)	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	270
KIIIM1 6.7.4	<i>Adverse effects on beneficial and other organisms apart from target organisms</i>	KIIIB1 6.6.4	Adverse effects on beneficial and other organisms apart from target organisms	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	271
KIIIM1 6.8	<i>Summary and assessment of data according to points 6.1 to 6.7.4</i>	KIIIB1 6.7	Summary and assessment of data presented under points 6.1 to 6.6	OECD point does not exist; new OECD point inserted. OECD point corresponds with EC point.	272
KIIIM1 6.9	<i>List of test facilities including the corresponding certificates</i>	(KIIIB1 6.8)	List of test facilities including the corresponding certificates	OECD point does not exist; new OECD point inserted. OECD point corresponds with EC point. Remark: KIIIB1 6.8 is also not an EC point, however, this point is important and is always delivered by the companies.	273
KIIIM1 7	Toxicological Studies and Exposure Data and Information for the Microbial Pest Control Product	KIIIB1 7	Effects on human health	OECD point corresponds with EC point.	274
KIIIM1 7.1	<i>Acute toxicity studies</i>	KIIIB1 7.1	Basic acute toxicity studies	OECD point does not exist; new OECD point inserted. OECD point corresponds with EC point.	275
KIIIM1 7.1.1	Acute oral toxicity	KIIIB1 7.1.1	Acute oral toxicity	OECD point corresponds with EC point.	276
KIIIM1 7.1.2	Acute percutaneous (dermal) toxicity	KIIIB1 7.1.3	Acute percutaneous toxicity	OECD point corresponds with EC point.	277
KIIIM1 7.1.3	Acute inhalation toxicity to rats	KIIIB1 7.1.2	Acute inhalation toxicity	OECD point corresponds with EC point.	278
		KIIIB1 7.2	Additional acute toxicity studies	Additional OECD point not necessary since EC point is only a heading.	279
KIIIM1 7.1.4	Skin irritation	KIIIB1 7.2.1	Skin irritation	OECD point corresponds with EC point.	280
KIIIM1 7.1.5	Eye irritation	KIIIB1 7.2.2	Eye irritation	OECD point corresponds with EC point.	281

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OECD code (CADDY-Format)	OECD code text	EC code (CADDY-Format)	EC code text	Remarks (Explanations see end of table)	Line
KIIIM1 7.1.6	Skin sensitisation	KIIIB1 7.2.3	Skin sensitization	OECD point corresponds with EC point.	282
KIIIM1 7.2	Operator, bystander and worker exposure: monitoring data	KIIIB1 7.3	Data on exposure	OECD point allocation depending on information.	283
KIIIM1 7.3	Operator and bystander exposure: reporting of hypersensitivity incidents before and after registration			no EC data requirement.	284
KIIIM1 7.4	Safety data sheet for each additive	KIIIB1 7.4	Available toxicological data relating to non-active substances	OECD point corresponds with EC point.	285
KIIIM1 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	KIIIB1 7.5	Supplementary studies for combinations of plant protection products	OECD point corresponds with EC point.	286
KIIIM1 7.6	Summary and evaluation of health effects	KIIIB1 7.6	Summary and evaluation of health effects	OECD point corresponds with EC point.	287
KIIIM1 8	Rationale to waive residue studies on MPCP <i>new wording: Residues in/on Food and Feed products for the Microbial Pest Control Product (Rationale to waive residue studies on MPCP)</i>	KIIIB1 8	Residues in or on treated products, food and feed	OECD code text has been changed. OECD point corresponds with EC point.	288
KIIIM1 9	Rationale to waive testing, based on adequacy of information provided for MPCA, to permit an assessment of the fate and behaviour of MPCP in the environment <i>new wording: Fate and Behaviour in the environment for the Microbial Pest Control Product (Rationale to waive testing, based on adequacy of information provided for MPCA, to permit an assessment of the fate and behaviour of MPCP in the environment)</i>	KIIIB1 9	Fate and behaviour in the environment	OECD code text has been changed. OECD point corresponds with EC point.	289
KIIIM1 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	KIIIB1 10	Effects on non-target organisms	OECD point corresponds with EC point.	290
KIIIM1 10.1	Effects on birds	KIIIB1 10.1	Effects on birds	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	291
KIIIM1 10.2	Effects on aquatic organisms	KIIIB1 10.2	Effects on aquatic organisms	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	292
KIIIM1 10.3	Effects on bees	KIIIB1 10.3	Effects on bees	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	293
KIIIM1 10.4	Effects on terrestrial arthropods other than bees	KIIIB1 10.4	Effects on arthropods other than bees	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	294
KIIIM1 10.5	Effects on earthworms	KIIIB1 10.5	Effects on earthworms	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	295
KIIIM1 10.6	Effects on soil micro-organisms	KIIIB1 10.6	Effects on soil micro-organisms	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	296
KIIIM1 10.7	Additional studies	KIIIB1 10.7	Additional studies	OECD subpoint does not exist; new OECD number inserted. OECD point corresponds with EC point.	297
KIIIM1 11	Summary and evaluation of environmental impact: summarise all data relevant to environmental impact and assess environmental risk by:	KIIIB1 11	Summary and evaluation of environmental impact	OECD code text has been changed as new subpoints were inserted. OECD point corresponds with EC point.	298
KIIIM1 11 new number: KIIIM1 11.1	- addressing distribution and fate of MPCP	KIIIB1 11	Summary and evaluation of environmental impact	OECD subpoint does not exist; new OECD number inserted. EC subpoint does not exist.	299
KIIIM1 11 new number: KIIIM1 11.2	- identifying non-target species at risk and the extent of their exposure	KIIIB1 11	Summary and evaluation of environmental impact	OECD subpoint does not exist; new OECD number inserted. EC subpoint does not exist.	300
KIIIM1 11 new number: KIIIM1 11.3	- identifying precautions necessary to minimise environmental contamination and to protect non-target species	KIIIB1 11	Summary and evaluation of environmental impact	OECD subpoint does not exist; new OECD number inserted. EC subpoint does not exist.	301

Comparison list for
dossier submission in CADDY-Format
(OECD vs. EC)

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OECD code (CADDY-Format)	OECD code text	EC code (CADDY-Format)	EC code text	Remarks (Explanations see end of table)	Line
Explanations:					
light yellow colour and <i>italics</i> = new OECD point (agreed by OECD at WGP November 2006)			light green colour = the allocation of this OECD point to an EC point differs from the allocation used in the OECD dossier guidance document. Hence, a different EC point allocation was proposed to OECD and agreed at WGP November 2006	OECD point corresponds with EC point: the OECD point concerned is covered by an EC point according to Council Directive 91/414/EEC. Hence, data/documents need to be submitted.	
light brown colour and <i>italics</i> = new OECD number (agreed by OECD at WGP November 2006)				EC subpoint does not exist: the OECD point concerned is not covered by an EC point according to Council Directive 91/414/EEC at the same level of differentiation but is part of an EC point at a higher level. Data/documents need to be submitted.	
light blue colour and <i>italics</i> = new wording for existing OECD point (agreed by OECD at WGP November 2006)				OECD point allocation depending on study title: the OECD point concerned is covered by an EC point according to Council Directive 91/414/EEC. However, only from the title/content of the study/document, is an allocation of the corresponding OECD point possible. Data/documents need to be submitted.	
				no EC data requirement: the OECD point concerned is not covered by or part of an EC point according to Council Directive 91/414/EEC. Hence data/documents do not need to be submitted.	
end					