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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](mailto:kemi@kemi.se) | |

| Point | Data requirement | Information/value | Reference to the application |
| --- | --- | --- | --- |
| A1. Information about identity of the active substance | | | |
| A1.1 | Common name  State 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 formula  State e.g. optical isomers |  |  |
| A1.7 | Molecular weight |  |  |
| A2. Information on the active substance in the technical product | | | |
| A2.1 | Purity  State in weight % (w/w) |  |  |
| A2.2 | Chemical name and content of impurities  State 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 | Additives  State 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 substance  State 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 | Manufacturer  State 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 | Density  If the substance is a gas, state the density at 0oC and 760 mm Hg |  |  |
| A5.6 | Vapour pressure  State 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 coefficient  n-octanol/ water |  |  |
| A5.11 | Solubility in organic solvents |  |  |
| A5.12 | Thermal stability  State solvent and concentrations in mg/100 ml |  |  |
| A5.13 | Flash-point |  |  |
| A5.14 | Flammability  State 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 constant  State the lowest temperature for complete incineration |  |  |
| A5.18 | Other physical-chemical properties  State the pKa-value |  |  |
| A6. Toxicological properties of the active substance | | | |
| A6.1 | Acute oral toxicity  Should be stated if the information is missing for the formulation | | |
| Animal species |  |  |
| LD50 (mg/kg) |  |  |
| Observed effects, organ injuries etc. |  |  |
| A6.2 | Acute dermal toxi­city  Should be stated if the information is missing for the formulation | | |
| Animal species |  |  |
| LD50 (mg/kg) |  |  |
| Observed effects, organ injuries etc. |  |  |
| A6.3 | Acute inhalation toxicity  Should be stated if the information is missing for the formulation | | |
| Animal species |  |  |
| LC50 (mg/L) |  |  |
| Observed effects, organ injuries etc. |  |  |
| A6.4 | Skin irritation  Should be stated if the information is missing for the formulation |  |  |
| A6.5 | Eye irritation  Should 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 | Kinetics  These 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 studies  Should 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 intervals  Should be stated if documentation is available |  |  |
| A6.12 | Chronic toxicity  Can 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 | Carcinogenicity  The 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 toxicity  The 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 | Neurotoxicity  The study must be performed with oral administration for active substances that demands an ADI (Acceptable Daily Intake) |  |  |
| A6.17 | Effects on humans  State 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 levels  Studies 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-systems  For 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 substance  State classification according to Directive 67/548/EEC, or proposed classification |  |  |
| A18. Recommended risk and protection information in relation to: | | | |
| A18.1 | Handling  Enclose proposed safety data sheet |  |  |
| A18.2 | Storage |  |  |
| A18.3 | Transport |  |  |
| A18.4 | Danger of fire |  |  |
| A19. Destruction methods | | | |
| A19.1 | Destruction methods  State method, appropriate chemicals, final product etc |  |  |
| A20. Reference list | | | |
| A20.1 | Reference list  State title, author, lab, and other information that can facilitate the identification of each annex |  |  |