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| A-form: Information on chemical active substance in biocidal product |
| **All the points** in the form should be filled with information. In cases where the data requirement is not covered by a study/report, a **detailed justification should be given**. Data requirements marked with an **asterisk** (\*) are core data requirements that **always shall be provided** to the application, independent of product type and intended use of the product. For guidance on the data requirements, see the **BPR Guidance** at ECHA’s website.If you have questions, please contact the Swedish Chemicals Agency at: kemi@kemi.se  |

| Point | Data requirement | Information/value | Reference to the application |
| --- | --- | --- | --- |
| A1. Information about identity of the active substance |
| A1.1 | Common nameState the ISO-name |  |  |
| A1.2 | Chemical name according to CA- or IUPAC nomenclature |  |  |
| A1.3 | Manufacturer’s development code  |  |  |
| A1.4 | CAS and EC numbers, if available |  |  |
| A1.5 | Molecular formula |  |  |
| A1.6 | Structural formulaState e.g. optical isomers |  |  |
| A1.7 | Molecular weight |  |  |
| A2. Information on the active substance in the technical product |
| A2.1 | PurityState in weight % (w/w) |  |  |
| A2.2 | Chemical name and content of impuritiesState optical isomers, by-products from the synthesis, decomposition products etc. In % (w/w) with the largest contributor first with an unambiguous chemical name according to CA or IUPAC nomenclature as well as the CAS No., the method of analysis as well as its accuracy |  |  |
| A2.3 | AdditivesState the name and the type of the additive, e.g. stabilisators, inhibitors etc as well as the content in % (w/w) or ppm. |  |  |
| A3. Information about analysis of the active substance |
| A3.1 | Methods of analysis for qualitative and quantitative analysis of the active substanceState analytical method for the active substance in soil, water, air and biological material. |  |  |
| A4. Information about production and origin of the active substance |
| A4.1 | ManufacturerState name or company |  |  |
| A4.2 | Production plant(s)State address(es) of all production plant(s) |  |  |
| A4.3 | Description of the production of the active substance |  |  |
| A5. Physical- chemical properties of the active substance |
| A5.1 | Appearance, physical state, colour, odour etc. |  |  |
| A5.2 | Aggregation state at ambient temperature |  |  |
| A5.3 | Melting point or temperature for sublimation, decomposition |  |  |
| A5.4 | Boiling point |  |  |
| A5.5 | DensityIf the substance is a gas, state the density at 0oC and 760 mm Hg |  |  |
| A5.6 | Vapour pressureState the vapour pressure (Pa) for at least 2 temperatures in degree Celsius, or in a vapour pressure diagram |  |  |
| A5.7 | Surface tension  |  |  |
| A5.8 | Water solubility |  |  |
| A5.9 | Fat solubility |  |  |
| A5.10 | Partition coefficientn-octanol/ water |  |  |
| A5.11 | Solubility in organic solvents  |  |  |
| A5.12 | Thermal stabilityState solvent and concentrations in mg/100 ml |  |  |
| A5.13 | Flash-point |  |  |
| A5.14 | FlammabilityState the classification of flammability |  |  |
| A5.15 | Oxidising properties |  |  |
| A5.16 | Decomposition or other reaction during incineration State whether or not the substance can entertain, speed up or catalyse the incineration |  |  |
| A5.17 | Dissociation constantState the lowest temperature for complete incineration |  |  |
| A5.18 | Other physical-chemical propertiesState the pKa-value |  |  |
| A6. Toxicological properties of the active substance |
| A6.1 | Acute oral toxicityShould be stated if the information is missing for the formulation |
| Animal species  |  |  |
| LD50 (mg/kg) |  |  |
| Observed effects, organ injuries etc. |  |  |
| A6.2 | Acute dermal toxi­cityShould be stated if the information is missing for the formulation |
