

CADDY Forum (formerly Joint CADDY Steering Group)

CADDY Standard Table of Content

Standard Structure to be used for a CADDY Submission

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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.

The content of this document is based on information gained during many discussions and talks with industry representatives from regulatory affairs departments and from regulatory authorities. Thanks to everyone for devoting the time and contributing their experience and knowledge to this project.

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1 Introduction

This document describes the standardized structure of the CADDY Table of Content of CADDY Plant Protection dossiers.

The European Rev. 8 CADDY table of content was created in 1998 and has been used in the CADDY submissions since then. As the European Commission has decided to change the dossier format from EU rev. 8 to OECD format, the CADDY table of content had to be adapted accordingly and is included in the second part of this document. This table of content was prepared by a Commission Working Group including representatives of the Commission, the Member States and ECPA.

The document was prepared on behalf of:

- The European Commission
- Regulatory Authorities of the European Union Member States
- European Crop Protection Association (ECPA)

2 European Rev. 8 Standard TOC

The following Standardized European Table of Contents is proposed for CADDY dossiers prepared according to the current EU formatting guidelines (document 1663/VI/94 rev 8 dated 22 April 1998 [3]). The CADDY dossier is an exact representation of the paper dossier and therefore the structure follows the presentation of the dossier required in the formatting guide.

This proposed Standardized European Table of Contents was agreed by a working group consisting of representatives from Member States and ECPA in 1998 and has not been changed, except that the words "and reference lists" were added to the description of items "Document LIIA" and "Document LIIIA1" to clarify where the reference lists should be linked in.

Three comments should be made regarding the design chosen for the Standardized European Table of Contents and its use in practice:

The table of contents was designed to be the index to the summary documents and study reports contained in the CADDY dossier. It thus follows that the numbering through the K-document will show gaps, since not all data points will have a study report or a summary document linked to them and would always be empty. For instance, the KIIA-document starts with KIIA 1.8 - Method of manufacture of the active substance, as this is the first Annex point which actually contains a document/report. Data points KIIA 1.1-1.7 are simply paragraphs within the Tier II (MII) , Section 1, Annex II rather than individual documents or reports and thus would always be empty. Following the same logic, the numbering in KIIIA1 starts at KIIIA1 - Detailed composition of the product.

The suggested table of contents provides a minimum structure to be used in the CADDY submission. It may be appropriate to add further subpoints, depending on the number and type of reports provided in the dossier.

For a full submission (Annex II plus one or more Annex IIIs) items in the table of contents containing no study reports should be left empty rather than deleted. However, where only an Annex III is submitted, the respective KIIA, LIIA and MIIA entries can be removed if not needed.

Proposed Standardized European Table of Contents

| 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 | A summary of the (proposed) authorized uses in the EU |
| 1 | Document E | MRLs |
| 2 | E 1 | Listing of (intended) uses (GAPs) on food and feed crops in EU countries |
| 2 | E 2 | Listing of GAPs on food and feed crops in exporting countries (to EU) |
| 2 | E 3 | Listing of Community MRLs (at Community and/or Member State level) |
| 2 | E 4 | Listing of MRLs in exporting countries (to EU) |
| 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 |

CADDY Standard Table of Content

| Level | Dossier File No | Description |
|----------|------------------|---|
| 1 | Annex IIA | Active substance (Annex IIA) |
| 2 | Document KIIA | Study reports |
| 3 | KIIA 1 | Identity of the active substance |
| 4 | KIIA 1.8 | Method of manufacture of the active substance |
| 4 | KIIA 1.9 | Specification of purity of the active substance in g/kg |
| 4 | KIIA 1.10 | Identity of inactive isomers, impurities and additives |
| 4 | KIIA 1.11 | Analytical profile of batches |
| 3 | KIIA 2 | Physical and chemical properties of the active substance |
| 4 | KIIA 2.1 | Melting-, freezing-, boiling-, decomposition-temperatures |
| 4 | KIIA 2.2 | Relative density |
| 4 | KIIA 2.3 | Vapour pressure & Henry's law constant |
| 4 | KIIA 2.4 | Appearance (physical state, colour & odour) |
| 4 | KIIA 2.5 | Spectra (UV/VIS, IR, NMR, MS) |
| 4 | KIIA 2.6 | Solubility in water including effects of pH |
| 4 | KIIA 2.7 | Solubility in organic solvents |
| 4 | KIIA 2.8 | Partition coefficient n-octanol/water, incl. effects of pH |
| 4 | KIIA 2.9 | Stability and degradation in water |
| 5 | KIIA 2.9.1 | Hydrolysis of pure active substance, rate, metabolites, DT50 |
| 5 | KIIA 2.9.2 | Photolysis, photochemical DT50, metabolites |
| 5 | KIIA 2.9.3 | Photodegradation, quantum yield |
| 5 | KIIA 2.9.4 | Dissociation in water of pure active substance (pKa values) |
| 4 | KIIA 2.10 | Stability in air, photochemical degradation |
| 4 | KIIA 2.11 | Flammability and auto-flammability of active substance |
| 4 | KIIA 2.12 | Flash point of active substance as manufactured |
| 4 | KIIA 2.13 | Explosive properties of active substance as manufactured |
| 4 | KIIA 2.14 | Surface tension of active substance as manufactured |
| 4 | KIIA 2.15 | Oxidizing properties of active substance as manufactured |
| 3 | KIIA 3 | Further information on the active substance |
| 4 | KIIA 3.7 | Safety data sheet |
| 4 | KIIA 3.8 | Procedures for destruction and decontamination |
| 3 | KIIA 4 | Analytical methods |
| 4 | KIIA 4.1 | Methods for the technical active substance |
| 5 | KIIA 4.1.1 | Methods for pure active substance in the techn. a.s. |
| 5 | KIIA 4.1.2 | Methods for impurities and additives in the techn. a.s. |
| 4 | KIIA 4.2 | Methods for the determination of residues |
| 5 | KIIA 4.2.1 | Residues in plants |
| 5 | KIIA 4.2.2 | Residues in soil |
| 5 | KIIA 4.2.3 | Residues in water |
| 5 | KIIA 4.2.4 | Residues in air |
| 5 | KIIA 4.2.5 | Residues in body fluids and tissues |
| 3 | KIIA 5 | Toxicological and metabolism studies on the active substance |
| 4 | KIIA 5.1 | Absorption, distribution, excretion and metabolism in animals |
| 4 | KIIA 5.2 | Acute toxicity |
| 5 | KIIA 5.2.1 | Acute oral toxicity |
| 5 | KIIA 5.2.2 | Acute percutaneous toxicity |

CADDY Standard Table of Content

| Level | Dossier File No | Description |
|-------|-----------------|--|
| 5 | KIIA 5.2.3 | Acute inhalation toxicity |
| 5 | KIIA 5.2.4 | Skin irritation |
| 5 | KIIA 5.2.5 | Eye Irritation |
| 5 | KIIA 5.2.6 | Skin sensitization |
| 4 | KIIA 5.3 | Short-term toxicity |
| 5 | KIIA 5.3.1 | Oral 28-day toxicity |
| 5 | KIIA 5.3.2 | Oral short-term toxicity (90-day and 1 year) |
| 5 | KIIA 5.3.3 | Short term toxicity, other routes |
| 4 | KIIA 5.4 | Genotoxicity |
| 5 | KIIA 5.4.1 | In vitro studies |
| 5 | KIIA 5.4.2 | In vivo studies |
| 5 | KIIA 5.4.3 | In vivo studies in germ cells |
| 4 | KIIA 5.5 | Long-term toxicity and carcinogenicity |
| 4 | KIIA 5.6 | Reproductive toxicity |
| 5 | KIIA 5.6.1 | Multi-generation studies |
| 5 | KIIA 5.6.2 | Developmental toxicity studies |
| 4 | KIIA 5.7 | Delayed neurotoxicity studies |
| 4 | KIIA 5.8 | Supplementary studies |
| 5 | KIIA 5.8.1 | Toxicity studies on metabolites |
| 5 | KIIA 5.8.2 | Supplementary studies on the active substance |
| 4 | KIIA 5.9 | Medical and clinical data |
| 3 | KIIA 6 | Residues and plant metabolism |
| 4 | KIIA 6.0 | Stability of residues |
| 4 | KIIA 6.1 | Metabolism, distribution and expression of residues in plants |
| 4 | KIIA 6.2 | Metabolism, distribution and expression of residues in livestock |
| 4 | KIIA 6.3 | Residue trials (supervised field trials) |
| 4 | KIIA 6.4 | Livestock feeding studies |
| 4 | KIIA 6.5 | Effects of industrial processing and/or household preparation |
| 4 | KIIA 6.6 | Residues in succeeding crops |
| 3 | KIIA 7 | Fate and behaviour in the environment |
| 4 | KIIA 7.1 | Fate and behaviour in soil |
| 5 | KIIA 7.1.1 | Route and rate of degradation in soil |
| 6 | KIIA 7.1.1.1 | Route of degradation in soil |
| 7 | KIIA 7.1.1.1.1 | Aerobic degradation in soil |
| 7 | KIIA 7.1.1.1.2 | Supplementary degradation studies (anaerobic, soil-photolysis) |
| 6 | KIIA 7.1.1.2 | Rate of degradation in soil |
| 7 | KIIA 7.1.1.2.1 | Rate of degradation in soil - laboratory studies |
| 7 | KIIA 7.1.1.2.2 | Rate of degradation in soil - field studies |
| 5 | KIIA 7.1.2 | Adsorption and desorption |
| 5 | KIIA 7.1.3 | Mobility in soil |
| 6 | KIIA 7.1.3.1 | Column leaching studies |
| 6 | KIIA 7.1.3.2 | Aged residue column leaching studies |
| 6 | KIIA 7.1.3.3 | Lysimeter or field leaching studies |
| 4 | KIIA 7.2 | Fate and behaviour in water and air |
| 5 | KIIA 7.2.1 | Route and rate of degradation in water |

