

**Active substance**

**DOCUMENT OCA**

**COMPLETENESS CHECK FORM**

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## Version history<sup>1</sup>

| Date | Data points containing amendments or additions and brief description | Document identifier and version number |
|------|--|--|
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<sup>1</sup> It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

## OCA Evaluation Form Active Substance

for use in checking that all test and study reports required in accordance with SANCO/11802 have been provided

Active Substance: hydrolysed proteins

Applicant: SICIT 2000 S.p.A.

Date: 19/02/2018

| SANCO/<br>11802 data<br>point | Information, test or study   | Information,<br>test or<br>study<br>provided | Justification<br>provided | Undertaking<br>provided | Data<br>gap              |
|-------------------------------|--|--|---------------------------|-------------------------|--------------------------|
| 1                             | Identity of the active substance                                       |  |                           |                         |                          |
| 1.1                           | Applicant  | yes  |                           |                         | <input type="checkbox"/> |
| 1.2                           | Producer   | yes  |                           |                         | <input type="checkbox"/> |
| 1.3                           | Common name proposed or ISO-accepted and synonyms                      | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 1.4                           | Chemical name (IUPAC and CA nomenclature)                              | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 1.5                           | Producer's development code numbers                                    | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 1.6                           | CAS, EC and CIPAC numbers  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 1.7                           | Molecular and structural formula, molar mass                           | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 1.8                           | Method of manufacture (synthesis pathway) of the active substance      | yes  |                           |                         | <input type="checkbox"/> |
| 1.9                           | Specification of purity of the active substance in g/kg                | yes  |                           |                         | <input type="checkbox"/> |
| 1.10                          | Identity and content of additives (such as stabilisers) and impurities |  |                           |                         |                          |
| 1.10.1                        | Additives  | yes  |                           |                         | <input type="checkbox"/> |
| 1.10.2                        | Significant impurities   | yes  |                           |                         | <input type="checkbox"/> |
| 1.10.3                        | Relevant impurities  | yes  |                           |                         | <input type="checkbox"/> |
| 1.11                          | Analytical profile of batches  | yes  |                           |                         | <input type="checkbox"/> |
| 2                             | Physical and chemical properties of the active substance               |  |                           |                         |                          |
| 2.1                           | Melting point and boiling point  | yes  |                           |                         | <input type="checkbox"/> |
| 2.2                           | Vapour pressure and volatility   | no   | not relevant              |                         | <input type="checkbox"/> |
| 2.3                           | Appearance (physical state, colour)                                    | yes  |                           |                         | <input type="checkbox"/> |

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|-------------------------------|---|--|---------------------------|-------------------------|--------------------------|
| 2.4                           | Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity                                     | yes  |                           |                         | <input type="checkbox"/> |
| 2.5                           | Solubility in water   | yes  |                           |                         | <input type="checkbox"/> |
| 2.6                           | Solubility in organic solvents  | yes  |                           |                         | <input type="checkbox"/> |
| 2.7                           | Partition coefficient n-octanol/water   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 2.8                           | Dissociation in water   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 2.9                           | Flammability and self-heating   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 2.10                          | Flash point   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 2.11                          | Explosive properties  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 2.12                          | Surface tension   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 2.13                          | Oxidising properties  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 2.14                          | Other studies   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 3                             | Further information on the active substance (function, mode of action, handling)  |  |                           |                         |                          |
| 3.1                           | Use of the active substance   | yes  |                           |                         | <input type="checkbox"/> |
| 3.2                           | Function  | yes  |                           |                         | <input type="checkbox"/> |
| 3.3                           | Effects on harmful organisms  | yes  |                           |                         | <input type="checkbox"/> |
| 3.4                           | Fields of use envisaged   | yes  |                           |                         | <input type="checkbox"/> |
| 3.5                           | Harmful organisms controlled and crops or products protected or treated   | yes  |                           |                         | <input type="checkbox"/> |
| 3.6                           | Mode of action  | yes  |                           |                         | <input type="checkbox"/> |
| 3.7                           | Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies | yes  |                           |                         | <input type="checkbox"/> |
| 3.8                           | Methods and precautions concerning handling, storage transport or fire  | yes  |                           |                         | <input type="checkbox"/> |
| 3.9                           | Procedures for destruction or decontamination   | yes  |                           |                         | <input type="checkbox"/> |
| 3.10                          | Emergency measures in case of an accident   | yes  |                           |                         | <input type="checkbox"/> |
| 4                             | Analytical methods  |  |                           |                         |                          |

