Finnish Safety and Chemicals Agency

30 September 2015

Guide to apply advance approval of wood preservatives and slimicides

Table of contents

1 GENERAL

This guide outlines regulations concerning the advance approval of wood preservatives and slimicides, application procedures and detailed instructions for documentation requirements. Its purpose is to make applying easier, harmonise the application procedures, and thus promote the rapid processing of applications by the Finnish Safety and Chemicals Agency (Tukes).

Finnish national advance approval procedure will be replaced by the procedure according to Biocidal Products Regulation (EU) No 528/2012 by the end of the transitional period.

1.1 For which chemicals must advance approval be applied for

According to the Chemicals Act (599/2013) a protective chemical must not be manufactured, imported, delivered for sale, or used without advance approval. Here protective chemicals refer to wood preserving and slime controlling chemicals. The advance approval of protective chemicals has been enacted in paragraphs 26 - 34 of the Chemicals Act (599/2013), in the Ministry of the Environment Decree (419/2014) on the Applications and Notifications Concerning Biocidal Products and Their Active Substances, and in the Decision (256/1994) of the Ministry of the Environment. Approval must be applied for chemicals that are intended for:

1) wood treatment to protect wood from deterioration or damage caused by harmful organisms (**wood preserving chemical**) or

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

2) use in pulp and paper industry for cooling and circulating water systems to prevent the formation of slime and to prevent clogging caused by the growth of harmful micro-organisms or for the protection of chemical and mechanical pulp from deterioration and damage caused by harmful organisms (**slime controlling chemical; slimicide**).

If it is unclear whether the chemical should be categorised as a wood preservative or a slimicide as defined by the Chemicals Act, it is better to consult Tukes on the issue. For example, enzymes fall within the scope of the approval system if their intended use corresponds to the definition of a slimicide. Approval can be applied for only those products which active substances are included in the review programme under the Review Regulation for the Biocidal Products Regulation (BPR).

1.1.1 Exemptions from the approval procedure

It is possible to perform **tests** with wood preservatives and slimicides without advance approval in order to find out their properties, effects, and usability. Notification of tests must, however, be made to Tukes if they are not laboratory or some other small-scale tests. Tukes prepares a permit to run the test and may restrict the test conditions if necessary.

The Ministry of the Environment may give orders concerning exemptions from the advance approval regulations and from the orders which are based on them, providing that an adequate level of safety can be achieved in some other manner.

1.1.2 Applying for renewed approval

Authorisation may be granted at maximum until the end of the transitional period of the BPR (i.e. until 31 December, 2024), however, *at maximum until a decision is made on a possible application for authorisation as a biocidal product* (Chemicals Act 27 §). In practice this means that authorisation as a biocidal product must be applied for at the date of approval of active substance contained in a product at the latest. In case such application is made, national authorisation remains valid until the decision according to BPR is made.

If approval is granted for a certain period of time, the applicant has to check the deadline for renewal of current authorisation. The deadline for application is normally 12 months before the valid approval period ends. The application for renewal has to be made in the same way as the advance approval application. Any new studies required by the authorities and any other possible new studies must be sent to Tukes in this connection. Any new information has to be mentioned in the application.

Authorisation required by the BPR must also be requested for biocidal products that have already been issued with a national authorisation decision. The application must be submitted by the date of the active substance approval. These applications are not applications for renewal.

1.1.3 Altering and cancelling of the approval

Tukes needs to be notified of all changes which relate to the product.

Any **changes in the applicant**, i.e. if the identity of the manufacturer or importer changes, have to be notified to the SYKE without delay. When necessary, a new letter of authorization from the owner of the documentation shall be submitted to make it possible to refer to the documentation submitted earlier. Also, **changes in the product name** must be notified in advance to Tukes. In this case any renewed labels, safety data sheets and instructions for use must also be submitted to Tukes. Tukes will confirm the change of the product name in writing.

If **the composition of the product** is to be changed, a written request to Tukes must be made in good time. The request must include detailed information on the new composition and any possible changes in classification, labelling etc. The planned timetable for the change must also be presented as well as a clearly reasoned account of the feasibility of using the documentation for the previous formulation in the evaluation of health and environmental effects of the new formulation. Tukes will make a decision on the composition change. However, if the suggested change is fundamental, the product will be considered to be a new one. In such a case an advance approval must be applied for.