CADDY Standard Table of Content

| Level | Dossier File No | Description |
|----------|--------------------|--|
| 6 | KIIA 7.2.1.1 | Rate of hydrolysis of relevant metabolites |
| 6 | KIIA 7.2.1.2 | Phototransformation of relevant metabolites |
| 6 | KIIA 7.2.1.3 | Biodegradability |
| 7 | KIIA 7.2.1.3.1 | Ready biodegradability |
| 7 | KIIA 7.2.1.3.2 | Water/sediment degradation |
| 6 | KIIA 7.2.1.4 | Degradation in the saturated zone |
| 5 | KIIA 7.2.2 | Route and rate of degradation in air |
| 4 | KIIA 7.4 | Monitoring data concerning fate and behaviour |
| 3 | KIIA 8 | Ecotoxicological studies on the active substance |
| 4 | KIIA 8.1 | Effects on birds |
| 5 | KIIA 8.1.1 | Acute oral toxicity to birds |
| 5 | KIIA 8.1.2 | Short-term dietary toxicity to birds |
| 5 | KIIA 8.1.3 | Subchronic toxicity and reproduction |
| 4 | KIIA 8.2 | Effects on aquatic organisms |
| 5 | KIIA 8.2.1 | Acute toxicity to fish |
| 5 | KIIA 8.2.2 | Chronic toxicity, life cycle studies in fish |
| 5 | KIIA 8.2.3 | Bioconcentration potential in fish |
| 5 | KIIA 8.2.4 | Acute toxicity to aquatic invertebrates |
| 5 | KIIA 8.2.5 | Chronic toxicity to aquatic invertebrates |
| 5 | KIIA 8.2.6 | Effects on algal growth and growth |
| 5 | KIIA 8.2.7 | Effects on sediment dwelling organisms |
| 5 | KIIA 8.2.8 | Effects on aquatic plants |
| 4 | KIIA 8.3 | Effects on non-target arthropods |
| 5 | KIIA 8.3.1 | Effects on bees |
| 5 | KIIA 8.3.2 | Effects on other non-target terrestrial arthropods |
| 4 | KIIA 8.4 | Effects on earthworms |
| 4 | KIIA 8.5 | Effects on soil non-target micro-organisms |
| 4 | KIIA 8.6 | Effects on other non-target species (flora and fauna) |
| 4 | KIIA 8.7 | Effects on biological methods for sewage treatment |
| 2 | Document LIIA | Quality check of reports (Tier I) and reference list |
| 3 | LIIA Sec 2 | Analytical methods |
| 3 | LIIA Sec 3 | Toxicological and metabolism studies on the active substance |
| 3 | LIIA Sec 4 | Residues and plant metabolism |
| 3 | LIIA Sec 5 | Fate and behaviour in the environment |
| 3 | LIIA Sec 6 | Ecotoxicological studies on the active substance |
| 2 | Document MIIA | Summary and evaluation (Tier II) |
| 3 | MIIA Sec 1 | Identity, physical and chemical properties and further information |
| 3 | MIIA Sec 2 | Analytical methods |
| 3 | MIIA Sec 3 | Toxicological and metabolism studies on the active substance |
| 3 | MIIA Sec 4 | Residues and plant metabolism |
| 3 | MIIA Sec 5 | Fate and behaviour in the environment |
| 3 | MIIA Sec 6 | Ecotoxicological studies on the active substance |
| 1 | Annex IIIA1 | Plant protection product 1 (Annex IIIA) |
| 2 | Document KIIIA1 | Study reports |
| 3 | KIIIA1 1 | Identity of the plant protection product |

CADDY Standard Table of Content

| Level | Dossier File No | Description |
|-------|-----------------|---|
| 4 | KIIIA1 1.4 | Detailed composition of the product |
| 3 | KIIIA1 2 | Physical, chemical and technical properties of the product |
| 4 | KIIIA1 2.1 | Physical state, colour and odour |
| 4 | KIIIA1 2.2 | Explosive and oxidizing properties |
| 4 | KIIIA1 2.3 | Flash point, flammability, auto-flammability |
| 4 | KIIIA1 2.4 | Acidity or alkalinity and pH |
| 4 | KIIIA1 2.5 | Viscosity and surface tension |
| 4 | KIIIA1 2.6 | Relative density and bulk density |
| 4 | KIIIA1 2.7 | Storage stability and shelf-life |
| 4 | KIIIA1 2.8 | Technical characteristics of the product |
| 4 | KIIIA1 2.9 | Compatibility with other products |
| 4 | KIIIA1 2.10 | Distribution and adherence to seed |
| 3 | KIIIA1 3 | Data on application |
| 4 | KIIIA1 3.9 | Proposed instructions for use |
| 3 | KIIIA1 4 | Further information on the product |
| 4 | KIIIA1 4.1 | Packaging |
| 4 | KIIIA1 4.2 | Procedures for cleaning application equipment and protective clothing |
| 3 | KIIIA1 5 | Analytical methods |
| 4 | KIIIA1 5.1 | Methods for the formulated product |
| 5 | KIIIA1 5.1.1 | Methods for the active substance(s) in the product |
| 4 | KIIIA1 5.2 | Methods for the determination of residues |
| 5 | KIIIA1 5.2.1 | Residues in plants |
| 5 | KIIIA1 5.2.2 | Residues in soil |
| 5 | KIIIA1 5.2.3 | Residues in water |
| 5 | KIIIA1 5.2.4 | Residues in air |
| 5 | KIIIA1 5.2.5 | Residues in body fluids and tissues |
| 3 | KIIIA1 6 | Efficacy data |
| 3 | KIIIA1 7 | Toxicological studies on the product |
| 4 | KIIIA1 7.1 | Acute toxicity |
| 5 | KIIIA1 7.1.1 | Acute oral toxicity |
| 5 | KIIIA1 7.1.2 | Acute percutaneous toxicity |
| 5 | KIIIA1 7.1.3 | Acute inhalation toxicity |
| 5 | KIIIA1 7.1.4 | Skin irritation |
| 5 | KIIIA1 7.1.5 | Eye Irritation |
| 5 | KIIIA1 7.1.6 | Skin sensitization |
| 5 | KIIIA1 7.1.7 | Supplementary studies for combinations of products |
| 4 | KIIIA1 7.2 | Exposure |
| 5 | KIIIA1 7.2.1 | Operator exposure |
| 5 | KIIIA1 7.2.2 | Bystander exposure |
| 5 | KIIIA1 7.2.3 | Worker exposure |
| 4 | KIIIA1 7.3 | Dermal absorption |
| 4 | KIIIA1 7.4 | Toxicological data for individual formulants |
| 3 | KIIIA1 8 | Residues |
| 4 | KIIIA1 8.0 | Stability of residues |
| 4 | KIIIA1 8.1 | Studies on metabolism in plants or livestock |

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| Level | Dossier File No | Description |
|----------|---|--|
| 4 | KIIIA1 8.2 | Residue trials |
| 4 | KIIIA1 8.3 | Livestock feeding studies |
| 4 | KIIIA1 8.4 | Industrial processing/household preparation studies |
| 4 | KIIIA1 8.5 | Residues in succeeding crops |
| 3 | KIIIA1 9 | Fate and behaviour in the environment |
| 4 | KIIIA1 9.1 | Fate and behaviour in soil |
| 5 | KIIIA1 9.1.1 | Rate of degradation in soil |
| 6 | KIIIA1 9.1.1.1 | Laboratory studies |
| 6 | KIIIA1 9.1.1.2 | Field studies |
| 5 | KIIIA1 9.1.2 | Mobility in soil |
| 6 | KIIIA1 9.1.2.1 | Laboratory studies |
| 6 | KIIIA1 9.1.2.2 | Lysimeter, field leaching |
| 5 | KIIIA1 9.1.3 | Predicted environmental concentrations in soil |
| 4 | KIIIA1 9.2 | Fate and behaviour in water |
| 5 | KIIIA1 9.2.1 | Predicted environmental concentrations in groundwater |
| 5 | KIIIA1 9.2.2 | Impact on water treatment procedures |
| 5 | KIIIA1 9.2.3 | Predicted environmental concentrations in surface water |
| 4 | KIIIA1 9.3 | Fate and behaviour in air |
| 3 | KIIIA1 10 | Ecotoxicological studies on the product |
| 4 | KIIIA1 10.1 | Effects on birds |
| 4 | KIIIA1 10.2 | Effect on aquatic organisms |
| 4 | KIIIA1 10.3 | Effects on terrestrial vertebrates other than birds |
| 4 | KIIIA1 10.4 | Effects on bees |
| 4 | KIIIA1 10.5 | Effects on arthropods other than bees |
| 4 | KIIIA1 10.6 | Effects on soil non-target macro-organisms |
| 5 | KIIIA1 10.6.1 | Effects on earthworms |
| 5 | KIIIA1 10.6.2 | Effects on other soil non-target macro-organisms |
| 4 | KIIIA1 10.7 | Effects on soil non-target micro-organisms |
| 4 | KIIIA1 10.8 | Available data from biological primary screening |
| 2 | Document LIIIA1 | Quality checks of reports (Tier I) and reference list Product 1 |
| 3 | LIIIA1 Sec 2 | Analytical methods |
| 3 | LIIIA1 Sec 3 | Toxicological studies on the product |
| 3 | LIIIA1 Sec 4 | Residues |
| 3 | LIIIA1 Sec 5 | Fate and behaviour in the environment |
| 3 | LIIIA1 Sec 6 | Ecotoxicological studies on the product |
| 2 | Document MIIIA1 | Summary and Evaluation (Tier II) Product A |
| 3 | MIIIA1 Sec 1 | Identity, physical and chemical properties and further information |
| 3 | MIIIA1 Sec 2 | Analytical methods |
| 3 | MIIIA1 Sec 3 | Toxicological studies on the product |
| 3 | MIIIA1 Sec 4 | Residues |
| 3 | MIIIA1 Sec 5 | Fate and behaviour in the environment |
| 3 | MIIIA1 Sec 6 | Ecotoxicological studies on the product |
| 3 | MIIIA1 Sec 7 | Efficacy data |
| 1 | Annex IIIA2 | Plant protection product 2 (Annex III) |
| | Replicate Annex III documents K,L,M for product 2 | |

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| Level | Dossier File No | Description |
|--------------|------------------------|--------------------------------|
| 1 | Document N | Overall conclusions (Tier III) |
| 1 | Document O | Initial evaluation forms |
| 2 | OA-J | Documents A-J |
| 2 | OIIA | Active substance |
| 2 | OIIIA | Plant protection product(s) |

3 European Standard TOC in OECD Format

The European Commission has now decided to replace the Rev. 8 dossier format with the OECD dossier format, which also requires an adaptation of the table of contents of the CADDY. 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 Rev. 8 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 to 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 |
| 2 | D 3 | List of supported uses in exporting countries |
| 1 | Document E | MRLs |
| 2 | E 1 | Listing of Community and Member States MRLs |
| 2 | E 2 | Listing of MRLs in exporting countries |
| 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 IIA | Active substance: <AI_NAME>(Annex IIA) |
| 2 | Document KIIA | Individual test and study reports |
| | | |
| 3 | KIIA 1 | Identity of the active substance |
| 4 | KIIA 1.1 | Applicant (name, address, contact, phone and fax numbers) |
| 4 | KIIA 1.2 | Manufacturer(s) (name, address, contact, phone and fax numbers) |
| 4 | KIIA 1.3 | ISO common name proposed or accepted, and synonyms |
| 4 | KIIA 1.4 | Chemical name |
| 4 | KIIA 1.5 | Manufacturer's codes, names and patent status |
| 5 | KIIA 1.5.1 | Manufacturer's code number(s), incl. countries and periods where used |
| 5 | KIIA 1.5.2 | Trade name(s) * |
| 5 | KIIA 1.5.3 | Patent status * |
| 4 | KIIA 1.6 | Existing CAS, CIPAC, EINECS and ELINCS numbers |
| 4 | KIIA 1.7 | Molecular formula, molecular mass and structural formula |
| 4 | KIIA 1.8 | Method of manufacture |