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|-------------------------------|--|--|---------------------------|-------------------------|--------------------------|
| 4                             | Introduction   |  |                           |                         |                          |
| 4.1                           | Methods used for the generation of pre-approval data                     | yes  |                           |                         | <input type="checkbox"/> |
| 4.1.1                         | Methods of the analysis of the active substance as manufactured          | yes  |                           |                         | <input type="checkbox"/> |
| 4.1.2                         | Methods for risk assessment  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 4.2                           | Methods for post-approval control and monitoring purposes                | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5                             | Toxicological and toxicokinetic studies on the active substance          |  |                           |                         |                          |
| 5.1                           | Studies on absorption, distribution, excretion and metabolism in mammals |  |                           |                         |                          |
| 5.1.1                         | Absorption, distribution, excretion and metabolism by oral route         | yes  |                           |                         | <input type="checkbox"/> |
| 5.1.2                         | Absorption, distribution, excretion and metabolism by other routes       | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.2                           | Acute toxicity   |  |                           |                         |                          |
| 5.2.1                         | Oral   | yes  |                           |                         | <input type="checkbox"/> |
| 5.2.2                         | Dermal   | yes  |                           |                         | <input type="checkbox"/> |
| 5.2.3                         | Inhalation   | yes  |                           |                         | <input type="checkbox"/> |
| 5.2.4                         | Skin irritation  | yes  |                           |                         | <input type="checkbox"/> |
| 5.2.5                         | Eye irritation   | yes  |                           |                         | <input type="checkbox"/> |
| 5.2.6                         | Skin sensitization   | yes  |                           |                         | <input type="checkbox"/> |
| 5.2.7                         | Phototoxicity  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.3                           | Short-term toxicity  |  |                           |                         |                          |
| 5.3.1                         | Oral 28-day study  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.3.2                         | Oral 90-day study  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.3.3                         | Other routes   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.4                           | Genotoxicity   |  |                           |                         |                          |

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| 5.4.1                         | <i>In vitro</i> studies  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.4.2                         | <i>In vivo</i> studies in somatic cells  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.4.3                         | <i>In vivo</i> studies in germ cells   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.5                           | Long-term toxicity and carcinogenicity   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.6                           | Reproductive toxicity  |  |                           |                         |                          |
| 5.6.1                         | Generational studies   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.6.2                         | Developmental toxicity studies   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.7                           | Neurotoxicity  |  |                           |                         |                          |
| 5.7.1                         | Neurotoxicity studies in rodents   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.7.2                         | Delayed polyneuropathy studies   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.8                           | Other toxicological studies  |  |                           |                         |                          |
| 5.8.1                         | Toxicity studies of metabolites as referred to in the introduction   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.8.2                         | Supplementary studies on the active substance  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.8.3                         | Endocrine disrupting properties  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.9                           | Medical data   |  |                           |                         |                          |
| 5.9.1                         | Medical surveillance on manufacturing plant personnel and monitoring studies   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.9.2                         | Data collected on humans   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.9.3                         | Direct observations  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.9.4                         | Epidemiological studies  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 5.9.5                         | Diagnosis of poisoning (determination of active substance, metabolites), specific signs of poisoning, clinical tests | yes  |                           |                         | <input type="checkbox"/> |
| 5.9.6                         | Proposed treatment: first aid measures, antidotes, medical treatment   | yes  |                           |                         | <input type="checkbox"/> |
| 5.9.7                         | Expected effects of poisoning  | yes  |                           |                         | <input type="checkbox"/> |
| 6                             | Metabolism and residues data   |  |                           |                         |                          |