| Animal species |  |  |
| LD50 (mg/kg) |  |  |
| Observed effects, organ injuries etc. |  |  |
| A6.3 | Acute inhalation toxicityShould be stated if the information is missing for the formulation |
| Animal species |  |  |
| LC50 (mg/L) |  |  |
| Observed effects, organ injuries etc. |  |  |
| A6.4 | Skin irritationShould be stated if the information is missing for the formulation |  |  |
| A6.5 | Eye irritationShould be stated if the information is missing for the formulation |  |  |
| A6.6 | Skin sensitisation Should be stated if the information is missing for the formulation |  |  |
| A6.7 | KineticsThese studies should be performed on laboratory animals and also on (all) other animals when the intention is to use the active substance for treatment of food-producing animals |
| A6.7.1 | Oral absorption (%)\* |  |  |
| A6.7.2 | Distribution |  |  |
| A6.7.3 | Excretion  |  |  |
| A6.7.4 | Metabolism |  |  |
| A6.8  | Dermal absorption (%)Should be stated if the information is missing for the formulation |  |  |
| A6.9 | Mechanistic studiesShould be stated if documentation is available |  |  |
| A6.10 | Oral 90-day study\* |
| Animal species |  |  |
| LOAEL/NOAEL (mg/kg/day) |  |  |
| Observed effects, organ injuries etc. |  |  |
| A6.11 | Other administration-routes or time intervalsShould be stated if documentation is available |  |  |
| A6.12 | Chronic toxicityCan often be combined with carcinogenicity. The study must be performed with oral administration for active substances that demands an ADI (Acceptable Daily Intake) |
| Animal species |  |  |
| LOAEL/NOAEL (mg/kg/day) |  |  |
| Observed effects, organ injuries etc. |  |  |
| A6.13 | CarcinogenicityThe study must be performed with oral administration for active substances that demands an ADI (Acceptable Daily Intake). |  |  |
| A6.14 | Genotoxicity\* |
| In vitro |  |  |
| In vivo |  |  |
| A6.15 | Reproductive toxicityThe studies must be performed with oral administration for active substances that demands an ADI (Acceptable Daily Intake) |
| Multigenerational study \* |
| Animal species |  |  |
| LOAEL/NOAEL (mg/kg/day) |  |  |
| Observed effects, organ injuries etc. |  |  |
| Teratogenicity\* |
| Animal species |  |  |
| LOAEL/NOAEL (mg/kg/day) |  |  |
| Observed effects, organ injuries etc. |  |  |
| A6.16 | NeurotoxicityThe study must be performed with oral administration for active substances that demands an ADI (Acceptable Daily Intake) |  |  |
| A6.17 | Effects on humansState experiences acquired during the professional manufacturing process or in relation with a case of poisoning. Anti-dotes and therapeutic regimes should be stated when available.Enclose epidemiological studies if these are available |  |  |
| A6.18 | Toxicity of metabolites |  |  |
| A7. Residue data of the active substance in exposed food, feeding stuffs or livestock that will be used for food manufacturing industry*For products that will be used in e.g. storage spaces for food and feeding stuffs, for treatment of food, feeding stuffs and drinking water, or nearby or directly on livestock that will be used for food manufacturing industry* |
| A7.1 | Identification of the residues (identity and concentrations), degradation and reaction products and of metabolites of the active substance on livestock that will be used for food manufacturing industry and in contaminated foods or feeding stuffs |  |  |
| A7.2 | Behaviour of the residues of the active substance, its degradation and reaction products and, where relevant, its metabolites on livestock that will be used for food manufacturing industry and in contaminated foods or feeding stuffs, including the kinetics of disappearance |  |  |