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| Level | Dossier File No | Description |
|-------|-----------------|--|
| 5 | KIIA 1.8.1 | Method of manufacture for each plant |
| 5 | KIIA 1.8.2 | Description of starting materials |
| 4 | KIIA 1.9 | Specification of purity of the active substance |
| 5 | KIIA 1.9.1 | Minimum and/or nominal content (g/kg) of pure active substance |
| 5 | KIIA 1.9.2 | Certified limits of the active substances * |
| 5 | KIIA 1.9.3 | Control product specification form/confidential statement of formula * |
| 4 | KIIA 1.10 | Identity, content and structure of isomers, impurities and additives |
| 5 | KIIA 1.10.1 | Inactive isomers |
| 5 | KIIA 1.10.2 | Impurities and additives |
| 4 | KIIA 1.11 | Batch analysis data |
| 5 | KIIA 1.11.1 | Analytical profile of batches |
| 5 | KIIA 1.11.2 | Results of analyses of batches used in toxicological testing |
| 4 | KIIA 1.12 | Other/special studies |
| 3 | KIIA 2 | Physical and chemical properties of the active substance |
| 4 | KIIA 2.1 | Melting point and boiling point |
| 5 | KIIA 2.1.1 | Melting point, freezing point or solidification point, purified a.s. |
| 5 | KIIA 2.1.2 | Boiling point of purified active substance |
| 5 | KIIA 2.1.3 | Temperature at which decomposition or sublimation occurs |
| 4 | KIIA 2.2 | Relative density of purified active substance |
| 4 | KIIA 2.3 | Vapour pressure and volatility |
| 5 | KIIA 2.3.1 | Vapour pressure of purified active substance |
| 5 | KIIA 2.3.2 | Henry's law constant |
| 4 | KIIA 2.4 | Appearance |
| 5 | KIIA 2.4.1 | Description of the physical state and colour, pur. and techn. a.s. |
| 5 | KIIA 2.4.2 | Description of the odour - purified and technical active substance |
| 4 | KIIA 2.5 | Spectra and molecular extinction at relevant wavelengths |
| 5 | KIIA 2.5.1 | Spectra for purified active substance |
| 6 | KIIA 2.5.1.1 | UV/VIS |
| 6 | KIIA 2.5.1.2 | IR |
| 6 | KIIA 2.5.1.3 | NMR |
| 6 | KIIA 2.5.1.4 | MS |
| 6 | KIIA 2.5.1.5 | Wavelengths at which UV/VIS molecular extinction occurs, max > 290 nm |
| 6 | KIIA 2.5.1.6 | optical purity |
| 5 | KIIA 2.5.2 | Spectra for impurities |
| 6 | KIIA 2.5.2.1 | UV/VIS |
| 6 | KIIA 2.5.2.2 | IR |
| 6 | KIIA 2.5.2.3 | NMR |
| 6 | KIIA 2.5.2.4 | MS |
| 4 | KIIA 2.6 | Solubility of purified active substance in water (pH 4-10) |
| 4 | KIIA 2.7 | Solubility in organic solvents at 15 to 25 °C |
| 4 | KIIA 2.8 | Partition coefficient |
| 5 | KIIA 2.8.1 | n-Octanol/water partition coefficient |
| 5 | KIIA 2.8.2 | Effect of pH (4 to 10) on the n-octanol/water partition coefficient |
| 4 | KIIA 2.9 | Hydrolysis and photolysis |
| 5 | KIIA 2.9.1 | Hydrolysis rate at pH 4, 7 and 9 under sterile and dark conditions |
| 5 | KIIA 2.9.2 | Direct phototransformation in sterile water using artificial light |
| 5 | KIIA 2.9.3 | Quantum yield of direct phototransformation |

CADDY Standard Table of Content

| Level | Dossier File No | Description |
|-------|-----------------|--|
| 5 | KIIA 2.9.4 | Lifetime in the top layer of aqueous systems (calculated and real) |
| 5 | KIIA 2.9.5 | Dissociation in water of purified active substance |
| 4 | KIIA 2.10 | Estimated photochemical oxidative degradation |
| 4 | KIIA 2.11 | Flammability including auto-flammability |
| 5 | KIIA 2.11.1 | Flammability of the active substance as manufactured |
| 5 | KIIA 2.11.2 | Auto-flammability of the active substance as manufactured |
| 4 | KIIA 2.12 | Flash point of the active substance as manufactured |
| 4 | KIIA 2.13 | Explosive properties of the active substance as manufactured |
| 4 | KIIA 2.14 | Surface tension of the active substance as manufactured |
| 4 | KIIA 2.15 | Oxidizing properties of the active substance as manufactured |
| 4 | KIIA 2.16 | pH * |
| 4 | KIIA 2.17 | Stability * |
| 5 | KIIA 2.17.1 | Storage stability * |
| 5 | KIIA 2.17.2 | Stability (temperature, metals) *) |
| 4 | KIIA 2.18 | Other/special studies |
| 3 | KIIA 3 | Further Information on the active substance |
| 4 | KIIA 3.1 | Function e.g. fungicide |
| 4 | KIIA 3.2 | Effects on harmful organisms e.g. contact action |
| 5 | KIIA 3.2.1 | Nature of the effects on harmful organisms |
| 5 | KIIA 3.2.2 | Translocation in plants |
| 4 | KIIA 3.3 | Fields of use e.g. forestry |
| 4 | KIIA 3.4 | Harmful organisms controlled and crops / products protected or treated |
| 5 | KIIA 3.4.1 | Details of existing and intended uses |
| 5 | KIIA 3.4.2 | Details of harmful organisms against which protection is afforded |
| 5 | KIIA 3.4.3 | Effects achieved e.g. sprout suppression |
| 4 | KIIA 3.5 | Mode of action |
| 5 | KIIA 3.5.1 | Mode of action, mechanism(s) and pathway(s) involved |
| 5 | KIIA 3.5.2 | Details of active metabolites and degradation products |
| 5 | KIIA 3.5.3 | Formation of active metabolites and degradation products |
| 4 | KIIA 3.6 | Possible development of resistance or cross-resistance |
| 4 | KIIA 3.7 | A material safety data sheet for the active substance |
| 4 | KIIA 3.8 | Procedures for destruction and decontamination |
| 5 | KIIA 3.8.1 | Pyrolytic behaviour under controlled conditions at 800 °C |
| 5 | KIIA 3.8.2 | Detailed instructions for safe disposal |
| 5 | KIIA 3.8.3 | Methods other than controlled incineration for disposal |
| 4 | KIIA 3.9 | Procedures for decontamination of water in case of an accident |
| 4 | KIIA 3.10 | Other/special studies |
| 3 | KIIA 4 | Analytical Methods and Validation |
| 4 | KIIA 4.1 | Analytical standards and samples |
| 5 | KIIA 4.1.1 | Analytical standards for pure active substance |
| 5 | KIIA 4.1.2 | Samples of the active substance as manufactured |
| 5 | KIIA 4.1.3 | Analytical standards for relevant metabolites and other components |
| 5 | KIIA 4.1.4 | Samples of reference substances for relevant impurities |
| 4 | KIIA 4.2 | Methods for the analysis of the active substance as manufactured |
| 5 | KIIA 4.2.1 | Methods for the analysis of the active substance as manufactured |

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| Level | Dossier File No | Description |
|-------|-----------------|--|
| 5 | KIIA 4.2.2 | Applicability of existing CIPAC methods |
| 5 | KIIA 4.2.3 | Description of analytical methods for the determination of impurities |
| 5 | KIIA 4.2.4 | Description of analytical methods for the determination of additives |
| 5 | KIIA 4.2.5 | Enforcement analytical methodology * |
| 5 | KIIA 4.2.6 | Inter-Laboratory analytical methodology validation * |
| 5 | KIIA 4.2.7 | Storage stability of working solutions in analytical methodology * |
| 4 | KIIA 4.3 | Description of analytical methods for the determination of residues |
| 4 | KIIA 4.4 | Description of methods for analysis of soil (parent and metabolites) |
| 4 | KIIA 4.5 | Description of methods of analysis of water (parent and metabolites) |
| 4 | KIIA 4.6 | Method for determining pesticides in sediment * |
| 4 | KIIA 4.7 | Methods for analysis of air (parent and metabolites) |
| 4 | KIIA 4.8 | Methods for analysis of body fluid/tissues (parent and metabolites) |
| 4 | KIIA 4.9 | Other/special studies |
| 3 | KIIA 5 | Toxicological and Toxicokinetic Studies on the Active Substance |
| 4 | KIIA 5.1 | Absorption, distribution, excretion and metabolism in mammals |
| 5 | KIIA 5.1.1 | Toxicokinetic studies - Single dose, oral route, in rats |
| 5 | KIIA 5.1.2 | Toxicokinetic studies - Second single dose, oral route, in rats |
| 5 | KIIA 5.1.3 | Toxicokinetic studies - Repeated dose, oral route, in rats |
| 4 | KIIA 5.2 | Acute toxicity |
| 5 | KIIA 5.2.1 | Acute oral toxicity |
| 5 | KIIA 5.2.2 | Acute percutaneous toxicity |
| 5 | KIIA 5.2.3 | Acute inhalation toxicity |
| 5 | KIIA 5.2.4 | Skin irritation |
| 5 | KIIA 5.2.5 | Eye Irritation |
| 5 | KIIA 5.2.6 | Skin sensitization |
| 5 | KIIA 5.2.7 | Potential/interactions of multiple active substances or products * |
| 4 | KIIA 5.3 | Short-term toxicity |
| 5 | KIIA 5.3.1 | Oral 28-day toxicity |
| 5 | KIIA 5.3.2 | Oral 90-day toxicity (rodents) |
| 5 | KIIA 5.3.3 | Oral 90-day toxicity (dog) |
| 5 | KIIA 5.3.4 | Oral 1 year toxicity (dog) |
| 5 | KIIA 5.3.5 | 28-day inhalation toxicity (rodents) |
| 5 | KIIA 5.3.6 | 90-day inhalation toxicity (rodents) |
| 5 | KIIA 5.3.7 | Percutaneous 28-day toxicity (rodents) |
| 5 | KIIA 5.3.8 | Percutaneous 90-day toxicity (rodents) |
| 4 | KIIA 5.4 | Genotoxicity |
| 5 | KIIA 5.4.1 | <i>In vitro</i> genotoxicity - Bacterial assay for gene mutation |
| 5 | KIIA 5.4.2 | <i>In vitro</i> genotoxicity - Test for clastogenicity in mammalian cells |
| 5 | KIIA 5.4.3 | <i>In vitro</i> genotoxicity - Test for gene mutation in mammalian cells |
| 5 | KIIA 5.4.4 | <i>In vivo</i> genotoxicity (somatic cells) - Bone marrow or micronucleus |
| 5 | KIIA 5.4.5 | <i>In vivo</i> genotoxicity (somatic cells) - DNA repair or mouse spot tests |
| 5 | KIIA 5.4.6 | <i>In vivo</i> studies in germ cells |
| 4 | KIIA 5.5 | Long-term toxicity and carcinogenicity |
| 5 | KIIA 5.5.1 | Long-term (2 years) oral toxicity in the rat |
| 5 | KIIA 5.5.2 | Carcinogenicity study in the rat |
| 5 | KIIA 5.5.3 | Carcinogenicity study in the mouse |
| 5 | KIIA 5.5.4 | Mechanism of action and supporting data |

