

CADDY Standard Table of Content for Micro-organisms

Standard Structure to be used for a CADDY Submission
in OECD Format

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CADDY Standard Table of Content for Micro-organisms

Acknowledgments

This document references other standards like TIFF, ISO standards and others. We would like to thank all those who have worked on these standards.

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1 Introduction

This document describes the standardized structure of the CADDY Table of Content of CADDY Plant Protection dossiers for micro-organisms.

CADDY Standard Table of Content for Micro-organisms

2 European Standard TOC in OECD Format

The European Commission has decided to replace the EU dossier format with the OECD dossier format. Therefore a standardized table of contents for micro-organisms in OECD format - which was not available before - has been developed. A Commission Working group including EU Member States and representatives of ECPA met several times to define the technical details of this format switch. Based on past experience with CADDY dossiers and to maximize the usefulness to Member States, the OECD-style table of content is much more detailed than the previous EU one. It covers all OECD Annex points and it should therefore not be necessary to add additional annex points. Also, the Commission Working Group recommended that annex points, which do not contain documents, should be left empty and not be removed.

The CADDY specification requires that headings do not exceed a length of 70 characters and therefore some headings had to be shortened. These are highlighted in yellow in the table below.

Standardized Table of Contents for a CADDY submission in OECD format:

Level	Dossier File No	Description
1	Document A	Statement of the context in which the dossier is submitted
1	Document B	Documentation relating to the joint submission of dossiers
1	Document C	Existing or proposed labels
1	Document D	Uses
2	D 1	Intended uses supported in the EU for which data have been provided
2	D 2	List of currently authorized uses and extent of use
1	Document F	Notification submitted to the Commission
1	Document G	Permission of each formulant in accordance with EU legislation
1	Document H	Safety data sheets for the formulants
1	Document I	Other data on the formulants
1	Document J	Confidential data and information
1	Annex IIM	Microbial Pest Control Agent (MCPA): <AI_NAME>(Annex IIM)
2	Document KIIM	Individual test and study reports
3	KIIM 1	Identity of the Microbial Pest Control Agent
4	KIIM 1.1	Applicant (name, address, contact, telephone and telefax numbers)
4	KIIM 1.2	Producer (name, address, contact, telephone and telefax numbers)
4	KIIM 1.3	Scientific information
5	KIIM 1.3.1	Scientific name of micro-organism to species level or a level ...
5	KIIM 1.3.2	- accession no. of sample in a recognised culture collection
5	KIIM 1.3.3	- test procedures and criteria, using best available technology, ...
5	KIIM 1.3.4	- for mutant or genetically-modified strains, indicate all known ...
5	KIIM 1.3.5	- include any trade names, common names, developmental code names
5	KIIM 1.3.6	- indigenous or non-indigenous at the species level to the ...