Tukes can **cancel the approval decision or alter its conditions**, if it becomes evident after the product has been approved that the protective chemical no longer fulfils the prerequisites for approval or the conditions attached to the approval decision. Also the holder of the approval may propose the cancellation of approval to Tukes. In such cases proposals concerning the necessary transitional periods for finishing the manufacturing, importing, placing on the market and use must also be presented.

1.2 Who can apply for approval

Approval has to be applied for by the entrepreneur who first places the product in the market in Finland, being usually the manufacturer or importer. If the manufacturer of a protective chemical or its active substance is a foreign company, the party applying for advance approval has to present an account for its right to represent its principal in Finland in matters concerning the product or the active substance.

The product may be marketed by companies other than the holder of the approval. If the product is marketed with many trade names, all of its names must be declared to Tukes.

1.3 Approval of wood preservatives and slimicides during the transitional period of the Biocidal Products Regulation

Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market was implemented in Finland with Amendment 1198/1999 of the Chemicals Act. This amendment Act came into force on 13 May 2000 and it repealed the previous regulations on wood preservatives and slimicides. However, section 2 of the transitional provision of Amendment Act 1198/1999 states that previous regulations which

were in force before this Act are applied on biocidal products containing active substances which were on the EC market when this Act came into force, until the decision on the inclusion of the active substance into an Annex of the Biocides Directive has been made. This procedure will continue during Biocidal Products Regulation, which came into force on 17 July, 2012 and was applied after 1 September 2013. Therefore, for products containing existing active substances the approval system of wood preservatives and slimicides continues as before until a decision is made on the active substance according to the BPR. The aim is to evaluate all existing biocidal active substances on the market according to the provisions of the BPR by 31 December 2024.

The applicant for the approval of a wood preservative or slimicide must check whether the active substance in the product has been on the market before 14 May 2000, whether the active substance is included in Annex II to Commission delegated regulation (EU) No 1062/2014 in correct product type, and whether decision has possibly been made on approval the active substance; that is whether the national regulations on wood preservatives and slimicides can be applied on the product. Further information on the BPR and provisions during its transitional period are available e.g. on the Internet-site www.tukes.fi/biocides

2 CONTENTS OF THE APPLICATION AND REQUIRED STUDIES

The contents of an application for the approval of a protective chemical have been enacted in The Ministry of the Environment Decree concerning applications and notifications of biocidal products and their active substances (419/2014)). The detailed instructions below (item 5) show which information and research reports the applicant must provide in each separate case. The application can be made in Finnish or English.

In connection with the application, the applicant must clearly identify any information which is considered to involve business and professional secrets and justify each claim made. This information can be presented in separate appendixes. Information that cannot be considered secret has been listed in the Chemicals Act 58 §. If the applicant wishes to refer to studies and reports related to other products previously submitted to the authorities, he has to justify his right to use them.

Studies concerning the properties of wood preservatives and slimicides must be conducted either according to the guidelines mentioned in Council Regulation 440/2008/EC laying down test methods pursuant to Regulation (EC) No 1907/2006 (REACH regulation) or according to the OECD (Organisation for Economic Co-operation and Development) guidelines for testing of chemicals. In addition, studies should be conducted in compliance with the EC and OECD principles of good laboratory practice (Chemicals Act 24 §) about which a statement has to be attached to the study report. **The composition and impurities of the tested chemical must be precisely given.**

If it is not technically possible or scientifically justifiable to give the required information or carry out the required studies, or if the studies are not conducted according to the guidelines given above, then the reasons why this is so must be given in the application. If the relevant

information can be obtained using other studies than those presented in the Decision of the Ministry of the Environment (256/1994), the use of such studies **has to be justified in the application**. If such justifications are not given, or if the application is otherwise insufficient, Tukes will ask the applicant to submit the missing information and studies. The processing of the application will continue after the supplementary data has been presented. If the application is still inadequate an additional fee will be charged for a further request to complete the application. The decision on the application may be taken even in that case that supplementary data are not delivered in due time (Administrative Act 434/2003 33§).

The test methods and guidelines must, whenever possible, be chosen so that the use of laboratory animals is minimised or totally avoided (BPR art. 62). According to this principle, before starting a new test, literature searches should be conducted and the other owners of the required documentation should be consulted in order to find out, whether the available information is sufficient for the reliable evaluation of the possible hazards of the chemical. If information is available, but it is inadequate, the scope of the additional studies required should be considered on a case-by-case basis.