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| Level | Dossier File No | Description |
|-------|-----------------|---|
| 4 | KIIA 5.6 | Reproductive toxicity |
| 5 | KIIA 5.6.1 | Two generation reproductive toxicity in the rat |
| 5 | KIIA 5.6.2 | Separate male and female studies |
| 5 | KIIA 5.6.3 | Three segment designs |
| 5 | KIIA 5.6.4 | Dominant lethal assay for the male fertility |
| 5 | KIIA 5.6.5 | Cross-matings of treated males with untreated females and <i>vice versa</i> |
| 5 | KIIA 5.6.6 | Effects on spermatogenesis |
| 5 | KIIA 5.6.7 | Effects on oogenesis |
| 5 | KIIA 5.6.8 | Sperm motility, mobility and morphology |
| 5 | KIIA 5.6.9 | Investigation of hormonal activity |
| 5 | KIIA 5.6.10 | Teratogenicity test by the oral route in the rat |
| 5 | KIIA 5.6.11 | Teratogenicity test by the oral route in the rabbit |
| 4 | KIIA 5.7 | Neurotoxicity * |
| 5 | KIIA 5.7.1 | Acute neurotoxicity - rat |
| 5 | KIIA 5.7.2 | Delayed neurotoxicity following acute exposure |
| 5 | KIIA 5.7.3 | 28-day delayed neurotoxicity |
| 5 | KIIA 5.7.4 | Subchronic neurotoxicity - rat - 90-day |
| 5 | KIIA 5.7.5 | Postnatal developmental neurotoxicity |
| 4 | KIIA 5.8 | Toxicity studies on metabolites |
| 4 | KIIA 5.9 | Medical and clinical data |
| 5 | KIIA 5.9.1 | Report on medical surveillance on manufacturing plant personnel |
| 5 | KIIA 5.9.2 | Report on clinical cases and poisoning incidents |
| 5 | KIIA 5.9.3 | Observations on general population exposure & epidemiological studies |
| 5 | KIIA 5.9.4 | Clinical signs and symptoms of poisoning and details of clinical tests |
| 5 | KIIA 5.9.5 | First aid measures |
| 5 | KIIA 5.9.6 | Therapeutic regimes |
| 5 | KIIA 5.9.7 | Expected effects & duration of poisoning as a function of exposure |
| 5 | KIIA 5.9.8 | Effects & duration of poisoning as a function of time |
| 5 | KIIA 5.9.9 | Dermal penetration |
| 4 | KIIA 5.10 | Other/special studies |
| 4 | KIIA 5.11 | Summary of mammalian toxicity and overall evaluation |
| 3 | KIIA 6 | Metabolism and Residues Data |
| 4 | KIIA 6.1 | Stability of residues |
| 5 | KIIA 6.1.1 | Stability of residues during storage of samples |
| 5 | KIIA 6.1.2 | Stability of residues in samples extracts |
| 4 | KIIA 6.2 | Metabolism, distribution and expression of residues |
| 5 | KIIA 6.2.1 | In plants, at least three crops from three different crop categories |
| 5 | KIIA 6.2.2 | Poultry |
| 5 | KIIA 6.2.3 | Lactating ruminants (goat or cow) |
| 5 | KIIA 6.2.4 | Pigs |
| 5 | KIIA 6.2.5 | Nature of residue in fish * |
| 5 | KIIA 6.2.6 | Chemical identity * |
| 4 | KIIA 6.3 | Residue trials (supervised field trials) |
| 5 | KIIA 6.3.1 | Crop 1 (e.g. wheat) |
| 5 | KIIA 6.3.2 | Crop 2 (e.g. oilseed rape) |
| 5 | KIIA 6.3.3 | Crop 3 |
| 5 | KIIA 6.3.4 | Crop 4, etc. |

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| Level | Dossier File No | Description |
|-------|-----------------|---|
| 4 | KIIA 6.4 | Livestock feeding studies |
| 5 | KIIA 6.4.1 | Poultry |
| 5 | KIIA 6.4.2 | Lactating ruminants (goat or cow) |
| 5 | KIIA 6.4.3 | Pigs |
| 5 | KIIA 6.4.4 | Fish * |
| 4 | KIIA 6.5 | Effects of industrial processing and/or household preparation on |
| 5 | KIIA 6.5.1 | The nature of residue |
| 5 | KIIA 6.5.2 | Distribution of the residue in peel/pulp |
| 5 | KIIA 6.5.3 | Residue levels - balance studies on set of representative processes |
| 5 | KIIA 6.5.4 | Residue levels - follow-up studies: concentration or dilution factors |
| 4 | KIIA 6.6 | Residues in succeeding crops |
| 5 | KIIA 6.6.1 | Theoretical consideration of the nature and level of the residue |
| 5 | KIIA 6.6.2 | Metabolism and distribution studies on representative crops |
| 5 | KIIA 6.6.3 | Field trials on representative crops |
| 4 | KIIA 6.7 | Proposed residue definition and maximum residue levels |
| 5 | KIIA 6.7.1 | Proposed residue definition |
| 5 | KIIA 6.7.2 | Proposed maximum residue levels (MRLs) and justification |
| 4 | KIIA 6.8 | Proposed pre-harvest intervals, re-entry or withholding periods |
| 5 | KIIA 6.8.1 | Pre-harvest interval (in days) for each relevant crop |
| 5 | KIIA 6.8.2 | Re-entry period (in days) for livestock, to areas to be grazed |
| 5 | KIIA 6.8.3 | Re-entry period for man to crops, buildings or spaces treated |
| 5 | KIIA 6.8.4 | Withholding period (in days) for animals feedingstuffs |
| 5 | KIIA 6.8.5 | Waiting period between last application and sowing or planting |
| 5 | KIIA 6.8.6 | Waiting period between application and handling treated products |
| 5 | KIIA 6.8.7 | Waiting period before sowing/planting succeeding crops |
| 4 | KIIA 6.9 | Estimation of exposure through diet and other means |
| 5 | KIIA 6.9.1 | TMDI calculations |
| 5 | KIIA 6.9.2 | NEDI calculations |
| 5 | KIIA 6.9.3 | NESTI calculations |
| 4 | KIIA 6.10 | Other/special studies |
| 4 | KIIA 6.11 | Summary and evaluation of residue behaviour and reasonable grounds |
| 5 | KIIA 6.11.1 | Summary and evaluation of residue behaviour |
| 5 | KIIA 6.11.2 | Reasonable grounds in support of the petition * |
| 3 | KIIA 7 | Fate and Behaviour in the Environment |
| 4 | KIIA 7.1 | Route of degradation in soil - laboratory studies |
| 5 | KIIA 7.1.1 | Aerobic degradation |
| 5 | KIIA 7.1.2 | Anaerobic degradation |
| 5 | KIIA 7.1.3 | Soil photolysis |
| 4 | KIIA 7.2 | Rate of degradation in soil(s) - laboratory studies |
| 5 | KIIA 7.2.1 | Aerobic degradation of the active substance in soils at 20 °C |
| 5 | KIIA 7.2.2 | Aerobic degradation of the active substance in soils at 10 °C |
| 5 | KIIA 7.2.3 | Aerobic degradation of relevant metabolites in soils at 20 °C |
| 5 | KIIA 7.2.4 | Anaerobic degradation of the active substance in soil |
| 5 | KIIA 7.2.5 | Anaerobic degradation of relevant metabolites in soil |
| 4 | KIIA 7.3 | Field studies |
| 5 | KIIA 7.3.1 | Soil dissipation testing in a range of representative soils |
| 5 | KIIA 7.3.2 | Soil residue testing |

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| Level | Dossier File No | Description |
|-------|-----------------|--|
| 5 | KIIA 7.3.3 | Soil accumulation testing on relevant soils |
| 4 | KIIA 7.4 | Mobility studies |
| 5 | KIIA 7.4.1 | Adsorption and desorption of the active substance |
| 5 | KIIA 7.4.2 | Adsorption & desorption of rel. metabolites, degr. & react. products |
| 5 | KIIA 7.4.3 | Column leaching studies with the active substance |
| 5 | KIIA 7.4.4 | Column leaching studies rel. metabolites, degr. & react. products |
| 5 | KIIA 7.4.5 | Aged residue column leaching |
| 5 | KIIA 7.4.6 | Leaching (TLC) * |
| 5 | KIIA 7.4.7 | Lysimeter studies |
| 5 | KIIA 7.4.8 | Field leaching studies |
| 5 | KIIA 7.4.9 | Volatility - laboratory study |
| 4 | KIIA 7.5 | Hydrolysis rate of relevant metabolites at pH values 4, 7 and 9 |
| 4 | KIIA 7.6 | Direct phototransformation of relevant metabolites in water |
| 4 | KIIA 7.7 | Ready biodegradability of the active substance |
| 4 | KIIA 7.8 | Degradation in aquatic systems |
| 5 | KIIA 7.8.1 | Aerobic biodegradation in aquatic systems * |
| 5 | KIIA 7.8.2 | Anaerobic biodegradation in aquatic systems * |
| 5 | KIIA 7.8.3 | Water/sediment studies |
| 4 | KIIA 7.9 | Degradation in the saturated zone |
| 4 | KIIA 7.10 | Rate and route of degradation in air |
| 4 | KIIA 7.11 | Definition of the residue |
| 4 | KIIA 7.12 | Monitoring data concerning fate and behaviour |
| 4 | KIIA 7.13 | Other/special studies |
| 3 | KIIA 8 | Ecotoxicological Studies on the Active Substance |
| 4 | KIIA 8.1 | Avian toxicity |
| 5 | KIIA 8.1.1 | Acute oral toxicity to quail species, mallard duck or other bird |
| 5 | KIIA 8.1.2 | Avian dietary toxicity (5-day) test in quail species or mallard duck |
| 5 | KIIA 8.1.3 | Avian dietary toxicity (5-day) test in a second unrelated species |
| 5 | KIIA 8.1.4 | Subchronic and reproductive toxicity to birds |
| 4 | KIIA 8.2 | Fish toxicity |
| 5 | KIIA 8.2.1 | Acute toxicity of the active substance to fish |
| 6 | KIIA 8.2.1.1 | Rainbow trout (<i>oncorhynchus mykiss</i>) |
| 6 | KIIA 8.2.1.2 | Warm water fish species |
| 6 | KIIA 8.2.1.3 | Acute toxicity of metabolites to the more sensitive of fish species |
| 5 | KIIA 8.2.2 | Chronic toxicity to fish |
| 5 | KIIA 8.2.3 | Chronic toxicity (28 day exposure) to juvenile fish |
| 5 | KIIA 8.2.4 | Fish early life stage toxicity test |
| 5 | KIIA 8.2.5 | Fish life cycle test |
| 5 | KIIA 8.2.6 | Bioconcentration potential in fish |
| 6 | KIIA 8.2.6.1 | Bioconcentration potential of the active substance in fish |
| 6 | KIIA 8.2.6.2 | Bioconcentration potential of the metabolites, degr. & react. products |
| 5 | KIIA 8.2.7 | Aquatic bioavailability/ biomagnification / depuration * |
| 4 | KIIA 8.3 | Toxicity to aquatic species other than fish, aquatic field tests |
| 5 | KIIA 8.3.1 | Acute toxicity to aquatic invertebrates |
| 6 | KIIA 8.3.1.1 | Acute toxicity (24 and 48 hour) for <i>Daphnia</i> preferably (<i>Daphnia magna</i>) |
| 6 | KIIA 8.3.1.2 | Acute toxicity (24/48 h) for representative species of aquatic insects |
| 6 | KIIA 8.3.1.3 | Acute toxicity for representative species of aquatic crustaceans |