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Level	Dossier File No	Description
4	KIIM 1.4	Composition of Technical Grade of MPCA/Active Substance
5	KIIM 1.4.1	Concentration of micro-organism (and metabolite, if appropriate) ...
5	KIIM 1.4.2	Composition of microbial material used for manufacture of end use ...
6	KIIM 1.4.2.1	- the MPCA. This information is not required if Technical Grade of ...
6	KIIM 1.4.2.2	- additives (preservatives, stabilisers, diluents). This ...
6	KIIM 1.4.2.3	- microbial impurities, classified/identified to a taxonomic level ...
6	KIIM 1.4.2.4	- non-microbial impurities (e.g. metabolic products, impurities in ...
6	KIIM 1.4.2.5	Composition in terms of % g/kg or g/L, (for US and Canada also in ...
5	KIIM 1.4.3	Methods of production and quality criteria for the production and ...
6	KIIM 1.4.3.1	- criteria for consistency and integrity of the master and working ...
6	KIIM 1.4.3.2	- acceptable range for content of MPCA, in appropriate terms;
6	KIIM 1.4.3.3	- presence of human/mammalian pathogens;
6	KIIM 1.4.3.4	- presence or maximum accepted level of known mammalian toxins, if ...
6	KIIM 1.4.3.5	- maximum accepted level for microbial impurities, using suitable ...
5	KIIM 1.4.4	Quality control data (measures of quality criteria) from 3 - 5 ...
5	KIIM 1.4.5	The formation, presence and/or impact of unintentional ingredients *
6	KIIM 1.4.5.1	A theoretical discussion regarding the formation and/or presence ... *
6	KIIM 1.4.5.2	A theoretical discussion regarding the impact of these ... *
6	KIIM 1.4.5.3	A theoretical discussion regarding appropriate quality criteria *
5	KIIM 1.4.6	Physical and chemical properties, if MPCA is produced as a ... *
5	KIIM 1.4.7	International regulatory status of micro-organism *
5	KIIM 1.4.8	Sample of MPCA and analytical standard of metabolite
6	KIIM 1.4.8.1	Sample of MPCA: if requested
6	KIIM 1.4.8.2	Analytical standard of metabolite: if requested
6	KIIM 1.4.8.3	Reference substances for the relevant impurities: if requested
4	KIIM 1.5	Patent status *
3	KIIM 2	Biological Properties of the Microbial Pest Control Agent
4	KIIM 2.1	Origin of the isolate; method of isolation; preservation and ...
4	KIIM 2.2	Natural occurrence of the micro-organism including geographic ...
4	KIIM 2.3	Information on target organism(s)
5	KIIM 2.3.1	Description of the target organism(s)
5	KIIM 2.3.2	Information on mode of action, kind of antagonism to target host, ...
4	KIIM 2.4	Available information on host specificity; possible effects on ...
4	KIIM 2.5	Life cycle of the micro-organism including various forms that may ...
4	KIIM 2.6	Potential of the micro-organism to produce metabolites that are of ...
4	KIIM 2.7	Information regarding closely related species
5	KIIM 2.7.1	Among closely related species, provide information on ...
5	KIIM 2.7.2	Among closely related species, provide information on formation of ...
4	KIIM 2.8	Physiological properties, especially effect of environmental ...

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Level	Dossier File No	Description
4	KIIM 2.9	Description of any plasmids or other extra chromosomal genetic ... *
4	KIIM 2.10	Genetic stability (mutation rate of traits related to the mode of ...
4	KIIM 2.11	Detailed discussion of relationship of micro-organism to any ... *
4	KIIM 2.12	Resistance/sensitivity to antibiotics/anti-microbial agents used ...
3	KIIM 3	Further Information on the Microbial Pest Control Agent (Function, ...
4	KIIM 3.1	Function, e.g. fungicide
4	KIIM 3.2	<i>placeholder</i>
4	KIIM 3.3	Fields of use, e.g. forestry
4	KIIM 3.4	Information on target crop and target organism(s)
5	KIIM 3.4.1	Details of existing and intended uses (crops, groups of crops, ...
5	KIIM 3.4.2	Details of harmful organisms against which protection is afforded
5	KIIM 3.4.3	Effects achieved e.g. sprout suppression *
4	KIIM 3.5	Information on mode of action and metabolites
5	KIIM 3.5.1	Statement of the mode of action of the Microbial Pest Control ...
5	KIIM 3.5.2	Details of active metabolites (especially toxins) and degradation ...
6	KIIM 3.5.2.1	- IUPAC and CA names
6	KIIM 3.5.2.2	- ISO common name proposed or accepted
6	KIIM 3.5.2.3	- CAS, CIPAC, EINECS and ELINCS numbers
6	KIIM 3.5.2.4	- molecular and structural formula
6	KIIM 3.5.2.5	- molecular mass
5	KIIM 3.5.3	Information relative to the formation of active metabolites (...
6	KIIM 3.5.3.1	- the processes, mechanisms and reactions involved
6	KIIM 3.5.3.2	- kinetic and other data concerning the rate of conversion and if ...
6	KIIM 3.5.3.3	- environmental and other factors effecting the rate and extent of ...
4	KIIM 3.6	Information on the possible occurrence of the development of ...
4	KIIM 3.7	A material safety data sheet for the Microbial Active Substance
4	KIIM 3.8	Detailed instructions for safe disposal
4	KIIM 3.9	Procedures for decontamination of water in case of an accident
4	KIIM 3.10	Other/special studies
4	KIIM 3.11	Crops or products to be protected or treated (see IIM 3.4.1)
4	KIIM 3.12	Measures to render micro-organism harmless, in case of an accident
3	KIIM 4	Analytical Methods
4	KIIM 4.1	Method to preserve and maintain the master seed stock; criteria ...
4	KIIM 4.2	Production process for Technical Grade of MPCA, describing ...
4	KIIM 4.3	Quality control and post-registration monitoring methods
5	KIIM 4.3.1	Methods to detect, isolate, and enumerate the micro-organism
5	KIIM 4.3.2	Methods to differentiate a mutant or genetically-modified micro-...
5	KIIM 4.3.3	Methods to detect spontaneous change in major characteristics of ...

