Data requirements for biocidal pesticides and their active substances

In addition to the data requirements mentioned in this Annex, also information about the applicant, manufacturer and the composition and range of use of the product shall be submitted.

The studies shall be made according to the OECD Guidelines for Testing of Chemicals or EU testing methods (Dir 67/548/EEC) following the OECD Principles of Good Laboratory Practice (GLP).

A justification/explanation shall be given, if it is technically impossible to execute or scientifically justifiable not to execute a study, or if the studies submitted are not made according to the above mentioned guidelines.

A. Active substance

A.1 Information and studies on physical and chemical properties and analytical methods

A.2. Toxicological data

A.3. Studies on environmental effects

B. Product

B.1. Information and studies on physical and chemical properties and analytical methods

B.2. Toxicological data

B.3. Studies on environmental effects

Finnish Safety and Chemicals Agency

Helsinki
P.O. Box 66 (Opastinsilta 12 B)
FI-00521 Helsinki
Finland

Tampere
Kalevantie 2
FI-33100 Tampere
Finland

Rovaniemi
Valtakatu 2
96100 Rovaniemi
Finland

Tel. +358 29 5052 000
www.tukes.fi
e-mail kirjaamo@tukes.fi
Business ID 1021277-9

A. Active substance

A.1. Information and studies on physical and chemical properties and analytical methods

Information/study	**Data requirements**
1. Identity of the active substance *Common name, chemical name according to IUPAC, CAS and EC No, molecular and structural formula (also isomers), molecular weight*	Shall always be submitted
2. Purity of the technical active substance *State in % (w/w)*	Shall always be submitted
3. Quality and quantity of impurities in the active substance *State optical isomers, by-products of synthesis, decomposition products etc. in % (w/w). Use IUPAC or CA nomenclature. Analytical methods and their accuracy shall be stated.*	Shall always be submitted
4. Other additives in the active substance *e.g. stabilizing agents, inhibitors etc. Concentrations in % or ppm*	Shall always be submitted
5. Manufacturer of the active substance, contact information	Shall always be submitted
6. Description of synthesis of the active substance	Shall always be submitted

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7. The origin of the active substance or precursors to active substance if derived from nature *e.g. flower extract*	Shall be submitted if active substance is derived from nature.
8. Melting point, boiling point, relative density	Shall always be submitted
9. Vapour pressure (Pa)	Shall always be submitted
10. Appearance *Physical state, colour*	Shall always be submitted
11. Spectral data: UV/VIS, IR, NMR, MS	Shall always be submitted
12. Water solubility	Shall always be submitted. The influence of pH (5-9) and temperature on solubility shall be stated.
13. Dissociation constant	Shall be submitted if possible to measure.
14. Solubility in organic solvents	Shall always be submitted. Should be made using at least two commonly used organic solvents, which have different polarities. The influence of temperature shall be stated.
15. Stability in organic solvents and information on identity of significant decomposition products	Shall be submitted if active substance is dissolved in organic solvent (e.g. for transportation or storage).
16. Partition coefficient n-octanol/water	Shall always be submitted. The influence of pH (5-8) and temperature shall be stated.
17. Thermal stability and information on identity of significant decomposition products	Shall always be submitted
18. Flammability including auto-flammability and identity of combustion products	Shall always be submitted

19. Flash-point	Shall always be submitted
20. Surface tension and viscosity	Shall always be submitted on liquids.
21. Explosive properties	Shall always be submitted
22. Oxidizing properties	Shall always be submitted
23. Reactivity toward container material	Shall always be submitted
24. Analytical methods including yields and detection limits to determine active substance and, if needed, significant decomposition products, isomers and impurities, if appropriate, in soil, water and biological material (fluids and tissues of animals and humans, treated foodstuff and feed).	Shall always be submitted.

A.2. Toxicological data

Way of application

In toxicological research the basic way of application is oral. That is the best way of finding out the endogenic properties or the possible risk caused by product. Depending on the properties of the pesticide or the methods of application it might be recommendable to do tests for dermal or inhalation toxicity, e.g. if the metabolism of the active substance differs due to the route of exposure or if the main way of exposure is through skin or inhalation.