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| Level | Dossier File No | Description |
|-------|-----------------|--|
| 6 | KIIA 8.3.1.4 | Acute toxicity for repr. species of aquatic gastropod molluscs |
| 5 | KIIA 8.3.2 | Chronic toxicity to aquatic invertebrates |
| 6 | KIIA 8.3.2.1 | Chronic toxicity in Daphnia magna (21-day) |
| 6 | KIIA 8.3.2.2 | Chronic toxicity for representative species of aquatic insects |
| 6 | KIIA 8.3.2.3 | Chronic toxicity for repr. species of aquatic gastropod molluscs |
| 5 | KIIA 8.3.3 | Aquatic field testing * |
| 4 | KIIA 8.4 | Effects on algal growth and growth rate (2 species) |
| 4 | KIIA 8.5 | Effects on sediment dwelling organisms |
| 5 | KIIA 8.5.1 | Acute test |
| 5 | KIIA 8.5.2 | Chronic test |
| 4 | KIIA 8.6 | Effects on aquatic plants |
| 4 | KIIA 8.7 | Effects on bees |
| 5 | KIIA 8.7.1 | Acute oral toxicity |
| 5 | KIIA 8.7.2 | Acute contact toxicity |
| 5 | KIIA 8.7.3 | Toxicity of residues on foliage to honey bees * |
| 5 | KIIA 8.7.4 | Bee brood feeding test |
| 4 | KIIA 8.8 | Effects on non-target terrestrial arthropods |
| 5 | KIIA 8.8.1 | Effects on non-target terrestrial arthropods, artificial substrates |
| 6 | KIIA 8.8.1.1 | Parasitoid |
| 6 | KIIA 8.8.1.2 | Predatory mites |
| 6 | KIIA 8.8.1.3 | Ground dwelling predatory species |
| 6 | KIIA 8.8.1.4 | Foliage dwelling predatory species |
| 5 | KIIA 8.8.2 | Effects on non-target terrestrial arthropods in lab/semi-field test |
| 6 | KIIA 8.8.2.1 | Parasitoid |
| 6 | KIIA 8.8.2.2 | Predatory mites |
| 6 | KIIA 8.8.2.3 | Ground dwelling predatory species |
| 6 | KIIA 8.8.2.4 | Foliage dwelling predatory species |
| 6 | KIIA 8.8.2.5 | Other terrestrial invertebrates |
| 4 | KIIA 8.9 | Effects on earthworms |
| 5 | KIIA 8.9.1 | Acute toxicity to earthworms |
| 5 | KIIA 8.9.2 | Sublethal effects on earthworms |
| 4 | KIIA 8.10 | Effects on soil microbial activity |
| 5 | KIIA 8.10.1 | Nitrogen transformation |
| 5 | KIIA 8.10.2 | Carbon mineralization |
| 5 | KIIA 8.10.3 | Rates of recovery following treatment |
| 4 | KIIA 8.11 | Effects on marine and estuarine organisms * |
| 5 | KIIA 8.11.1 | Marine or estuarine organisms acute toxicity LC50/EC50 * |
| 5 | KIIA 8.11.2 | Marine/Estuarine fish - salinity challenge * |
| 4 | KIIA 8.12 | Effects on terrestrial vascular plants |
| 4 | KIIA 8.13 | Effects on terr. vertebrates other than birds / wild mammal toxicity * |
| 4 | KIIA 8.14 | Effects on other non-target organisms believed to be at risk |
| 5 | KIIA 8.14.1 | Summary of preliminary data: biological activity & dose range finding |
| 5 | KIIA 8.14.2 | Assessment of relevance to potential impact on non-target species |
| 4 | KIIA 8.15 | Effects on biological methods for sewage treatment |
| 4 | KIIA 8.16 | Other/special studies |
| 5 | KIIA 8.16.1 | Other/special studies - laboratory studies |
| 5 | KIIA 8.16.2 | Other/special studies - field studies |
| 4 | KIIA 8.17 | Summary and evaluation of points IIA 7 and IIA 8.1 to 8.16 |

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| Level | Dossier File No | Description |
|----------|--------------------|--|
| 3 | KIIA 9 | Proposals for classification and labelling of the a.s. |
| 2 | Document LIIA | Quality check of reports (Tier I) and reference lists |
| 3 | LIIA Sec 1 | Identity, physical and chemical properties and further information |
| 3 | LIIA Sec 2 | Analytical methods |
| 3 | LIIA Sec 3 | Toxicological and metabolism studies on the active substance |
| 3 | LIIA Sec 4 | Residues and plant metabolism |
| 3 | LIIA Sec 5 | Fate and behaviour in the environment |
| 3 | LIIA Sec 6 | Ecotoxicological studies on the active substance |
| 2 | Document MIIA | Summary and evaluation (Tier II) |
| 3 | MIIA Sec 1 | Identity, physical and chemical properties and further information |
| 3 | MIIA Sec 2 | Analytical methods |
| 3 | MIIA Sec 3 | Toxicological and metabolism studies on the active substance |
| 3 | MIIA Sec 4 | Residues and plant metabolism |
| 3 | MIIA Sec 5 | Fate and behaviour in the environment |
| 3 | MIIA Sec 6 | Ecotoxicological studies on the active substance |
| 1 | Annex IIIA1 | Plant protection product <PRO_NAME> (Annex IIIA) |
| 2 | Document KIIIA1 | Individual test and study reports |
| 3 | KIIIA1 1 | Identity of the Plant Protection Product |
| 4 | KIIIA1 1.1 | Applicant |
| 4 | KIIIA1 1.2 | Manufacturer of preparation and a.s., purity of a.s. |
| 5 | KIIIA1 1.2.1 | Manufacturer(s) of the preparation |
| 5 | KIIIA1 1.2.2 | Manufacturer(s) of the active substance |
| 5 | KIIIA1 1.2.3 | Statement of purity of the active substance |
| 4 | KIIIA1 1.3 | Trade name or proposed trade name and manufacturers code number(s) |
| 4 | KIIIA1 1.4 | Detailed composition of the preparation |
| 5 | KIIIA1 1.4.1 | Contents of techn. active substance, pure active substance, formulants |
| 5 | KIIIA1 1.4.2 | Certified limits of each component * |
| 5 | KIIIA1 1.4.3 | Names and codes identifying the active substance |
| 6 | KIIIA1 1.4.3.1 | ISO common name proposed or accepted for a.s. and synonyms |
| 6 | KIIIA1 1.4.3.2 | Existing CIPAC, EINECS and ELINCS numbers fro the active substance |
| 6 | KIIIA1 1.4.3.3 | Salt, ester, anion or cation present for each active substance |
| 5 | KIIIA1 1.4.4 | Chemical name, CIPAC, EINECS, ELINCS numbers and function of formulant |
| 5 | KIIIA1 1.4.5 | Formulation process |
| 6 | KIIIA1 1.4.5.1 | Description of formulation process * |
| 6 | KIIIA1 1.4.5.2 | Discussion of the formulation of impurities of toxicological concern * |
| 4 | KIIIA1 1.5 | Type of preparation (formulation) and code |
| 4 | KIIIA1 1.6 | Function |
| 4 | KIIIA1 1.7 | Other/special studies |
| 3 | KIIIA1 2 | Physical, Chemical and Technical Properties of the Product |
| 4 | KIIIA1 2.1 | Physical state of the preparation and its colour and odour |
| 4 | KIIIA1 2.2 | Explosivity and oxidizing properties |
| 5 | KIIIA1 2.2.1 | Explosive properties of the preparation |

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| Level | Dossier File No | Description |
|-------|-----------------|--|
| 5 | KIIIA1 2.2.2 | Oxidizing properties of the preparation |
| 4 | KIIIA1 2.3 | Flash point & other indication of flammability or spontaneous ignition |
| 5 | KIIIA1 2.3.1 | The flash point of the preparation |
| 5 | KIIIA1 2.3.2 | The flammability of the preparation |
| 5 | KIIIA1 2.3.3 | The auto-flammability of the preparation |
| 4 | KIIIA1 2.4 | Acidity/alkalinity and if necessary pH value |
| 5 | KIIIA1 2.4.1 | Acidity or alkalinity and pH value |
| 5 | KIIIA1 2.4.2 | pH of a 1% aqueous dilution, emulsion or dispersion |
| 4 | KIIIA1 2.5 | Viscosity and surface tension |
| 5 | KIIIA1 2.5.1 | Kinematic viscosity of the preparation |
| 5 | KIIIA1 2.5.2 | Viscosity of the preparation and details of the test conditions |
| 5 | KIIIA1 2.5.3 | Surface tension of the preparation |
| 4 | KIIIA1 2.6 | Relative density and bulk density |
| 5 | KIIIA1 2.6.1 | Relative density of the preparation |
| 5 | KIIIA1 2.6.2 | Bulk or tap density of the preparation |
| 4 | KIIIA1 2.7 | Storage stability and shelf-life |
| 5 | KIIIA1 2.7.1 | Stability after storage for 14 days at 54°C |
| 5 | KIIIA1 2.7.2 | Stability after storage for other periods and/or temperature |
| 5 | KIIIA1 2.7.3 | Minimum content after heat stability testing |
| 5 | KIIIA1 2.7.4 | Effect of low temperature on stability |
| 5 | KIIIA1 2.7.5 | Shelf life following storage at ambient temperature |
| 5 | KIIIA1 2.7.6 | Shelf life in months |
| 4 | KIIIA1 2.8 | Technical characteristics of the product |
| 5 | KIIIA1 2.8.1 | Wettability |
| 5 | KIIIA1 2.8.2 | Persistent foaming |
| 5 | KIIIA1 2.8.3 | Suspensibility and suspension stability |
| 6 | KIIIA1 2.8.3.1 | Suspensibility |
| 6 | KIIIA1 2.8.3.2 | Spontaneity of dispersion |
| 5 | KIIIA1 2.8.4 | Dilution stability |
| 5 | KIIIA1 2.8.5 | Sieve test |
| 6 | KIIIA1 2.8.5.1 | Dry sieve test |
| 6 | KIIIA1 2.8.5.2 | Wet sieve test |
| 5 | KIIIA1 2.8.6 | Particle size distribution |
| 6 | KIIIA1 2.8.6.1 | Size distribution of particles |
| 6 | KIIIA1 2.8.6.2 | Nominal size range of granules |
| 6 | KIIIA1 2.8.6.3 | Dust content |
| 6 | KIIIA1 2.8.6.4 | Particle size of dust |
| 6 | KIIIA1 2.8.6.5 | Friability and attrition characteristics of granules |
| 5 | KIIIA1 2.8.7 | Emulsion characteristics |
| 6 | KIIIA1 2.8.7.1 | Emulsifiability |
| 6 | KIIIA1 2.8.7.2 | Emulsion stability |
| 6 | KIIIA1 2.8.7.3 | Re-emulsifiability |
| 6 | KIIIA1 2.8.7.4 | Stability of dilute emulsions |
| 6 | KIIIA1 2.8.7.5 | Stability of emulsions |
| 5 | KIIIA1 2.8.8 | Flowability, pourability and dustability |
| 6 | KIIIA1 2.8.8.1 | Flowability |
| 6 | KIIIA1 2.8.8.2 | Pourability (including rinsed residue) |
| 6 | KIIIA1 2.8.8.3 | Dustability following accelerate storage |