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Level	Dossier File No	Description
5	KIIM 4.3.4	Methods to define content of micro-organism in appropriate terms (...)
5	KIIM 4.3.5	Methods to show control to a specified and acceptable level, of ...
5	KIIM 4.3.6	Methods to show presence of any human and mammalian pathogens
4	KIIM 4.4	Storage stability test, data and determination of shelf life, if ... *
4	KIIM 4.5	Post-registration monitoring methods to determine and quantify ...
5	KIIM 4.5.1	Food (where relevant)
5	KIIM 4.5.2	Feed (where relevant)
5	KIIM 4.5.3	Animal tissue (where relevant)
5	KIIM 4.5.4	Soil (where relevant)
5	KIIM 4.5.5	Water (where relevant)
5	KIIM 4.5.6	Air (where relevant)
5	KIIM 4.5.7	Analytical methods for amount or activity of proteinaceous ...
3	KIIM 5	Toxicological and Exposure Data and Information on the Microbial ...
4	KIIM 5.1	Summary: potential of microbial pest control agent to be hazardous ...
4	KIIM 5.2	Occupational health surveillance report on workers during ...
5	KIIM 5.2.1	The sensitisation and allergenic response of workers
5	KIIM 5.2.2	Details on any occurrence of hypersensitivity and chronic ...
5	KIIM 5.2.3	Any significant clinical findings related to exposure, with ...
5	KIIM 5.2.4	Published reports of adverse effects, especially reports of ...
5	KIIM 5.2.5	Proposed first aid measures and medical treatment
4	KIIM 5.3	Basic studies
5	KIIM 5.3.1	Sensitisation properties
5	KIIM 5.3.2	Acute oral infectivity, toxicity and pathogenicity
5	KIIM 5.3.3	Acute intratracheal/inhalation infectivity, toxicity and pathogenicity
5	KIIM 5.3.4	Acute intravenous/intraperitoneal infectivity
5	KIIM 5.3.5	Genotoxic potential, especially for fungi and actinomycetes: a ...
5	KIIM 5.3.6	Cell culture study, for viruses and viroids or specific bacteria ...
5	KIIM 5.3.7	Short-term toxicity (including inhalatory short-term toxicity), ...
6	KIIM 5.3.7.1	Short-term toxicity, pathogenicity, infectivity (28-day minimum)
6	KIIM 5.3.7.2	Inhalatory short-term toxicity
4	KIIM 5.4	Toxicity studies on metabolites (especially toxins)
4	KIIM 5.5	Other/special studies
5	KIIM 5.5.1	Specific toxicity, pathogenicity and infectiveness studies
5	KIIM 5.5.2	In vivo studies in somatic cells
5	KIIM 5.5.3	Genotoxicity - In vivo studies in germ cells
4	KIIM 5.6	Summary of mammalian toxicity and overall evaluation
3	KIIM 6	Metabolism and Residues Studies on the Microbial Pest Control Agent
4	KIIM 6.1	Rationale for waiver of residue data based on information showing ...