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|-------------------------------|--|--|---------------------------|-------------------------|--------------------------|
| 6.1                           | Storage stability of residues  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.2.                          | Metabolism, distribution and expression of<br>residues   |  |                           |                         |                          |
| 6.2.1                         | Plants   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.2.2                         | Poultry  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.2.3                         | Lactating ruminants  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.2.4                         | Pigs   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.2.5                         | Fish   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.3                           | Magnitude of residue trials in plants  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.4                           | Feeding studies  |  |                           |                         |                          |
| 6.4.1                         | Poultry  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.4.2                         | Ruminants  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.4.3                         | Pigs   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.4.4                         | Fish   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.5                           | Effects of processing  |  |                           |                         |                          |
| 6.5.1                         | Nature of the residue  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.5.2                         | Distribution of the residue in inedible peel/pulp  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.5.3                         | Magnitude of residues in processed commodities   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.6                           | Residues in rotational crops   |  |                           |                         |                          |
| 6.6.1                         | Metabolism in rotational crops   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.6.2                         | Magnitude of residues in rotational crops  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.7                           | Proposed residue definition and maximum residue<br>levels  |  |                           |                         |                          |
| 6.7.1                         | Proposed residue definitions   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.7.2                         | Proposed maximum residue levels (MRLs) and<br>justification of the acceptability of the levels<br>proposed | not relevant                                 |                           |                         | <input type="checkbox"/> |

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| 6.7.3                         | Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed for imported products (import tolerances) | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.8                           | Proposed safety intervals  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.9                           | Estimation of the potential and actual exposure through diet and other sources   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.10                          | Other studies  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 6.10.1                        | Effect on the residue level in pollen and bee products   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7                             | Fate and behaviour in the environment  |  |                           |                         |                          |
| 7.1.1                         | Fat and behaviour in soil  |  |                           |                         |                          |
| 7.1.1.1                       | Aerobic degradation  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.1.1.2                       | Anaerobic degradation  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.1.1.3                       | Soil photolysis  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.1.2                         | Rate of degradation in soil  |  |                           |                         |                          |
| 7.1.2.1                       | Laboratory studies   |  |                           |                         |                          |
| 7.1.2.1.1                     | Aerobic degradation of the active substance  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.1.2.1.2                     | Aerobic degradation metabolites, breakdown and reaction products   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.1.2.1.3                     | Anaerobic degradation of the active substance  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.1.2.1.4                     | Anaerobic degradation of metabolites, breakdown and reaction products  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.1.2.2                       | Field studies  |  |                           |                         |                          |
| 7.1.2.2.1                     | Soil dissipation studies   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.1.2.2.2                     | Soil accumulation studies  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.1.3                         | Adsorption and desorption in soil  |  |                           |                         |                          |
| 7.1.3.1                       | Adsorption and desorption  |  |                           |                         |                          |
| 7.1.3.1.1                     | Adsorption and desorption of the active substance  | not relevant                                 |                           |                         | <input type="checkbox"/> |



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| 7.1.3.1.2                     | Adsorption and desorption of metabolites, breakdown and reaction products                 | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.1.3.2                       | Aged sorption   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.1.4                         | Mobility in soil  |  |                           |                         |                          |
| 7.1.4.1                       | Column leaching studies   |  |                           |                         |                          |
| 7.1.4.1.1                     | Column leaching of the active substance   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.1.4.1.2                     | Column leaching of metabolites, breakdown and reaction products                           | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.1.4.2                       | Lysimeter studies   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.1.4.3                       | Field leaching studies  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.2                           | Fate and behaviour in water and sediment  |  |                           |                         |                          |
| 7.2.1                         | Route and rate of degradation in aquatic systems (chemical and photochemical degradation) |  |                           |                         |                          |
| 7.2.1.1                       | Hydrolytic degradation  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.2.1.2                       | Direct photochemical degradation  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.2.1.3                       | Indirect photochemical degradation  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.2.2                         | Route and rate of biological degradation in aquatic systems                               |  |                           |                         |                          |
| 7.2.2.1                       | “Ready biodegradability”  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.2.2.2                       | Aerobic mineralisation in surface water   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.2.2.3                       | Water/sediment study  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.2.2.4                       | Irradiated water/sediment study   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.2.3                         | Degradation in the saturated zone   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.3                           | Fate and behaviour in air   |  |                           |                         |                          |
| 7.3.1                         | Route and rate of degradation in air  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.3.2                         | Transport via air   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.3.3                         | Local and global effects  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.4                           | Definition of the residue   |  |                           |                         |                          |