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| Level | Dossier File No | Description |
|-------|-----------------|---|
| 4 | KIIIA1 2.9 | Physical compatibility with other products |
| 5 | KIIIA1 2.9.1 | Physical compatibility of tank mixes |
| 5 | KIIIA1 2.9.2 | Chemical compatibility of tank mixes |
| 4 | KIIIA1 2.10 | Distribution and adherence to seed |
| 5 | KIIIA1 2.10.1 | Distribution (seed treatment) |
| 5 | KIIIA1 2.10.2 | Adhesion (seed treatment) |
| 4 | KIIIA1 2.11 | Miscibility * |
| 4 | KIIIA1 2.12 | Dielectric breakdown voltage * |
| 4 | KIIIA1 2.13 | Corrosion characteristics * |
| 4 | KIIIA1 2.14 | Container Material * |
| 4 | KIIIA1 2.15 | Other/special studies |
| 4 | KIIIA1 2.16 | Summary and evaluation of points 2.1 to 2.15 |
| 3 | KIIIA1 3 | Data on Application |
| 4 | KIIIA1 3.1 | Fields of use e.g. forestry |
| 4 | KIIIA1 3.2 | Nature of the effects on harmful organisms e.g. contact action |
| 4 | KIIIA1 3.3 | Details of intended use |
| 5 | KIIIA1 3.3.1 | Details of existing and intended uses |
| 5 | KIIIA1 3.3.2 | Details of harmful organisms against which protection is afforded |
| 5 | KIIIA1 3.3.3 | Effects achieved e.g. sprout suppression |
| 4 | KIIIA1 3.4 | Rate of application per unit treated |
| 4 | KIIIA1 3.5 | Concentration of active substance in material used |
| 4 | KIIIA1 3.6 | Description of the method of application |
| 4 | KIIIA1 3.7 | Number and timing of applications and duration of protection |
| 5 | KIIIA1 3.7.1 | Maximum number of applications and their timing |
| 5 | KIIIA1 3.7.2 | Growth stages of the crop or plants to be protected |
| 5 | KIIIA1 3.7.3 | Development stages of the harmful organism concerned |
| 5 | KIIIA1 3.7.4 | Duration of protection afforded by each application |
| 5 | KIIIA1 3.7.5 | Duration of protection afforded by the maximum number of applications |
| 4 | KIIIA1 3.8 | Necessary waiting periods or other precautions |
| 5 | KIIIA1 3.8.1 | Minimum waiting periods |
| 5 | KIIIA1 3.8.2 | Limitations on choice of succeeding crops |
| 5 | KIIIA1 3.8.3 | Description of damage to rotational crops |
| 4 | KIIIA1 3.9 | Proposed instructions for use as printed, or to be printed, on labels |
| 4 | KIIIA1 3.10 | Other/special studies |
| 3 | KIIIA1 4 | Further Information on the Product |
| 4 | KIIIA1 4.1 | Packaging and compatibility with the preparation |
| 5 | KIIIA1 4.1.1 | Description and specification of the packaging |
| 5 | KIIIA1 4.1.2 | Suitability of the packaging and closures |
| 5 | KIIIA1 4.1.3 | Resistance of the packaging material to its contents |
| 4 | KIIIA1 4.2 | Procedures for cleaning application equipment |
| 5 | KIIIA1 4.2.1 | Procedures for cleaning application equipment and protective clothing |
| 5 | KIIIA1 4.2.2 | Effectiveness of the cleaning procedures |
| 4 | KIIIA1 4.3 | Re-entry periods to protect man, livestock and the environment |
| 5 | KIIIA1 4.3.1 | Pre-harvest interval (in days) for each relevant crop |
| 5 | KIIIA1 4.3.2 | Re-entry period (in days) for livestock, to areas to be grazed |
| 5 | KIIIA1 4.3.3 | Re-entry period for man to crops, buildings or spaces treated |

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| Level | Dossier File No | Description |
|-------|-----------------|--|
| 5 | KIIIA1 4.3.4 | Withholding period (in days) for animal feedingstuffs |
| 5 | KIIIA1 4.3.5 | Waiting period between application and handling treated products |
| 5 | KIIIA1 4.3.6 | Waiting period for sowing or planting succeeding crops |
| 5 | KIIIA1 4.3.7 | Conditions under which the preparation may or may not be used |
| 4 | KIIIA1 4.4 | Risks from recommended methods, precautions & procedures to minimize |
| 5 | KIIIA1 4.4.1 | Warehouse storage |
| 5 | KIIIA1 4.4.2 | User level storage |
| 5 | KIIIA1 4.4.3 | Transport |
| 5 | KIIIA1 4.4.4 | Fire |
| 5 | KIIIA1 4.4.5 | Protective clothing and equipment - Nature |
| 5 | KIIIA1 4.4.6 | Protective clothing and equipment - characteristics |
| 5 | KIIIA1 4.4.7 | Suitability and effectiveness of the protective clothing and equipment |
| 5 | KIIIA1 4.4.8 | Procedures to minimize the generation of waste |
| 5 | KIIIA1 4.4.9 | Information on likely combustion products in the event of fire |
| 4 | KIIIA1 4.5 | Detailed procedures in the event of an accident during transport |
| 5 | KIIIA1 4.5.1 | Containment of spillages |
| 5 | KIIIA1 4.5.2 | Decontamination of areas, vehicles and buildings |
| 5 | KIIIA1 4.5.3 | Disposal of damaged packaging, adsorbents and other material |
| 5 | KIIIA1 4.5.4 | Protection of emergency workers and bystanders |
| 5 | KIIIA1 4.5.5 | First aid measures |
| 4 | KIIIA1 4.6 | Neutralization procedures for use in the event of accidental spillages |
| 5 | KIIIA1 4.6.1 | Details of proposed procedures for small quantities |
| 5 | KIIIA1 4.6.2 | Evaluation of products of neutralization (small quantities) |
| 5 | KIIIA1 4.6.3 | Procedures for disposal of neutralized waste (small quantities) |
| 5 | KIIIA1 4.6.4 | Details of proposed procedures for large quantities |
| 5 | KIIIA1 4.6.5 | Evaluation of products of neutralization (large quantities) |
| 5 | KIIIA1 4.6.6 | Procedures for disposal of neutralized waste (large quantities) |
| 4 | KIIIA1 4.7 | Pyrolytic behaviour under controlled conditions at 800°C |
| 4 | KIIIA1 4.8 | Disposal procedures for the plant protection product |
| 5 | KIIIA1 4.8.1 | Detailed instructions for safe disposal on the product & its packaging |
| 5 | KIIIA1 4.8.2 | Methods other than controlled incineration for disposal |
| 4 | KIIIA1 4.9 | Other/special studies |
| 3 | KIIIA1 5 | Methods of Analysis |
| 4 | KIIIA1 5.1 | Analytic standards and samples |
| 5 | KIIIA1 5.1.1 | Samples of the preparation |
| 5 | KIIIA1 5.1.2 | Analytical standards for pure active substance |
| 5 | KIIIA1 5.1.3 | Samples of the active substance as manufactured |
| 5 | KIIIA1 5.1.4 | Analytical standards for relevant metabolites included DoR |
| 5 | KIIIA1 5.1.5 | Samples of reference substances for relevant impurities |
| 4 | KIIIA1 5.2 | Methods for the analysis of plant protection products |
| 5 | KIIIA1 5.2.1 | Analytical methods for the determination of the a.s. in product |
| 5 | KIIIA1 5.2.2 | Suitable method for preparations containing more than 1 a.s. |
| 5 | KIIIA1 5.2.3 | Applicability of existing CIPAC methods |
| 5 | KIIIA1 5.2.4 | Analytical methods for relevant impurities in the preparation |
| 5 | KIIIA1 5.2.5 | Analytical methods for formulants or their constituents in the product |
| 4 | KIIIA1 5.3 | Analytical methods for residues, stability of working solutions |
| 5 | KIIIA1 5.3.1 | Description of analytical methods for the determination of residues |

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| Level | Dossier File No | Description |
|-------|-----------------|---|
| 5 | KIIIA1 5.3.2 | Storage stability of working solutions * |
| 4 | KIIIA1 5.4 | Description of methods for analysis of soil (parent and metabolites) |
| 4 | KIIIA1 5.5 | Description of methods for analysis of sediment * |
| 4 | KIIIA1 5.6 | Description of methods for analysis of water (parent and metabolites) |
| 4 | KIIIA1 5.7 | Description of methods for analysis of air (parent and metabolites) |
| 4 | KIIIA1 5.8 | Methods for analysis of body fluid/tissues (parent and metabolites) |
| 4 | KIIIA1 5.9 | Other/special studies |
| 3 | KIIIA1 6 | Efficacy Data and Information (including Value Data) |
| 4 | KIIIA1 6.1 | Efficacy data |
| 5 | KIIIA1 6.1.1 | Preliminary range-finding tests |
| 5 | KIIIA1 6.1.2 | Minimum effective dose tests |
| 5 | KIIIA1 6.1.3 | Efficacy tests |
| 5 | KIIIA1 6.1.4 | Effects on yield and quality |
| 6 | KIIIA1 6.1.4.1 | Impact on the quality of plants and plant products |
| 6 | KIIIA1 6.1.4.2 | Effects on the processing procedure |
| 6 | KIIIA1 6.1.4.3 | Effects on the yield of treated plants and plant products |
| 4 | KIIIA1 6.2 | Adverse effects |
| 5 | KIIIA1 6.2.1 | Phytotoxicity to host crop |
| 5 | KIIIA1 6.2.2 | Adverse effects on health of host animals * |
| 5 | KIIIA1 6.2.3 | Adverse effects on site of application * |
| 5 | KIIIA1 6.2.4 | Adverse effects on beneficial organisms |
| 5 | KIIIA1 6.2.5 | Adverse effects on parts of plant used for propagating purposes |
| 5 | KIIIA1 6.2.6 | Impact on succeeding crops |
| 5 | KIIIA1 6.2.7 | Impact on other plants including adjacent crops |
| 5 | KIIIA1 6.2.8 | Possible development of resistance or cross-resistance |
| 4 | KIIIA1 6.3 | Economics * |
| 4 | KIIIA1 6.4 | Benefits * |
| 5 | KIIIA1 6.4.1 | Survey of alternative pest control measures * |
| 5 | KIIIA1 6.4.2 | Compatibility with current management practices including IPM * |
| 5 | KIIIA1 6.4.3 | Contribution to risk reduction * |
| 4 | KIIIA1 6.5 | Other/special studies |
| 4 | KIIIA1 6.6 | Summary and assessment of data according to points 6.1 to 6.5 |
| 4 | KIIIA1 6.7 | List of test facilities including the corresponding certificates |
| 3 | KIIIA1 7 | Toxicological Studies and Exposure Data and Information |
| 4 | KIIIA1 7.1 | Acute toxicity |
| 5 | KIIIA1 7.1.1 | Acute oral toxicity |
| 5 | KIIIA1 7.1.2 | Acute percutaneous (dermal) toxicity |
| 5 | KIIIA1 7.1.3 | Acute inhalation toxicity to rats |
| 5 | KIIIA1 7.1.4 | Skin irritation |
| 5 | KIIIA1 7.1.5 | Eye Irritation |
| 5 | KIIIA1 7.1.6 | Skin sensitization |
| 5 | KIIIA1 7.1.7 | Supplementary studies for combinations of plant protection products |
| 4 | KIIIA1 7.2 | Short-term toxicity studies * |
| 4 | KIIIA1 7.3 | Operator exposure |
| 5 | KIIIA1 7.3.1 | Estimation of operator exposure without personal protective equipment |
| 5 | KIIIA1 7.3.2 | Estimation of operator exposure using personal protective equipment |