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Level	Dossier File No	Description
4	KIIM 6.2	Rationale for waiver based on a substantiated estimation that ... *
4	KIIM 6.3	Persistence and likelihood of multiplication in or on crops, ...
4	KIIM 6.4	Further information required
5	KIIM 6.4.1	Non-viable residues
5	KIIM 6.4.2	Viable residues
4	KIIM 6.5	Summary of residue behaviour and overall evaluation
3	KIIM 7	Fate and Behaviour Studies on the Microbial Pest Control Agent in ...
4	KIIM 7.1	Sufficient information on the origin, properties, survival and ...
5	KIIM 7.1.1	Persistence and mobility in soil
5	KIIM 7.1.2	Water
5	KIIM 7.1.3	Air
4	KIIM 7.2	Other/special studies
3	KIIM 8	Ecotoxicological Studies on the Microbial Pest Control Agent (...)
4	KIIM 8.1	Effects on birds
4	KIIM 8.2	Effects on fish
4	KIIM 8.3	Effects on aquatic invertebrates
4	KIIM 8.4	Effects on algal growth and growth rate
4	KIIM 8.5	Effects on aquatic plants
4	KIIM 8.6	Effects on terrestrial plants *
4	KIIM 8.7	Effects on bees
4	KIIM 8.8	Effects on terrestrial arthropods other than bees
4	KIIM 8.9	Effects on other terrestrial invertebrates *
5	KIIM 8.9.1	Effects on earthworms
5	KIIM 8.9.2	Effects on other terrestrial invertebrates *
4	KIIM 8.10	Effects on soil micro-organisms
4	KIIM 8.11	Other/special studies
3	KIIM 9	Summary and evaluation of environmental impact: summarise all data ...
4	KIIM 9.1	- addressing distribution and fate of MPCA
4	KIIM 9.2	- identifying non-target species at risk and the extent of their ...
4	KIIM 9.3	- identifying precautions necessary to minimise environmental ...
2	Document LIIM	Quality check of reports (Tier I) and reference lists
3	LIIM Sec 1	Identity, biological properties and further information
3	LIIM Sec 2	Analytical methods
3	LIIM Sec 3	Toxicological and metabolism studies on the MPCA
3	LIIM Sec 4	Residues and plant metabolism