The manufacturer or the importer of the chemical must submit to Tukes all new data which is necessary for the evaluation of the hazardous properties of the chemical. Also information related to changes of the applicant, product name, composition etc. must always be submitted in advance to Tukes.

3 FILLING THE FORM AND APPENDIX MATERIAL

The applicant is responsible for giving the required information in the application and for including the research reports and other documents needed. Tukes has standard forms which can be used for applying for advance approval. These forms may be retrieved at the Internet www.tukes.fi/biocides. Applications need not be made using the standard forms; they can be made in any other format providing that all the necessary information is included. There are separate forms for notifications of tests concerning wood preservatives and slimicides. All the forms are available in Finnish and English.

The approval is applied for with a product application form which is filled with information about the product and its properties. For the evaluation of the active substance the applicant must provide a letter of access to the active substance dossier which is evaluated under the BPR or which is listed in art 95 list of the BPR.

The required information should be briefly presented on the form; **it is not enough to merely refer to an appendix**. If those studies and information are not submitted, the reasons for these omissions must be stated in the application. Original research reports and other documents on which the given information is based must be attached to the application. Any appendixes relevant to the application must be mentioned on the form. **All appendixes must be numbered using the same numbering scheme that is used in the application form (e.g. A 1, A 2.1 etc.)**. If several studies are related to one item, they should be separated by lower case letters following the appendix number.

The application and appendixes must be submitted to Tukes in a paper copy or electronically.

4 HANDLING OF THE APPLICATION

The first step Tukes will take when processing the application, is to check that all the required documents have been submitted. When necessary, the applicant will be asked to complete his application. When new appendixes are submitted, updated list of appendixes must also be attached (A 18). If the application is not completed before a set deadline, Tukes **can reject an insufficient application**.

Tukes will evaluate the health and environmental effects of the product and its active substance(s), the biological efficacy of the protective chemical and the safety measures required in safe use. In accordance with the Administrative Act (434/2003, 34§) the applicant will be afforded an opportunity to be heard following the submission of the statement(s) on health effects and safety measures. On the basis of the statements and evaluations Tukes will decide upon the approval of the protective chemical in accordance with paragraph 27 of the Chemicals Act and verify in this connection its intended use and the instructions for its use. Conditions and instructions can also be attached to the approval decision. In cases where the applicant disagrees with a decision, he may appeal the decision to the County Administrative Court (see Administrative Appeals Act 586/1996 with its amendments).

Tukes will charge a fee for processing an application after the decision has been made. Charges are determined by the date when the application has become effective according to Decree of the Ministry of Employment and the Economy on the Charges of Finnish Safety and Chemicals Agency.

The applicant is responsible for the direct submission of information on hazardous chemicals to the Tukes Product Register of Chemicals for registration in accordance with the Decree of the Ministry of Welfare and Health (553/2008). It is recommended that the registration notification is made after the decision on advance approval. Further information and necessary forms can be obtained from:

Finnish Safety and Chemicals Agency (Tukes)
Chemical Products Register
Kalevantie 2
FI-33100 Tampere
Finland

e-mail: tuoterekisteri@tukes.fi

5 DETAILED INSTRUCTIONS FOR FILLING IN AN ADVANCE APPROVAL FORM

PART A - INFORMATION ON THE FORMULATED PRODUCT

A 1 GENERAL INFORMATION

1.1 Name, address, telephone number and other contact information of the applicant	The name and contact information of the applicant, i.e. **the manufacturer or importer**.
1.2 Name and address of manufacturer	State if the application deals with a product manufactured abroad.
1.3 Name of the formulated product	The trade name or the trade mark of the product. If the product is marketed with several different names in Finland, they should be stated here. If the marketing company of the identical product is other than the applicant, this should be stated in connection with the product name.
1.4 Authorisation from the manufacturer	The authorisation letter should be attached to the application, if the manufacturer of the protective chemical is other than the applicant.
1.5 Is the name of the protective chemical a registered trademark in Finland?	Must always be stated.
1.6 The official employer identification number (LY code) of the applicant	Must always be stated.
1.7 Prior approval	Must always be stated either if the product has not been approved earlier (**a new application**) or if the product has been previously accepted as a protective chemical based on the Chemicals Act (**application for the reapproval**).