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| Level | Dossier File No | Description |
|-------|-----------------|--|
| 5 | KIIIA1 7.3.3 | Measurement of operator exposure |
| 4 | KIIIA1 7.4 | Bystander exposure |
| 5 | KIIIA1 7.4.1 | Estimation of bystander exposure without personal protective equipment |
| 5 | KIIIA1 7.4.2 | Measurement of bystander exposure |
| 4 | KIIIA1 7.5 | Worker exposure |
| 5 | KIIIA1 7.5.1 | Estimation of worker exposure without personal protective equipment |
| 5 | KIIIA1 7.5.2 | Estimation of worker exposure using personal protective equipment |
| 5 | KIIIA1 7.5.3 | Estimation of worker exposure using data on dislogeable residues |
| 5 | KIIIA1 7.5.4 | Measurement of worker exposure |
| 4 | KIIIA1 7.6 | Dermal absorption |
| 5 | KIIIA1 7.6.1 | Dermal absorption, in vivo in the rat |
| 5 | KIIIA1 7.6.2 | Comparative dermal absorption, in vivo using rat and human skin |
| 4 | KIIIA1 7.7 | Dislogeable residues * |
| 5 | KIIIA1 7.7.1 | Dislogeable residues - foliar * |
| 5 | KIIIA1 7.7.2 | Dislogeable residues - soil * |
| 5 | KIIIA1 7.7.3 | Dislogeable residues - indoor surface re-volatization * |
| 4 | KIIIA1 7.8 | Epidemiology * |
| 4 | KIIIA1 7.9 | Data on formulants |
| 5 | KIIIA1 7.9.1 | Material safety data sheet for each formulant |
| 5 | KIIIA1 7.9.2 | Available toxicological data for each formulant |
| 4 | KIIIA1 7.10 | Domestic animal/livestock safety * |
| 4 | KIIIA1 7.11 | Other/special studies |
| 3 | KIIIA1 8 | Metabolism and Residues Data |
| 4 | KIIIA1 8.1 | Stability of residues |
| 5 | KIIIA1 8.1.1 | Stability of residues during storage of samples |
| 5 | KIIIA1 8.1.2 | Stability of residues in sample extracts |
| 4 | KIIIA1 8.2 | Supplementary studies on metabolism in plants or livestock |
| 4 | KIIIA1 8.3 | Supplementary residue trials (supervised field trials) |
| 5 | KIIIA1 8.3.1 | Pre-harvest use on major crops |
| 5 | KIIIA1 8.3.2 | Pre-harvest use on minor crops |
| 5 | KIIIA1 8.3.3 | Post-harvest use |
| 5 | KIIIA1 8.3.4 | Tobacco |
| 4 | KIIIA1 8.4 | Supplementary livestock feeding studies |
| 5 | KIIIA1 8.4.1 | Poultry |
| 5 | KIIIA1 8.4.2 | Lactating ruminants (goat or cow) |
| 5 | KIIIA1 8.4.3 | Pigs |
| 5 | KIIIA1 8.4.4 | Nature of residue in fish * |
| 4 | KIIIA1 8.5 | Supp. studies on industrial processing and/or household preparation |
| 5 | KIIIA1 8.5.1 | Nature of residues |
| 5 | KIIIA1 8.5.2 | Distribution of the residue in peel/pulp |
| 5 | KIIIA1 8.5.3 | Balance studies on a core set of representative processes |
| 5 | KIIIA1 8.5.4 | Follow-up studies; potable waters; irrigated crops |
| 6 | KIIIA1 8.5.4.1 | Follow-up studies to determine concentration or dilution factors |
| 6 | KIIIA1 8.5.4.2 | Potable waters * |
| 6 | KIIIA1 8.5.4.3 | Irrigated crops * |
| 4 | KIIIA1 8.6 | Supplementary studies for residues in representative succeeding crops |
| 4 | KIIIA1 8.7 | Proposed residue definition and maximum residue levels |

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| Level | Dossier File No | Description |
|-------|-----------------|---|
| 5 | KIIIA1 8.7.1 | Proposed residue definition |
| 5 | KIIIA1 8.7.2 | Proposed maximum residue levels (MRLs) |
| 4 | KIIIA1 8.8 | Proposed pre-harvest intervals, re-entry or withholding periods |
| 5 | KIIIA1 8.8.1 | Pre-harvest interval (in days) for each relevant crop |
| 5 | KIIIA1 8.8.2 | Re-entry period (in days) for livestock, to areas to be grazed |
| 5 | KIIIA1 8.8.3 | Re-entry period for man to crops, buildings or spaces treated |
| 5 | KIIIA1 8.8.4 | Withholding period (in days) for animal feedingstuffs |
| 5 | KIIIA1 8.8.5 | Waiting period before sowing or planting crop to be protected |
| 5 | KIIIA1 8.8.6 | Waiting period between application and handling treated products |
| 5 | KIIIA1 8.8.7 | Waiting period (in days) before sowing or planting succeeding crops |
| 4 | KIIIA1 8.9 | Other/special studies |
| 4 | KIIIA1 8.10 | Estimation of exposure through diet and other mean |
| 5 | KIIIA1 8.10.1 | TMDI calculations |
| 5 | KIIIA1 8.10.2 | NEDI calculations |
| 5 | KIIIA1 8.10.3 | NESTI calculations |
| 4 | KIIIA1 8.11 | Summary and evaluation of residue behaviour |
| 3 | KIIIA1 9 | Fate and Behaviour in the Environment |
| 4 | KIIIA1 9.1 | Rate of degradation in soil |
| 5 | KIIIA1 9.1.1 | Aerobic degradation of the preparation in soil |
| 5 | KIIIA1 9.1.2 | Anaerobic degradation of the preparation in soil |
| 4 | KIIIA1 9.2 | Field studies |
| 5 | KIIIA1 9.2.1 | Soil dissipation testing on a range of representative soils |
| 5 | KIIIA1 9.2.2 | Soil residue testing |
| 5 | KIIIA1 9.2.3 | Soil accumulation testing |
| 5 | KIIIA1 9.2.4 | Aquatic (sediment) field dissipation * |
| 5 | KIIIA1 9.2.5 | Forestry field dissipation * |
| 4 | KIIIA1 9.3 | Mobility of the plant protection product in soil |
| 5 | KIIIA1 9.3.1 | Column leaching |
| 5 | KIIIA1 9.3.2 | Lysimeter studies |
| 5 | KIIIA1 9.3.3 | Field leaching studies |
| 5 | KIIIA1 9.3.4 | Volatility - laboratory studies |
| 5 | KIIIA1 9.3.5 | Volatility - field studies |
| 4 | KIIIA1 9.4 | Predicted environmental concentrations in soil, active substance |
| 5 | KIIIA1 9.4.1 | Initial PECs value |
| 5 | KIIIA1 9.4.2 | Short-term PECs values - 24hours, 2 and 4 days after last application |
| 5 | KIIIA1 9.4.3 | Long-term PECs values - 7, 28, 50 and 100 days after last application |
| 4 | KIIIA1 9.5 | Predicted environmental concentrations in soil, for rel. metabolites |
| 5 | KIIIA1 9.5.1 | Initial PECs value |
| 5 | KIIIA1 9.5.2 | Short-term PECs values - 24hours, 2 and 4 days after last application |
| 5 | KIIIA1 9.5.3 | Long-term PECs values - 7, 28, 50 and 100 days after last application |
| 4 | KIIIA1 9.6 | Predicted environmental concentrations in ground water (PECgw) |
| 5 | KIIIA1 9.6.1 | Active substance PECgw value |
| 5 | KIIIA1 9.6.2 | Relevant metabolites, degradation and reaction products PECgw values |
| 5 | KIIIA1 9.6.3 | Additional field testing |
| 5 | KIIIA1 9.6.4 | Information on impact on water treatment procedure |
| 4 | KIIIA1 9.7 | Predicted environmental concentrations in surface water (PECsw) |
| 5 | KIIIA1 9.7.1 | Initial PECsw value for static water bodies |

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|-------|------------------|---|
| 5 | KIIIA1 9.7.2 | Initial PEC _{sw} value for slow moving water bodies |
| 5 | KIIIA1 9.7.3 | Short-term PEC _{sw} values for static water bodies |
| 5 | KIIIA1 9.7.4 | Short-term PEC _{sw} values for slow moving water bodies |
| 5 | KIIIA1 9.7.5 | Long-term PEC _{sw} values for static water bodies |
| 5 | KIIIA1 9.7.6 | Long-term PEC _{sw} values for slow moving water bodies |
| 4 | KIIIA1 9.8 | PEC _{sw} for relevant metabolites |
| 5 | KIIIA1 9.8.1 | Initial PEC _{sw} value for static water bodies |
| 5 | KIIIA1 9.8.2 | Initial PEC _{sw} value for slow moving water bodies |
| 5 | KIIIA1 9.8.3 | Short-term PEC _{sw} values for static water bodies |
| 5 | KIIIA1 9.8.4 | Short-term PEC _{sw} values for slow moving water bodies |
| 5 | KIIIA1 9.8.5 | Long-term PEC _{sw} values for static water bodies |
| 5 | KIIIA1 9.8.6 | Long-term PEC _{sw} values for slow moving water bodies |
| 5 | KIIIA1 9.8.7 | Additional field studies |
| 4 | KIIIA1 9.9 | Fate and behaviour in air |
| 5 | KIIIA1 9.9.1 | Spray droplet size spectrum - laboratory studies * |
| 5 | KIIIA1 9.9.2 | Drift - field evaluation * |
| 4 | KIIIA1 9.10 | Other/special studies |
| 5 | KIIIA1 9.10.1 | Other/special studies - laboratory studies |
| 5 | KIIIA1 9.10.2 | Other/special studies - field studies |
| 3 | KIIIA1 10 | Ecotoxicological studies on the plant protection product |
| 4 | KIIIA1 10.1 | Effects on birds |
| 5 | KIIIA1 10.1.1 | Acute toxicity exposure ratio (TER _A) for birds |
| 5 | KIIIA1 10.1.2 | Short-term toxicity exposure ratio (TER _{ST}) for birds |
| 5 | KIIIA1 10.1.3 | In the case of bait, the concentration of active substance in the bait |
| 5 | KIIIA1 10.1.4 | In the case of pellets, granules, prills or treated seed |
| 6 | KIIIA1 10.1.4.1 | Amount of a.s. in or on each pellet, granule, prill or treated seed |
| 6 | KIIIA1 10.1.4.2 | Proportion of the DT ₅₀ for the a.s. in 100 particles / gram particles |
| 5 | KIIIA1 10.1.5 | In the case of pellets, granules and prills, their size and shape |
| 5 | KIIIA1 10.1.6 | Acute oral toxicity of the preparation to the more sensitive species |
| 5 | KIIIA1 10.1.7 | Supervised cage or field trials |
| 5 | KIIIA1 10.1.8 | Acceptance of bait, granules or treated seed by birds |
| 5 | KIIIA1 10.1.9 | Effects of secondary poisoning |
| 4 | KIIIA1 10.2 | Effect on aquatic organisms |
| 5 | KIIIA1 10.2.1 | Toxicity exposure ratios for aquatic species |
| 6 | KIIIA1 10.2.1.1 | TER _A for fish |
| 6 | KIIIA1 10.2.1.2 | TER _{LT} for fish |
| 6 | KIIIA1 10.2.1.3 | TER _A for Daphnia |
| 6 | KIIIA1 10.2.1.4 | TER _{LT} for Daphnia |
| 6 | KIIIA1 10.2.1.5 | TER _A for an aquatic insect species |
| 6 | KIIIA1 10.2.1.6 | TER _{LT} for an aquatic insect species |
| 6 | KIIIA1 10.2.1.7 | TER _A for an aquatic crustacean species |
| 6 | KIIIA1 10.2.1.8 | TER _{LT} for an aquatic crustacean species |
| 6 | KIIIA1 10.2.1.9 | TER _A for an aquatic gastropod mollusc species |
| 6 | KIIIA1 10.2.1.10 | TER _{LT} for an aquatic gastropod mollusc species |

