

APPENDIX 9

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

Chapter 1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)

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Function (*e.g.* fungicide)

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Country to which application is made

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Identity (OECD data point IIA 1)

Chemical name (IUPAC)

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Chemical name (CA)

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CIPAC No

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CAS No

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EEC No (EINECS or ELINCS)

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FAO Specification (including year of publication)

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Minimum purity of the active substance as
manufactured (g/kg)

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Identity of relevant impurities (of toxicological,
environmental and/or other significance) in the
active substance as manufactured (g/kg)

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Molecular formula

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Molecular mass

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Structural formula

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Physical-chemical properties (OECD data point IIA 2)

| | |
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| Melting point (state purity) | |
| Boiling point (state purity) | |
| Temperature of decomposition | |
| Appearance (state purity) | |
| Relative density (state purity) | |
| Surface tension | |
| Vapour pressure (in Pa, state temperature) | |
| Henry's law constant (Pa m ³ mol ⁻¹) | |
| Solubility in water (g/l or mg/l, state temperature) | pH 5: |
| | pH 7: |
| | pH 9: |
| Solubility in organic solvents (in g/l or mg/l, state temperature) | |
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| Partition co-efficient (log P _{OW}) (state pH and temperature) | pH 5: |
| | pH 7: |
| | pH 9: |
| Hydrolytic stability (DT ₅₀) (state pH and temperature) | pH 5: |
| | pH 7: |
| | pH 9: |
| Dissociation constant | |
| UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength) | |
| Photostability (DT ₅₀) (aqueous, sunlight, state pH) | |
| Quantum yield of direct phototransformation in water at λ > 290 nm | |
| Flammability | |
| Explosive properties | |

Company name Month and year

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Summary of intended uses

| Crop and/or situation (a) | Country and / or Region | Product name | F G or I (b) | Pests or Group of pests Controlled (c) | Formulation | | Application | | | | Application rate per treatment | | | PHI (days) (l) | Remarks: (m) |
|------------------------------|-------------------------|--------------|-----------------|---|---------------|--------------------|----------------------|------------------------------|-----------------------|--|--------------------------------|-----------------------|---------------------|-------------------|-----------------|
| | | | | | Type (d-f) | Conc. of as (i) | Method Kind (f-h) | growth stage & season (j) | number min max (k) | interval between applications (min) | Kg as/hL min max | water L/ha min max | kg as/ha min max | | |

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- (a) For crops, the Codex and EU (or other) classifications should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant - type of equipment used must be indicated
- (i) g/kg or g/l
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions

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Classification and proposed labelling (OECD data point IIA 10)

with respect to physical/chemical data

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| Classification: Proposed Label: Symbol: Indication of danger: Risk phrases: Safety phrases: |
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with respect to toxicological data

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| Classification: Proposed Label: Symbol: Indication of danger: Risk phrases: Safety phrases: |
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with respect to fate and behaviour data

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| Classification: Proposed Label: Symbol: Indication of danger: Risk phrases: Safety phrases: |
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with regard to ecotoxicological data

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| Classification: Proposed Label: Symbol: Indication of danger: Risk phrases: Safety phrases: |
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Chapter 2: Methods of Analysis

Analytical methods for the active substance (OECD data point IIA 4.2)

Technical as (principle of method)

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Impurities in technical as (principle of method)

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Plant protection product (principle of method)

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Analytical methods for residues (OECD data points IIA 4.3 to IIA 4.8)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)

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Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)

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Soil (principle of method and LOQ)

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Water (principle of method and LOQ)

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Air (principle of method and LOQ)

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Body fluids and tissues (principle of method and LOQ)

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Chapter 3: Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism in mammals (OECD data point IIA 5.1)

Rate and extent of absorption:

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Distribution:

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Potential for accumulation:

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Rate and extent of excretion:

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Metabolism in animals

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Toxicologically significant compounds (animals,
plants and environment)

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Acute toxicity (OECD data point IIA 5.2)

Rat LD₅₀ oral

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Rat LD₅₀ dermal

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Rat LC₅₀ inhalation

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Skin irritation

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Eye irritation

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Skin sensitization (test method used and result)

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Short term toxicity (OECD data point IIA 5.3)

Target/critical effect

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Lowest relevant oral NOAEL / NOEL