A 2 INFORMATION ON THE PRODUCT

2.1 Type of protective chemical	State, if the product is a wood preserving chemical and/or a slime controlling chemical.
2.2 Product's mode of action	State if known.
2.3 Ingredients of the product	
2.3.1 Names of active substance(s) in the product and their	All active substances in the product must be given using general names accepted or suggested by ISO (International Standardization Organization).

concentrations and classifications	The chemical names of active substances must be given according to IUPAC (International Union of Pure and Applied Chemistry) or CA (Chemical Abstracts), also a CAS number and either the EINECS (European Inventory of Existing Commercial Substances) or the ELINCS (European List of Notified Chemical Substances) number. The concentrations of the active substances in the product should be given either as g/l (in which case state also as % per weight) or as g/kg. The active substances are classified according to the decree of the Ministry of Social Affairs and Health (807/2001, changes 687/2005, 206/2007, 655/2008 and 6/2010) and according to CLP-regulation EU (Nr) 1272/2008, change 790/2009
2.3.2 Other ingredients in the product and their concentrations and classifications	The chemical name of each ingredient according to IUPAC or CA and their content in the product (either g/l **and** % per weight or g/kg), classification, CAS number and either EINECS or ELINCS number must be stated. **Trade names are not suitable**. The function of the ingredient must also be mentioned (e.g. solvent, stabiliser). If the composition of single ingredients varies (e.g. hydrocarbon solvents), it has to be mentioned The ingredients are classified according to the decree of the Ministry of Social Affairs and Health (807/2001, changes 687/2005, 206/2007, 655/2008 and 6/2010) and according to CLP-regulation EU (Nr) 1272/2008, change 790/2009 Some substances are classified in the Decision of the Ministry of Social Affairs and Health of Dangerous Substances (624/2001). Chemicals dangerous for health and the environment and flammable and explosive chemicals (see paragraph 11 of the Chemicals Act) are defined in detail in paragraph 3 of the Chemicals Decree.
2.4 Classification of the product	The preparation is classified according to the decree of the Ministry of Social Affairs and Health (807/2001 changes 687/2005, 206/2007, 655/2008 and 6/2010) and according to CLP-regulation (EU) Nr 1272/2008, change 790/2009.
2.5 Physical state and colour of the product	State if the product is solid (e.g. powder) or liquid (solution, emulsion etc.), and the colour of the product.
A 3 USE OF THE PRODUCT	
3.1 Intended use of the product	State e.g. what material the product is intended to protect and its range of use (e.g. for protecting timber against blue-staining, for protecting pulp against slime etc.).

3.2 Application concentration and method of addition

The recommended dose of the product and the active substance per object (e.g. per surface area of the material to be protected or as a concentration in a water system), and the method of addition for the product in different uses. If the product is to be diluted, the substance used for dilution and concentration of the active substance in the solution as a percentage must be stated.

3.3 Application techniques

The spreading or other application technique of the product (e.g. dipping, spreading, spraying etc.), the recommended duration of application and possible reapplications. The substances that may have to be added to the solution and their dosages must also be given.

3.4 Miscibility

State if the product cannot be mixed with other protective chemicals or other substances. If the use of the product together with other protective chemicals is recommended, they have to be mentioned separately, and a report on the inertness of the mixtures and the substances that can be generated by mixing has to be attached to the application.

3.5 Usability and biological efficacy

The applicant must always demonstrate that the product is biologically efficient and suitable for its intended use when applied according to the instructions for use. This can be confirmed either with laboratory, pilot plant or field tests or with any other test, the conditions of which are comparable with the Finnish environmental characteristics and with the purpose applied for. Actual efficacy studies need not to be supplied if a statement is available concerning the efficacy and usability of the product given by an expert institute or a similar objective organisation. Wood impregnating chemicals should have a statement given by the NTR (Nordiska Träskyddsrådet, i.e. the Nordic Wood Preservation Council - NWPC).

3.6 Binding of the active substance in the treated product

For wood preservatives, information on the minimum drying time of the treated timber has to be attached to the application, i.e. when it is dry enough to be given over for other treatment. Also information on the binding of the active substance to wood or other treated material, factors influencing binding properties and a report on how the active substance or the other ingredients in the product are released from the treated material by evaporating, dissolving or some other way should be supplied. For slimicides, information on residues in the commodity (e.g. paper or paperboard) due to the use of the chemical should be given.

3.7 Estimation of amounts manufactured or imported annually

Must be stated as kilograms or as metric tonnes. The estimate should be as accurate as possible.

3.8 Directions or restrictions as to the treated products

Possible restrictions or recommendations concerning the product in Finland or in other countries (e.g. concerning the use of impregnated wood inside or the avoidance of the continuous use of a slimicide in order to prevent the

development of resistant microbial strains) and their grounds. Instructions for use of the treated wood must be attached to the application of a wood preservative.

