

Appendix 9 Format for the listing of end points to be included in the *Tier III* overall summary and assessments

Company name Month and year Microbial Pest Control Agent (Name) page of

APPENDIX 9

FORMAT FOR THE LISTING OF END POINTS TO BE INCLUDED IN THE REASONED STATEMENT OF THE OVERALL CONCLUSIONS DRAWN BY THE REGULATORY AUTHORITY (LEVEL 2)⁸

General remark:

Testing of micro-organisms will often be made using specifically tailored studies. Therefore, e. g. toxicity/effects endpoints may differ from case to case. These endpoint list can therefore be seen as indicative only, to be amended in order to fit individual cases.

Chapter 1: Identity, Biological properties, Details of uses, Further information, and Proposed Classification and Labelling

Active micro-organism:	
Function (<i>e.g.</i> control of fungi):	
Country to which application is made:	
Identity of the Microbial Pest Control Agent / Active Substance (OECD data point IIM 1)	
Name of the organism:	
Taxonomy:	
Species, subspecies, strain:	
Identification / detection:	
Culture collection:	
Minimum and maximum concentration of the MPCA used for manufacturing of the formulated product (cfu; g/kg):	
Identity and content of relevant impurities, additives, contaminating organisms in the technical grade of MPCA:	
Is the MPCA genetically modified; if so provide type of modification	

⁸ Other endpoints will be relevant in particular cases - decisions as to the additional end points to be included can only be made on a cases by case basis

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Biological properties of the micro-organism (OECD data point IIM 2)

Origin and natural occurrence, Background level:	
Target organism(s):	
Mode of action:	
Host specificity:	
Life cycle:	
Infectivity, dispersal and colonisation ability:	
Relationships to known plant, animal or human pathogens:	
Genetic stability:	
Information on the production of relevant metabolites (especially toxins):	
Resistance/ sensitivity to antibiotics / anti-microbial agents used in human or veterinary medicine:	

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Summary of uses supported by available data

Crop and /or situation	Member state or Country	Product name	F G or	Pest or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
					Type (d-f)	Conc. of MPCA (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	kg MPCA/hL min max	water L/ha min max	kg MPCA/ha cfu MPCA/ha min max		
(a)			I (b)	(c)									(l)	(m)	

- a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- © e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes - Crop Life Technical Monograph No 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
- (I) cfu = colony forming units and g/kg or g/L
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions

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Classification and proposed labelling (Symbol, Indication of danger, Risk phrases, Safety phrases)

with regards to physical/chemical data:	
with regard to toxicological data:	
with regard to fate and behaviour:	
with regard to ecotoxicological data:	

Chapter 2: Methods of analysis

Analytical methods for the micro-organism (OECD data point IIM 4.2, 4.3 and IIM 5.4)

manufactured micro-organism (principle of method):	
Impurities and contaminating micro-organisms in manufactured material (principle of method):	
Microbial Pest Control Product (principle of method):	

Analytical methods for residues (viable and non-viable) in exposed compartments and organisms (OECD data point IIM 4.5)

of the active micro-organism (principle of method):	
of relevant metabolites (principle of method):	

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Chapter 3: Impact on Human and Animal Health

Medical data: (including medical surveillance on manufacturing plant personnel) (OECD data point IIM 5.1 & 5.2 & 5.8.1)	
Sensitisation: (OECD data point IIM 5.3.1 & IIM 7.1.6)	
Acute oral infectivity, toxicity and pathogenicity: (OECD data point IIM 5.3.2 & IIM 7.1.1)	
Acute intratracheal/inhalation infectivity, toxicity and pathogenicity: (OECD data point IIM 5.3.3 & IIM 7.1.3)	
Acute intravenous/intraperitoneal infectivity: Intraperitoneal/Subcutaneous single dose: (OECD data point IIM 5.3.4 & IIM 7.1.2)	
Genotoxicity: (OECD data point IIM 5.3.5)	
Cell culture study: (OECD data point IIM 5.3.6)	
Information on short-term toxicity and pathogenicity: (OECD data point IIM 5.3.7)	
Dermal toxicity: (OECD data point IIM 7.1.2)	
Specific-toxicity, pathogenicity and infectivity: (OECD data point IIM 5.5)	
Genotoxicity – in vivo studies in germ cells: (OECD data point IIM 5.5.3)	
Exposure (operator, workers, bystander, consumer): (OECD data point IIM 6.1, IIM 7.2, 7.3 and 8.0)	

Chapter 4: Residues (normally not required)

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Chapter 5: Fate and Behaviour in the Environment (OECD IIM 7 & IIM 9)

Persistence and multiplication in soil, water and air:	
Mobility:	

Chapter 6: Effects on non-target organisms (OECD IIM 8 & IIM 10)

Effects on birds (OECD IIM 8.1 & IIM 10.1)

Application rate (kg MPCA/ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)

Effects on aquatic organisms (OECD IIM 8.2, 8.3, & IIM 10.2)

Group	Test substance	Time-scale	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)
Laboratory tests			
Fish species (specify):			
Invertebrate species: (specify)			

Effects on algae:	
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(growth, growth rate, capacity to recover) (OECD IIM 8.4 & IIM 10.2)	
Effects on aquatic plants (OECD IIM 8.5 & IIM 10.2)	

Effects on bees (OECD IIM 8.7 & IIM 10.3)

Application rate (kg MPCA/ha)	Crop	Route	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)
Laboratory Tests			

Effects on terrestrial arthropods other than bees (OECD IIM 8.8 & IIM 10.4)

Species	Stage	Test Substance	Dose (kg MPCA/ha)	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)
Laboratory Tests				

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Effects on **other terrestrial** invertebrates (OECD IIM 8.9, 8.9.1, **8.9.2 & IIM 10.5**)

Toxicity, infectivity and pathogenicity: (endpoint, value or other description of effects)	
Further information:	

Effects on **non-target** soil micro-organisms (OECD IIM 8.10 & **IIM 10.6**)

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Additional studies (OECD IIM 8.11 & **IIM 10.7**)

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