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| 7.4.1                         | Definition of the residue for risk assessment  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.4.2                         | Definition of the residue for monitoring   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 7.5                           | Monitoring data  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8                             | Ecotoxicological studies   |  |                           |                         |                          |
| 8.1                           | Effects on birds and other terrestrial vertebrates                                   |  |                           |                         |                          |
| 8.1.1                         | Effects on birds   |  |                           |                         |                          |
| 8.1.1.1                       | Acute oral toxicity to birds   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.1.1.2                       | Short-term dietary toxicity to birds   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.1.1.3                       | Sub-chronic toxicity and reproductive to birds                                       | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.1.2                         | Effects on terrestrial vertebrates other than birds                                  |  |                           |                         |                          |
| 8.1.2.1                       | Acute oral toxicity to mammals   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.1.2.2                       | Long-term and reproductive toxicity to mammals                                       | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.1.3                         | Effects of active substance bioconcentration in prey of birds and mammals            | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.1.4                         | Effects on terrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians) | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.1.5                         | Endocrine disrupting properties  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.2                           | Effects on aquatic organisms   |  |                           |                         |                          |
| 8.2.1                         | Acute toxicity to fish   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.2.2                         | Long-term and chronic toxicity to fish   |  |                           |                         |                          |
| 8.2.2.1                       | Fish early life stage toxicity test  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.2.2.2                       | Fish full life cycle test  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.2.2.3                       | Bioconcentration in fish   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.2.3                         | Endocrine disrupting properties  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.2.4                         | Acute toxicity to aquatic invertebrates  |  |                           |                         |                          |
| 8.2.4.1                       | Acute toxicity to <i>Daphnia magna</i>   | not relevant                                 |                           |                         | <input type="checkbox"/> |

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| 8.2.4.2                       | Acute toxicity to an additional aquatic invertebrate species                        | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.2.5                         | Long term and chronic toxicity to aquatic invertebrates                             |  |                           |                         |                          |
| 8.2.5.1                       | Reproductive and development toxicity to <i>Daphnia magna</i>                       | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.2.5.2                       | Reproductive and development toxicity to an additional aquatic invertebrate species | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.2.5.3                       | Development and emergence in <i>Chironomus species</i>                              | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.2.5.4                       | Sediment dwelling organisms   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.2.6                         | Effects on algal growth   |  |                           |                         |                          |
| 8.2.6.1                       | Effects on growth of green algae  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.2.6.2                       | Effects on growth of an additional algal species                                    | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.2.7                         | Effects on aquatic macrophytes  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.2.8                         | Further testing on aquatic organisms  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.3                           | Effects on arthropods   |  |                           |                         |                          |
| 8.3.1                         | Effects on bees   |  |                           |                         |                          |
| 8.3.1.1                       | Acute toxicity to bees  |  |                           |                         |                          |
| 8.3.1.1.1                     | Acute oral toxicity   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.3.1.1.2                     | Acute contact toxicity  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.3.1.2                       | Chronic toxicity to bees  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.3.1.3                       | Effects on honeybees development and other honeybee life stages                     | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.3.1.4                       | Sub-lethal effects  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.3.2                         | Effects on non-target arthropods other than bees                                    | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.3.2.1                       | Effects on <i>Aphidius rhopalosiphi</i>   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.3.2.2                       | Effects on <i>Typhlodromus pyri</i>   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.4                           | Effects on non-target soil meso- and macrofauna                                     |  |                           |                         |                          |

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| 8.4.1                         | Earthworm – sub-lethal effects   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.4.2                         | Effects on non-target soil meso- and macrofauna<br>(other than earthworms) | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.4.2.1                       | Species level testing  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.5                           | Effects on soil nitrogen transformation                                    | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.6                           | Effects on terrestrial non-target higher plants                            |  |                           |                         |                          |
| 8.6.1                         | Summary of screening data  | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.6.2                         | Testing on non-target plants   | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.7                           | Effects on other terrestrial organisms (flora and<br>fauna)                | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.8                           | Effects on biological methods for sewage<br>treatment                      | not relevant                                 |                           |                         | <input type="checkbox"/> |
| 8.9                           | Monitoring data  | no   | not required              |                         | <input type="checkbox"/> |
| 9                             | Literature data  | yes  |                           |                         | <input type="checkbox"/> |
| 10                            | Classification and labelling   | yes  |                           |                         | <input type="checkbox"/> |