

## APPENDIX 9

### FORMAT FOR THE LISTING OF END POINTS TO BE INCLUDED IN THE *TIER III* OVERALL SUMMARY AND ASSESSMENT

**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 (e.g. 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





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

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

with regards to physical/chemical data:

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with regard to toxicological data:

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with regard to fate and behaviour:

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with regard to ecotoxicological data:

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**Chapter 2:      Methods of analysis**

**Analytical methods for the micro-organism** (OECD data point IIM 4.2.8, 4.3 and IIIM 5.3)

manufactured micro-organism (principle of method):

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Impurities and contaminating micro-organisms in  
manufactured material (principle of method):

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Microbial Pest Control Product (principle of  
method):

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**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):

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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)

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Sensitisation:  
(OECD data point IIM 7.1.6)

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Acute oral toxicity, pathogenicity and infectivity:  
(OECD data point IIM 5.3 & IIM 7.1.1)

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Acute inhalation toxicity, pathogenicity and  
infectivity:  
(OECD data point IIM 5.4 & IIM 7.1.3)

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Intraperitoneal/Subcutaneous single dose:  
(OECD data point IIM 5.5 & IIM 7.1.2)

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Genotoxicity:  
(OECD data point IIM 5.7)

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Cell culture study:  
(OECD data point IIM 5.6)

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Information on short-term toxicity and  
pathogenicity:

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Dermal toxicity:

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Specific-toxicity, pathogenicity and infectivity:  
(OECD data point IIM 5.10)

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Genotoxicity – in vivo studies in germ cells:  
(OECD data point IIM 5.10)

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**Exposure (operator, workers, bystander,  
consumer):**  
(OECD data point IIM 6.1, IIM 7.2, 7.3 and 8.0)

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**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)**

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)**

Group	Test substance	Time-scale	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)

<b>Laboratory tests</b>			
Fish species (specify):			
Invertebrate species: (specify)			

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**Effects on algae:**

(growth, growth rate, capacity to recover)

(OECD IIM 8.4 & IIM 10)

**Effects on plants other than algae**

(OECD IIM 8.6 & IIM 10)


**Effects on bees (OECD IIM 8.7 & IIM 10)**

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

**Effects on other arthropods species (OECD IIM 8.8 & IIM 10)**

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

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**Effects on nonarthropod invertebrates** (OECD IIM 8.9, 8.9.1 & IIM 10)

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

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Further information:

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**Effects on non-target soil micro-organisms** (OECD IIM 8.10 & IIM 10)

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**Additional studies** (OECD IIM 8.11 & IIM 10)

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