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Level	Dossier File No	Description
3	LIIM Sec 5	Fate and behaviour in the environment
3	LIIM Sec 6	Ecotoxicological studies on the MPCA
2	Document MIIM	Summary and evaluation (Tier II)
3	MIIM Sec 1	Identity, biological properties and further information
3	MIIM Sec 2	Analytical methods
3	MIIM Sec 3	Toxicological and metabolism studies on the MPCA
3	MIIM Sec 4	Residues and plant metabolism
3	MIIM Sec 5	Fate and behaviour in the environment
3	MIIM Sec 6	Ecotoxicological studies on the MPCA
1	Annex IIIM1	Microbial Pest Control Product (MPCP) <PRO_NAME> (Annex IIIM)
2	Document KIIIM1	Individual test and study reports
3	KIIIM1 1	Identity of the Microbial Pest Control Product
4	KIIIM1 1.1	Applicant (name, address, contact, telephone and telefax numbers)
4	KIIIM1 1.2	Manufacturer(s) of the preparation and producer of the microbial ...
5	KIIIM1 1.2.1	Manufacturer(s) of the preparation (name, address, contact, ...
5	KIIIM1 1.2.2	Producer of the microbial pest control agent (name, address, ...
4	KIIIM1 1.3	Trade name or proposed trade name and manufacturers code ...
4	KIIIM1 1.4	<i>placeholder</i>
4	KIIIM1 1.5	Physical state of MPCP (Crop Life formulation type)
4	KIIIM1 1.6	Function (herbicide, insecticide, etc.)
5	KIIIM1 1.6.1	Biological function category and field of use category, using ...
4	KIIIM1 1.7	Other/special studies
5	KIIIM1 1.7.1	Concentration of MPCA in MPCP, measured in terms of g/kg or g/L of ...
6	KIIIM1 1.7.1.1	Also indicate: scientific name and strain/serotype of MPCA, its ...
6	KIIIM1 1.7.1.2	Also indicate: development phase (e.g. spore) of MPCA in MPCP
5	KIIIM1 1.7.2	Composition in terms of g/kg or g/L and % w/w of each ingredient ...
6	KIIIM1 1.7.2.1	- technical Grade of MPCA
6	KIIIM1 1.7.2.2	- each additive: include chemical name and structure; CAS and EEC ...
6	KIIIM1 1.7.2.3	- microbial impurities: taxonomic identification as required by ...
6	KIIIM1 1.7.2.4	- non-microbial impurities (e.g. metabolic products, impurities in ...
5	KIIIM1 1.7.3	Quality criteria for the production and storage of the MPCP, ...
6	KIIIM1 1.7.3.1	- acceptable range for content of MPCA, in appropriate terms;
6	KIIIM1 1.7.3.2	- presence of human or non-target animal pathogens;
6	KIIIM1 1.7.3.3	- presence or maximum accepted level of known mammalian toxins, if ...
6	KIIIM1 1.7.3.4	- maximum accepted level for microbial impurities, using suitable ...
5	KIIIM1 1.7.4	Quality control data (measures of quality criteria) from 3 - 5 ... *
5	KIIIM1 1.7.5	The formation, presence and/or impact of unintentional ingredients *

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Level	Dossier File No	Description
6	KIIIM1 1.7.5.1	A theoretical discussion regarding the formation and/or presence ... *
6	KIIIM1 1.7.5.2	A theoretical discussion regarding the impact of these ... *
6	KIIIM1 1.7.5.3	A theoretical discussion regarding appropriate quality criteria *
6	KIIIM1 1.7.5.4	For metabolically-active MPCP, consider degradation or metabolic ... *
3	KIIIM1 2	Physical, Chemical and Technical Properties of the Microbial Pest ...
4	KIIIM1 2.1	Appearance (colour, odour, physical state)
4	KIIIM1 2.2	Storage stability and shelf-life for MPCP which must contain ...
4	KIIIM1 2.3	Explosivity, oxidising properties, flash point, flammability, ...
5	KIIIM1 2.3.1	Explosivity, oxidising properties: as appropriate
5	KIIIM1 2.3.2	Flash point, flammability, spontaneous ignition: as appropriate
5	KIIIM1 2.3.3	Acidity, alkalinity, pH: as appropriate
5	KIIIM1 2.3.4	Viscosity, surface tension: as appropriate
4	KIIIM1 2.4	Technical characteristics as appropriate:
5	KIIIM1 2.4.1	Wettability
5	KIIIM1 2.4.2	Persistent foaming
5	KIIIM1 2.4.3	Suspensibility, suspension stability
5	KIIIM1 2.4.4	Dry sieve test and wet sieve test
5	KIIIM1 2.4.5	Particle size distribution (dustable and wettable powders, granules...)
5	KIIIM1 2.4.6	Emulsifiability, re-emulsifiability, emulsion stability
5	KIIIM1 2.4.7	Flowability, pourability (rinsability), dustability
4	KIIIM1 2.5	Density *
4	KIIIM1 2.6	Adherence and distribution to seeds, for seed treatment products
4	KIIIM1 2.7	Summary and evaluation of data on properties of the MPCP
3	KIIIM1 3	Data on Application
4	KIIIM1 3.1	Pest to be controlled, crop to be protected, available information ...
4	KIIIM1 3.2	Available information on the development of resistance in target ...
4	KIIIM1 3.3	Application rate in terms of mass/vol of MPCP per unit area/volume ...
4	KIIIM1 3.4	Application rate in terms of units of micro-organism per unit area/...
4	KIIIM1 3.5	Method of application (incl. type of equipment and volume of diluent)
4	KIIIM1 3.6	Number, timing and conditions of applications, related to: host/ ...
5	KIIIM1 3.6.1	Number, timing and conditions of applications, related to: host/ ...
5	KIIIM1 3.6.2	Pre-harvest interval
4	KIIIM1 3.7	Precautions to avoid phytotoxic/ phytopathogenic effects on ...
4	KIIIM1 3.8	Proposed instructions for use as printed, or to be printed, on labels
3	KIIIM1 4	Further information on the MPCP
4	KIIIM1 4.1	Packaging: description
4	KIIIM1 4.2	Specifications of packaging and measures of its suitability