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Lowest relevant dermal NOAEL / NOEL

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Lowest relevant inhalation NOAEL / NOEL

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Genotoxicity (OECD data point IIA 5.4)

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Acceptable exposure scenarios (including method of calculation)

Operator

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Workers

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Bystanders

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Chapter 4: Residues

Metabolism in plants (OECD data points IIA 6.2.1, IIA 6.7, IIIA 8.2 & IIIA 8.7)

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|---|--|
| Plant groups covered | |
| Rotational crops | |
| Plant residue definition for monitoring | |
| Plant residue definition for risk assessment | |
| Conversion factor (monitoring to risk assessment) | |

Metabolism in livestock (OECD data points IIA 6.2.2 to IIA 6.2.5, IIA 6.7, IIIA 8.4 & IIIA 8.7)

| | |
|---|--|
| Animals covered | |
| Animal residue definition for monitoring | |
| Animal residue definition for risk assessment | |
| Conversion factor (monitoring to risk assessment) | |
| Metabolism in rat and ruminant similar (yes/no) | |
| Fat soluble residue: (yes/no) | |

Residues in succeeding crops (OECD data points IIA 6.6 and IIIA 8.6)

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Stability of residues (OECD data points IIA 6.1 and IIIA 8.1)

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Chapter 5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (OECD data point IIA 7.1.1)

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| Mineralization after 100 days | |
| Non-extractable residues after 100 days | |
| Relevant metabolites ²⁸ - name and/or code % of applied (range and maximum) | |

Route of degradation in soil (anaerobic & photolysis) (OECD data points IIA 7.1.2 & IIA 7.1.3)

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| Anaerobic degradation | |
| Soil photolysis | |

Rate of degradation in soil (OECD data points IIA 7.2, IIA 7.3, IIIA 9.1 & IIIA 9.2)

| | |
|---|---|
| Method of calculation | |
| Laboratory studies (range or median, with n value, with r ² value) | DT _{50lab} (20 °C, aerobic): |
| | DT _{90lab} (20 °C, aerobic): |
| | DT _{50lab} (10 °C, aerobic): |
| | DT _{50lab} (20 °C, anaerobic): |
| | degradation in the saturated zone: |
| Field studies (state location, range or median with n value) | DT _{50f} : |
| | DT _{90f} : |
| Soil accumulation and plateau concentration | |

²⁸ An internationally agreed definition of the term *relevant metabolites* has not been elaborated. Pending the development of such a definition, applicants should consult the regulatory authority of the country to which application is to be made, for guidance concerning selection of the metabolites for which information must be reported

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Soil adsorption/desorption (OECD data points IIA 7.4.1 & IIA 7.4.2)

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| K_f/K_{oc} | |
| K_d | |
| pH dependence (yes / no) (if yes type of dependence) | |

Mobility in soil (OECD data points IIA 7.4.3 to IIA 7.4.8 and IIIA 9.3)

| | |
|-----------------------------------|--|
| Column leaching | |
| Aged residues leaching | |
| Lysimeter/ field leaching studies | |

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PEC (ground water) (OECD data point IIIA 9.6)

Method of calculation and type of study (*e.g.*
Modelling, monitoring, lysimeter)

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Application rate

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PEC_(gw)

Maximum concentration

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Average annual concentration

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Fate and behaviour in air (OECD data points IIA 7.10 and IIIA 9.9)

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|---|---|
| Direct photolysis in air | |
| Quantum yield of direct phototransformation | |
| Photochemical oxidative degradation in air | Latitude: Season: DT ₅₀ : Henry's Law Constant: |
| Volatilization | from plant surfaces: |
| | from soil: |

PEC (air)

| | |
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| Method of calculation | |
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PEC_(a)

| | |
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| Maximum concentration | |
|-----------------------|--|

Definition of the Residue (OECD data point IIA 7.11)

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| Relevant to the environment | |
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Monitoring data, if available (OECD data point IIA 7.12)

| | |
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| Soil (indicate location and type of study) | |
| Surface water (indicate location and type of study) | |
| Ground water indicate location and type of study) | |
| Air (indicate location and type of study) | |

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Effects on soil micro-organisms (OECD data point IIA 8.10 and IIIA 10.7)

Nitrogen mineralization

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Carbon mineralization

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