

APPENDIX 6

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 (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 MPCA:

Is the organism 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

Appendix 6 **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)**

Regulatory authority	Month and year	Microbial Pest Control Agent (Name)	page of
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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

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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 7.1.6)			
Acute oral toxicity, pathogenicity and infectivity: (OECD data point IIM 5.3 & IIM 7.1.1)			
Acute inhalation toxicity, pathogenicity and infectivity: (OECD data point IIM 5.4 & IIM 7.1.3)			
Intraperitoneal/Subcutaneous single dose: (OECD data point IIM 5.5 & IIM 7.1.2)			
Genotoxicity: (OECD data point IIM 5.7)			
Cell culture study: (OECD data point IIM 5.6)			
Information on short-term toxicity and pathogenicity:			
Dermal toxicity:			
Specific-toxicity, pathogenicity and infectivity: (OECD data point IIM 5.10)			
Genotoxicity – in vivo studies in germ cells: (OECD data point IIM 5.10)			
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)

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

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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)

Laboratory tests			
Fish species (specify):			
Invertebrate species: (specify)			

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)

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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)
Laboratory Tests			

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)
Laboratory Tests				

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

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)

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Additional studies (OECD IIM 8.11 & IIM 10)

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