| A7.3 | Data of residue levelsStudies of residue levels should be performed both with and without radioactive labelled substance. These studies must be performed for all animals that are comprised in the application. Residues should be measured in liver, kidney, fat, muscle and also in milk, egg and honey when needed |  |  |
| A7.4 | Estimation of potential or actual exposure of the active substance to humans or animals through livestock, animal stables, food and feeding stuffs or other means. |  |  |
| A8. Fate and behaviour of the active substance in water |
| A8.1 | Abiotic degradation |
| A8.1.1 | Hydrolysis in water as a function of pH\* |  |  |
| A8.1.2 | Photolysis in water\* |  |  |
| A8.2 | Biotic degradation |
| A8.2.1 | Ready biodegradability \* |  |  |
| A8.2.2 | Inherent biodegradability\* |  |  |
| A8.2.3 | Aerobic biodegradation in water |  |  |
| A8.2.4 | Water/sediment degradation study  |  |  |
| A8.3 | Adsorption to organic material |
| A8.3.1 | Screening test of adsorption/desorption\*  |  |  |
| A8.3.2 | Field study on accumulation in the sediment  |  |  |
| A9. Fate and behaviour of the active substance in soil |
| A9.1 | Abiotic degradation |
| A9.1.1 | Photolysis on soil |  |  |
| A9.2 | Biotic degradation |
| A9.2.1 | Aerobic degradation in soil |  |  |
| A9.2.2 | Adsorption and desorption to soil particles |  |  |
| A9.2.3 | Accumulation in soil |  |  |
| A10. Fate and behaviour of the active substance in air |
| A10.1 | Photolysis in air |  |  |
| A11. Toxicity to aquatic organisms |
| A11.1 | Acute toxicity to fish\* |  |  |
| A11.2 | Acute toxicity to invertebrates *(Daphnia)\** |  |  |
| A11.3 | Growth inhibition test on algae\* |  |  |
| A11.4 | Inhibition to microbiological activity\* |  |  |
| A11.5 | Effects on reproduction and growth of fish  |  |  |
| A11.6 | Reproduction study with *Daphnia* |  |  |
| A11.7 | Bioconcentration (calculated value)\* |  |  |
| A11.8 | Bioaccumulation study |  |  |
| A11.9 | Tests with simulated eco-systemsFor example mesocosmstudies |  |  |
| A12. Toxicity to terrestrial organisms |
| A12.1 | Inhibition to microbial activity |  |  |
| A12.2 | Acute toxicity to earthworms or other soil non-target macro-organisms  |  |  |
| A12.3 | Acute toxicity to plants  |  |  |
| A12.4 | Reproduction study with earthworms or other soil non-target macro-organisms  |  |  |
| A12.5 | Long-term test with terrestrial plants |  |  |
| A12.6 | Bioconcentration (calculated value) |  |  |
| A12.7 | Bioconcentration study |  |  |
| A13. Toxicity to birds and mammals including bioaccumulation |
| A13.1 | Acute toxicity to bird |  |  |
| A13.2 | Short-term dietary test with bird |  |  |
| A13.3 | Reproduction study with bird |  |  |
| A13.4 | Other environmental toxi­cological studies (e.g. bioaccumulation, biomagnification) |  |  |
| A14. Acute toxicity to honeybees and other beneficial arthropods |
| A14.1 | Acute toxicity for bees and other beneficial arthropods |  |  |
| A14.2 | Effects on other terrestrial non-target organism State e.g. experiences from field tests or investigations with other arthropods of importance |  |  |
| A15. Measurements in the environment |
| A15.1 | Measurements in the environment State measured concentrations of active substance and its degradation products |  |  |
| A16. Resistance creating properties |
| A16.1 | Resistance creating properties |  |  |
| A17. Classification |
| A17.1 | Classification of the active substanceState classification according to Directive 67/548/EEC, or proposed classification |  |  |
| A18. Recommended risk and protection information in relation to: |
| A18.1 | HandlingEnclose proposed safety data sheet |  |  |
| A18.2 | Storage |  |  |
| A18.3 | Transport |  |  |
| A18.4 | Danger of fire |  |  |
| A19. Destruction methods |
| A19.1 | Destruction methodsState method, appropriate chemicals, final product etc |  |  |
| A20. Reference list |
| A20.1 | Reference listState title, author, lab, and other information that can facilitate the identification of each annex |  |  |