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Level	Dossier File No	Description
4	KIIM1 4.3	Label instructions regarding cleaning equipment and protective ...
4	KIIM1 4.4	Procedures to clean equipment and protective clothing; measures of ...
4	KIIM1 4.5	Necessary waiting periods for re-entry; recommended protective ...
4	KIIM1 4.6	Label instructions regarding: safe handling and storage
4	KIIM1 4.7	Recommendations regarding: handling, storage, transport, fire: ...
4	KIIM1 4.8	Label instructions regarding: cleanup of spills
4	KIIM1 4.9	Detailed procedures in case of accident to: contain a spill, ...
4	KIIM1 4.10	Procedures for destruction/disposal of MPCP and its packaging
5	KIIM1 4.10.1	Controlled incineration
5	KIIM1 4.10.2	Methods other than controlled incineration
3	KIIM1 5	Methods of Anylysis, Manufacturing, Quality Control and Post-...
4	KIIM1 5.1	Quality control and post-registration monitoring methods
5	KIIM1 5.1.1	Methods to differentiate a mutant or genetically-modified micro-...
5	KIIM1 5.1.2	Methods to detect spontaneous change in major characteristics of ...
5	KIIM1 5.1.3	Methods to define content of micro-organism in appropriate terms (...
5	KIIM1 5.1.4	Methods to identify contaminant micro-organisms in MPCP
5	KIIM1 5.1.5	Methods to show control to a specified and acceptable level, of ...
5	KIIM1 5.1.6	Methods to show presence of any human and mammalian pathogens.
4	KIIM1 5.2	Storage stability test and determination of shelf life (methods of ...
4	KIIM1 5.3	Production process for MPCP, describing techniques used to ... *
4	KIIM1 5.4	Method for determination of residues: required if information ...
3	KIIM1 6	Efficacy Data and Information (including Value Data) for the ...
4	KIIM1 6.1	Preliminary range finding tests
4	KIIM1 6.2	Performance assessment: field studies
5	KIIM1 6.2.1	Efficacy tests
5	KIIM1 6.2.2	Minimum effective dose tests
4	KIIM1 6.3	Toxic or pathogenic effects on the crop or host which is to be ...
4	KIIM1 6.4	Compatibility with products in authorised tank mixes and with ...
5	KIIM1 6.4.1	Physical compatibility
5	KIIM1 6.4.2	Chemical compatibility
5	KIIM1 6.4.3	Biological compatibility
4	KIIM1 6.5	Contribution to risk reduction and integrated pest management ... *
4	KIIM1 6.6	Effects on yield and quality
5	KIIM1 6.6.1	Impact on the quality of plants and plant products
5	KIIM1 6.6.2	Effects on the processing procedure
5	KIIM1 6.6.3	Effects on the the yield of treated plants and plant products
4	KIIM1 6.7	Adverse effects
5	KIIM1 6.7.1	Impact on succeeding crops