Information/study	**Research requirements**
1. Acute toxicity (oral, dermal or inhalation or any other ways of exposure)	Research should be made using at least two ways of application. Oral toxicity is always mandatory. Also, depending on the way of use, the dermal or inhalation toxicity shall be investigated. If both dermal and inhalation exposure is significant, dermal and inhalation toxicity shall be tested. Inhalation toxicity shall always be tested if • active substance is gaseous or liquefied gas • if it will be used as smoke, aerosol, steam or vapour

	• if its vapour pressure is more than 1 x 10^{-2} Pa • or if particle or drop size is less than 50 µm. Dermal toxicity shall always be tested, if the product that contains the active substance is spread straight on bare skin.
2. Skin irritation	Shall be submitted, except if serious skin damage is obvious because of corrosive properties of the active substance (pH $\leq$ 2 tai pH $\geq$ 11,5).
3. Eye irritation	Shall be submitted, except if the active substance is corrosive on the skin or pH $\leq$ 2 or pH $\geq$ 11,5.
4. Sensitization	Shall always be submitted.
5. 21- or 28-day study	Not mandatory, but if available, the data shall be submitted.
6. 90-day study	Shall always be submitted (rats). If necessary, the test needs to be made with another mammal than rodent.
7. Subacute or subchronic data for other ways of exposure, animals or duration of study	If other researches made (e.g. 1 year feeding study), the data shall be submitted. 1 year feeding study with dog might be necessary, if in 90 days study results show that the dogs are much more sensitive than rats.
8. Chronic toxicity	Shall be submitted if study is available.
9. Carcinogenicity	Shall be submitted if exposure is repeated or according to other investigations there is possibility for carcinogenicity.
10. Mutagenicity	At least three *in vitro* –tests needs to be delivered: gene mutation test on bacteria e.g. Ames test [OECD guideline 471], chromosome aberration test on mammalian cells [473] and gene mutation test on mammalian cells [476]. If some of the *in vitro* –tests is positive, *in vivo* –genotoxicity test (chromosome aberration test on mammalian bone

	marrow [475] or micro nucleus test[474]) is needed. If *in vivo* –genotoxicity test is negative (but some of the *in vitro* –tests is positive), there needs to be done another *in vivo* –test with another tissue than bone marrow [e.g. 484 and 486]. If *in vivo* –bone marrow test is positive, there may be requirement for testing the effects on reproductive cells with e.g. dominant lethal test [478] or spermatagonial chromosome aberration test [483].
11. Effects on reproduction, at least 2-generation study	Data of the effects on reproduction shall always be submitted.
12. Teratogenicity	Data at least for two species (rabbit and rodent) shall be submitted.
13. Neurotoxicity	If neutrotoxicity (toxic to nervous system) data is available, it shall be submitted. Neurotoxicity tests needs to be made always if in other researches have been noticed toxic symptoms to nervous system, especially if organophosphate, carbamate or pyrethroid is in question.
14. Toxicity of metabolites, degradation products, impurities etc.	If these researches have been made, the data shall be submitted.
15. Metabolism in animals	Data on high and low doses shall be submitted. If exposure is of long duration, it is recommended to study the effects of recurrent doses. If there is any risk of dermal exposure, it is recommended to submit data on the penetration of substances through the skin.
16. Toxic mechanism	The mechanism should be cleared.
17. Toxicity to humans	Information on poisonings and employee health control data shall be submitted

A.3. Studies on environmental effects

Exceptions in data requirements can be made if the product is used inside or around buildings only (do not apply to rodenticides) or if the formulation type is such (e.g. mosquito candle or smoke) that when used outside the exposure to the environment is insignificant. However, the information necessary for classification of the product (under 4, 9, 10, 11 and 12) as well as under 14 shall always be submitted for all the products.

Information/study	**Data requirements**
Environmental behaviour	
1. Adsorption/desorption, screening test	Shall always be submitted
2. Hydrolysis	Hydrolytic degradation as a function of pH shall always be submitted. Degradation products, which in some time point have formed 10 % of the active substance used, shall be identified.
3.Photochemical decomposition	Shall always be submitted. Degradation products, which in some time point have formed 10 % of active substance used, shall be identified.
4. Biological decomposition ”ready biodegradability”	Decomposition data on ”ready biodegradable” – test shall be submitted, if simulation test has not been made.
5. Biological decomposition ”inherent biodegradability”	Shall be submitted if data is available.
Effects	
6. Acute toxicity to birds	Shall always be submitted on rodenticides. Data on insecticides, pesticides against mite and insect repellents shall be submitted if the product is used outside buildings as baits, granule or powder.
7. Subacute toxicity to birds	Shall always be submitted on rodenticides. Data on insecticides, pesticides against mite and insect repellents shall be submitted if the product is used outside buildings as baits, granule or powder.
8. Reproduction studies on birds	Shall be submitted if data is available.
9. Acute toxicity to fish	Shall always be submitted