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| Level | Dossier File No | Description |
|-------|------------------|--|
| 6 | KIIIA1 10.2.1.11 | TER _{LT} for algae |
| 5 | KIIIA1 10.2.2 | Acute toxicity (aquatic) of the preparation |
| 6 | KIIIA1 10.2.2.1 | Fish acute toxicity LC ₅₀ , freshwater, cold-water species |
| 6 | KIIIA1 10.2.2.2 | Acute toxicity (24 & 48 h) for Daphnia preferably Daphnia magna |
| 6 | KIIIA1 10.2.2.3 | Effects on algal growth and growth rate |
| 6 | KIIIA1 10.2.2.4 | Marine or estuarine organisms acute toxicity LC ₅₀ /EC ₅₀ * |
| 6 | KIIIA1 10.2.2.5 | Marine sediment invertebrates, acute toxicity LC ₅₀ /EC ₅₀ * |
| 5 | KIIIA1 10.2.3 | Microcosm or mesocosm study |
| 5 | KIIIA1 10.2.4 | Residue data in fish (long term) |
| 5 | KIIIA1 10.2.5 | Chronic fish toxicity data |
| 6 | KIIIA1 10.2.5.1 | Chronic toxicity (28 day exposure) to juvenile fish |
| 6 | KIIIA1 10.2.5.2 | Fish early life stage toxicity test |
| 6 | KIIIA1 10.2.5.3 | Fish life cycle test |
| 5 | KIIIA1 10.2.6 | Chronic toxicity to aquatic invertebrates |
| 6 | KIIIA1 10.2.6.1 | Chronic toxicity to Daphnia magna (21-day) |
| 6 | KIIIA1 10.2.6.2 | Chronic toxicity for a representative species of aquatic insects |
| 6 | KIIIA1 10.2.6.3 | Chronic toxicity for a repres. species of aquatic gastropod molluscs |
| 5 | KIIIA1 10.2.7 | Accumulation in aquatic non-target organisms * |
| 4 | KIIIA1 10.3 | Effects on terrestrial vertebrates other than birds |
| 5 | KIIIA1 10.3.1 | Toxicity exposure ratios for terrestrial vertebrates other than birds |
| 6 | KIIIA1 10.3.1.1 | Acute toxicity exposure ratio (TER _A) |
| 6 | KIIIA1 10.3.1.2 | Short-term toxicity exposure ratio (TER _{ST}) |
| 6 | KIIIA1 10.3.1.3 | Long-term toxicity exposure ratio (TER _{LT}) |
| 5 | KIIIA1 10.3.2 | Effects on terrestrial vertebrates other than birds |
| 6 | KIIIA1 10.3.2.1 | Acute oral toxicity of the preparation |
| 6 | KIIIA1 10.3.2.2 | Acceptance of bait, granules or treated seed |
| 6 | KIIIA1 10.3.2.3 | Effects of secondary poisoning |
| 5 | KIIIA1 10.3.3 | Supervised cage or field trials or other appropriate studies |
| 4 | KIIIA1 10.4 | Effects on bees |
| 5 | KIIIA1 10.4.1 | Hazard Quotients for bees |
| 6 | KIIIA1 10.4.1.1 | Oral exposure Q _{HO} |
| 6 | KIIIA1 10.4.1.2 | Contact exposure Q _{HC} |
| 5 | KIIIA1 10.4.2 | Acute toxicity of the preparation to bees |
| 6 | KIIIA1 10.4.2.1 | Acute oral toxicity |
| 6 | KIIIA1 10.4.2.2 | Acute contact toxicity |
| 5 | KIIIA1 10.4.3 | Effects on bees of residues on crops |
| 5 | KIIIA1 10.4.4 | Cage tests |
| 5 | KIIIA1 10.4.5 | Field tests |
| 5 | KIIIA1 10.4.6 | Investigation of special effects |
| 6 | KIIIA1 10.4.6.1 | Larval toxicity |
| 6 | KIIIA1 10.4.6.2 | Long residual effects |
| 6 | KIIIA1 10.4.6.3 | Disorienting effects on bees |
| 5 | KIIIA1 10.4.7 | Tunnel tests - effects of feeding on contaminated honey dew or flowers |
| 4 | KIIIA1 10.5 | Effects on arthropods other than bees |
| 5 | KIIIA1 10.5.1 | Effects on sensitive species already tested, artificial substrates |
| 5 | KIIIA1 10.5.2 | Effects on non-target terrestrial arthropods in ext. laboratory tests |

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| Level | Dossier File No | Description |
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| 5 | KIIIA1 10.5.3 | Effects on non-target terrestrial arthropods in semi-field tests |
| 5 | KIIIA1 10.5.4 | Field tests on arthropods species |
| 4 | KIIIA1 10.6 | Effects on earthworms and other soil macro-organisms |
| 5 | KIIIA1 10.6.1 | Toxicity exposure ratios for earthworms, TER _A and TER _{LT} |
| 5 | KIIIA1 10.6.2 | Acute toxicity to earthworms |
| 5 | KIIIA1 10.6.3 | Sublethal effects on earthworms |
| 5 | KIIIA1 10.6.4 | Field tests (effects on earthworms) |
| 5 | KIIIA1 10.6.5 | Residue content of earthworms |
| 5 | KIIIA1 10.6.6 | Effects on other soil non-target macro-organisms |
| 5 | KIIIA1 10.6.7 | Effects on organic matter breakdown |
| 4 | KIIIA1 10.7 | Effects on soil microbial activity |
| 5 | KIIIA1 10.7.1 | Laboratory test to investigate impact on soil microbial activity |
| 5 | KIIIA1 10.7.2 | Further testing to investigate impact on soil microbial activity |
| 4 | KIIIA1 10.8 | Effects on non-target plants |
| 5 | KIIIA1 10.8.1 | Effects on non-target terrestrial plants |
| 6 | KIIIA1 10.8.1.1 | Seed germination |
| 6 | KIIIA1 10.8.1.2 | Vegetative vigour |
| 6 | KIIIA1 10.8.1.3 | Seedling emergence |
| 6 | KIIIA1 10.8.1.4 | Terrestrial field testing |
| 5 | KIIIA1 10.8.2 | Effects on non-target aquatic plants |
| 6 | KIIIA1 10.8.2.1 | Aquatic plant growth - Lemna |
| 6 | KIIIA1 10.8.2.2 | Aquatic field testing |
| 4 | KIIIA1 10.9 | Effects on other non-target organisms believed to be at risk |
| 5 | KIIIA1 10.9.1 | Summary of preliminary data: biological activity & dose range finding |
| 5 | KIIIA1 10.9.2 | Assessment of relevance to potential impact on non-target species |
| 4 | KIIIA1 10.10 | Other/special studies |
| 5 | KIIIA1 10.10.1 | Other/special studies - laboratory studies |
| 5 | KIIIA1 10.10.2 | Other/special studies - field studies |
| 4 | KIIIA1 10.11 | Summary and evaluation of points IIIA 9 and IIIA 10.1 to 10.10 |
| 5 | KIIIA1 10.11.1 | Predicted distribution and fate in the environment and time courses |
| 5 | KIIIA1 10.11.2 | Non-target species at risk and extent of potential exposure |
| 5 | KIIIA1 10.11.3 | Short and long term risks for non-target organisms |
| 5 | KIIIA1 10.11.4 | Risk of fish kills and fatalities in large vertebrates |
| 5 | KIIIA1 10.11.5 | Precautions necessary to avoid or minimize contamination |
| 3 | KIIIA1 11 | Further information |
| 4 | KIIIA1 11.1 | Information on authorizations in other countries |
| 4 | KIIIA1 11.2 | Information on established MRLs in other countries |
| 4 | KIIIA1 11.3 | Proposals for classification and labelling |
| 4 | KIIIA1 11.4 | Proposals for risk and safety phrases |
| 4 | KIIIA1 11.5 | Proposed label |
| 4 | KIIIA1 11.6 | Specimens of proposed packaging |
| 2 | Document LIIIA1 | Quality checks of reports (Tier I) and reference lists |
| 3 | LIIIA1 Sec 1 | Identity, physical and chemical properties and further information |
| 3 | LIIIA1 Sec 2 | Analytical methods |
| 3 | LIIIA1 Sec 3 | Toxicological studies on the product |
| 3 | LIIIA1 Sec 4 | Residues |

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| 3 | LIIIA1 Sec 5 | Fate and behaviour in the environment |
| 3 | LIIIA1 Sec 6 | Ecotoxicological studies on the product |
| 3 | LIIIA1 Sec 7 | Efficacy data |
| 2 | Document MIIIA1 | Summary and evaluation (Tier II) |
| 3 | MIIIA1 Sec 1 | Identity, physical and chemical properties and further information |
| 3 | MIIIA1 Sec 2 | Analytical methods |
| 3 | MIIIA1 Sec 3 | Toxicological studies on the product |
| 3 | MIIIA1 Sec 4 | Residues |
| 3 | MIIIA1 Sec 5 | Fate and behaviour in the environment |
| 3 | MIIIA1 Sec 6 | Ecotoxicological studies on the product |
| 3 | MIIIA1 Sec 7 | Efficacy data |
| 1 | Annex IIIA2 | Plant protection product <PRO_NAME> (Annex IIIA) |
| | | <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 | OIIA | Active substance |
| 2 | OIIIA | Plant protection product(s) |
| 2 | OIIIA Efficacy | Efficacy of plant protection 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. |

4 Version History

| Version | Date | Description / Changes |
|---------|--------------------|---|
| 1.0 | September 22, 2005 | First baselined version |
| 1.0.1 | June 30, 2006 | Level corrected for KIIIA1 10.2.2 and KIIIA1 10.3 |
| 1.0.2 | November 29, 2006 | Dossier File Number corrected for Annex IIA – Active substance: <AI_NAME>(Annex IIA) (page 12, was Annex IIA1) |
| 1.0.3 | April 16, 2008 | Field description corrected for Document D: shortened to "Uses" (page 12); Rows included for the fields "LIIIA1 Sec 7" (Efficacy data), "OL-N" (Documents L-N) and "OIIIA Efficacy" (Efficacy of plant protection product(s)) (page 30) |
| 1.0.4 | October 14, 2008 | Field description corrected for KIIA 7.4.9: Spelling correction "Volatility - laboratory study" (page 18) |
| 1.0.5 | June 1, 2010 | Field description corrected for D3: aligned to COM Dossier Guideline and OECD Dossier Guidance Docs (page 12) |