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Level	Dossier File No	Description
5	KIIM1 6.7.2	Impact on other plants including adjacent crops
5	KIIM1 6.7.3	Adverse effects on parts of plants used for propagating purposes (...)
5	KIIM1 6.7.4	Adverse effects on beneficial and other organisms apart from ...
4	KIIM1 6.8	Summary and assessment of data according to points 6.1 to 6.7.4
4	KIIM1 6.9	List of test facilities including the corresponding certificates
3	KIIM1 7	Toxicological Studies and Exposure Data and Information for the ...
4	KIIM1 7.1	Acute toxicity studies
5	KIIM1 7.1.1	Acute oral toxicity
5	KIIM1 7.1.2	Acute percutaneous (dermal) toxicity
5	KIIM1 7.1.3	Acute inhalation toxicity to rats
5	KIIM1 7.1.4	Skin irritation
5	KIIM1 7.1.5	Eye irritation
5	KIIM1 7.1.6	Skin sensitisation
4	KIIM1 7.2	Operator, bystander and worker exposure: monitoring data
4	KIIM1 7.3	Operator and bystander exposure: reporting of hypersensitivity ...*
4	KIIM1 7.4	Safety data sheet for each additive
4	KIIM1 7.5	Supplementary information on all data points in part 7: Effects on ...
4	KIIM1 7.6	Summary and evaluation of health effects
3	KIIM1 8	Residues in/on Food and Feed products for the Microbial Pest ...
3	KIIM1 9	Fate and Behaviour in the environment for the Microbial Pest ...
3	KIIM1 10	Rationale to waive additional testing, based on adequacy of ...
4	KIIM1 10.1	Effects on birds
4	KIIM1 10.2	Effects on aquatic organisms
4	KIIM1 10.3	Effects on bees
4	KIIM1 10.4	Effects on terrestrial arthropods other than bees
4	KIIM1 10.5	Effects on earthworms
4	KIIM1 10.6	Effects on soil micro-organisms
4	KIIM1 10.7	Additional studies
3	KIIM1 11	Summary and evaluation of environmental impact: summarise all data ...
4	KIIM1 11.1	- addressing distribution and fate of MPCP
4	KIIM1 11.2	- identifying non-target species at risk and the extent of their ...
4	KIIM1 11.3	- identifying precautions necessary to minimise environmental ...
2	Document LIIM1	Quality checks of reports (Tier I) and reference lists
3	LIIM1 Sec 1	Identity, physical and chemical properties and further information

CADDY Standard Table of Content for Micro-organisms

Level	Dossier File No	Description
3	LIIM1 Sec 2	Analytical methods
3	LIIM1 Sec 3	Toxicological studies on the product
3	LIIM1 Sec 4	Residues
3	LIIM1 Sec 5	Fate and behaviour in the environment
3	LIIM1 Sec 6	Ecotoxicological studies on the product
3	LIIM1 Sec 7	Efficacy data
2	Document MIIIM1	Summary and evaluation (Tier II)
3	MIIIM1 Sec 1	Identity, physical and chemical properties and further information
3	MIIIM1 Sec 2	Analytical methods
3	MIIIM1 Sec 3	Toxicological studies on the product
3	MIIIM1 Sec 4	Residues
3	MIIIM1 Sec 5	Fate and behaviour in the environment
3	MIIIM1 Sec 6	Ecotoxicological studies on the product
3	MIIIM1 Sec 7	Efficacy data
1	Annex IIIM2	Microbial Pest Control Product (MPCP) <PRO_NAME> (Annex IIIM)
		<i>(Continue with second formulation, if appropriate)</i>
1	Document N	Overall conclusions (Tier III)
1	Document O	Initial evaluation forms
2	OA-J	Documents A-J
2	OL-N	Documents L-N
2	OIIM	Microbial Pest Control Agent (MPCA)
2	OIIIM	Microbial Pest Control Product(s) (MPCP)
2	OIIIM Efficacy	Efficacy of Microbial Pest Control Product(s)
	Legend:	Yellow colour: Shortened headings to comply with CADDY 70 character limit
		* = 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.

3 Version History

Version	Date	Description / Changes
1.0	March 3, 2008	First baselined version