10. Bioconcentration	Bioconcentration shall be estimated or BCF-test on fish shall be submitted.
11. Acute toxicity to water flea	Shall always be submitted
12. Growth inhibition test on algae	Shall always be submitted
13. Effects on wastewater purification	Data on rodenticides shall be submitted if the product is used in wastewater drains or in other similar targets where it can end up in sewage plant.
14. Observations on unwanted or unintentional side effects	Shall always be submitted. Observations can be e.g. effects on beneficial or other than target organisms.

B. Product

B.1. Information and studies on physical and chemical properties and analytical methods

Information/study	**Data requirements**
1. Appearance *Physical state, colour*	Shall always be submitted
2. Explosive properties	Shall always be submitted
3. Oxidising properties	Shall always be submitted
4. Flash-point and other indications on flammability and spontaneous ignition	Shall always be submitted
5. Acidity/alkalinity and pH	Shall always be submitted. pH should be measured in 1 % aqueous solution.
6. Relative density	Shall always be submitted

7. Storage stability – Stability and shelf-life. *Effects of light, temperature and humidity on technical characteristics of the product; reactivity towards container material.*	Shall always be submitted
8. Technical properties of the biocidal product *e.g. wettability, permanent foaming, flowability, pourability and dusting*	Shall always be submitted
9. Surface tension and viscosity	Shall always be submitted on liquid products.
10. Particle size distribution	Shall be submitted if the product is in the form of powder or granules.
11. Analytical methods to measure active substance and, if necessary, significant decomposition products, isomers, impurities and additives in the product.	Shall always be submitted
12. Efficacy	If studies on biological efficacy and usability are available these shall be submitted. However, data on efficacy must be submitted when applying for an authorisation according to biocide directive at the latest.

B.2. Toxicological data

Information/study	**Research requirements**
1. Acute toxicity (oral, dermal or inhalation or any other ways of exposure)	Research shall be made using at least two ways of application. Oral toxicity is always mandatory. Also, depending on the way of use, the dermal or inhalation toxicity shall be investigated. If both dermal and inhalation exposure is significant, dermal and inhalation toxicity shall be tested. Inhalation toxicity shall always be tested if

	• active substance is gaseous or liquefied gas • if it will be used as smoke, aerosol, steam or vapour • if its vapour pressure is more than 1 x 10^{-2} Pa • or if particle or drop size is less than 50 µm. Dermal toxicity shall always be tested, if the product is spread directly on bare skin.
2. Skin irritation	Shall be submitted, except if serious skin damage is obvious because of corrosive properties of the product (pH $\leq$ 2 tai pH $\geq$ 11,5).
3. Eye irritation	Shall be submitted, except if the product is corrosive on the skin or pH $\leq$ 2 or pH $\geq$ 11,5.
4. Sensitisation	Shall be submitted, except when the product is known to be sensitising based on the properties of the active substance or other constituents.
5. Dermal adsorption	Shall be submitted if dermal exposure is to be expected.
6. Other toxicological data	If other toxicological researches have been made, the research data shall be submitted.
7. Toxicological properties of other constituents than the active substance	For other substances at least information on safety data sheet shall be submitted. Other toxicological information should be collected in a summary by the applicant.
8. Exposure information	Information and estimations on consumers and/or employees exposure to the product in a normal use and in a worst possible situation when product is used should be delivered. All possible ways of exposure (e.g. inhalation or dermal) should be estimated. If measured data, epidemiologic research data or modelled predictions on exposure are available, they shall be submitted.

B.3. Studies on environmental effects

Information/study	**Data requirements**
1. Foreseeable routes of entry into the environment on the basis of the use envisaged.	Shall always be submitted. E.g. entry of the active substance and other significant substances in the environment in the various stages of the product life cycle, estimation of the destination (soil, water, air) and the amount of discharge of the compounds.
2. Ecotoxicological data of the product	Shall be submitted if information cannot be derived from the data concerning the active substance.
3. Ecotoxicological data available on ecotoxicologically important substances other than active substance	Shall always be submitted. Information provided on safety data sheet is sufficient.

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Business ID 1021277-9