A 4 PRODUCT PACKAGE

4.1 Proposal for labelling

A proposal for the text on the sales or other package should always be attached to the application. The text should include the trade name of the protective chemical, the name, address and telephone number of the manufacturer or importer, the names and concentrations of the active substances, the names of dangerous substances in the product which influence the classification of the product, indications of danger and R and S phrases and the intended use of the product. Furthermore, the labelling must include a reference to the separate instructions for use and the approval by Tukes. In packages of chemicals sold by retailers, instructions for use and for the handling of the waste generated from the chemical and its package should also be mentioned. (See CLP Regulation (EC) No 1272/2008 and Biocides Regulation (EU) No 528/2012 art. 69 based on Chemicals Act. 30 §.)

4.2 Package

The package material and type (barrel, can, plastic bottle etc.) and package size (for liquids volume, for others weight).

A 5 HEALTH EFFECTS OF THE PRODUCT

Tests concerning the health effects of the protective chemical have to be conducted with the product for which approval is applied for.

5.1 Acute oral toxicity

Always required. The animal species used in the test, the effects observed, adverse effects in organs etc. and the LD_{50} (mg/kg) value with its 95% confidence interval must be stated. If the acute oral toxicity of the product is found to be low in the limit test, i.e. the LD_{50} value is over 2 000 mg/kg, an exact LD_{50} value does not have to be defined. The rat is the preferred test species. E.g. EC method number B.1. bis or B.1. tris or OECD guideline number 420 (Acute oral toxicity - fixed dose method) or OECD 423 (Acute toxic class method). Available studies made earlier according to EC method number B.1. or OECD guideline number 401 (Acute oral toxicity) are also accepted.

5.2 Acute dermal toxicity

Always required. The animal species used in the test, the effects observed, adverse effects in organs etc. and the LD_{50} (mg/kg) value with its 95% confidence interval must be stated. If the acute dermal toxicity of the product is found to be low in the limit test, i.e. the LD_{50} value is over 2 000 mg/kg, an exact LD_{50} value does not have to be defined. The rat and the rabbit are the preferred test species. E.g. EC method number B.3. or OECD

guideline number 402 (Acute dermal toxicity).

5.3 Acute inhalation toxicity

Always required. The animal species used in the test, method of exposure (e.g. gas, solid or liquid aerosol), exposure period, the effects observed, adverse effects in organs etc. and the LC_{50} (mg/l) value with its 95% confidence interval must be stated. If the acute inhalation toxicity of the product is found to be low in the limit test, i.e. the LC_{50} value is > 5 mg/l, an exact LC_{50} value does not have to be defined. The rat is the preferred test species. E.g. EC method number B.2. or OECD guideline no. 403 (Acute inhalation toxicity).

5.4 Dermal irritation

A study is always required if the product is not a strong acid or base (pH is not below 2 or above 11.5). The means of scores describing erythema, eschar formation and oedema should be given on the form. The rabbit is the preferred test species. E.g. EC method number B.4. or OECD guideline number 404 (Acute dermal irritation/corrosion).

5.5 Eye irritation

If the product irritates the skin or is corrosive, eye irritation does not have to be studied. In other cases a study is always required. The values describing the intensity of the effect regarding corneal opacity, injuries of the iris, redness and chemosis of the conjunctivae should be given on the form. The rabbit is the preferred test species. E.g. EC method number B.5. or OECD guideline number 405 (Acute eye irritation/corrosion).

5.6 Other toxicological studies

Other toxicological studies conducted with the product, e.g. subacute or sub-chronic toxicity, if they are available.

5.7 Evaluation of the toxicity of the other ingredients in the product

A short evaluation of the basic toxicological properties (acute toxicity, irritation, sensitisation etc.) of the other substances (e.g. solvents) in the product must be attached to the application. The sources (literature references) of the information presented have to be given in the evaluation. The original studies do not have to be attached.

5.8 Sensitisation

An evaluation of the sensitising properties of the product. The sources of the information presented have to be stated in the evaluation. The original studies do not have to be attached.

A 6 ENVIRONMENTAL EFFECTS OF THE PRODUCT

The tests concerning the fate and effects of the protective chemical product in the environment have to be conducted with the product for which approval is applied for.

6.1 Fate in the environment

6.1.1 Mobility and adsorption

Can be required if studies with the active substance are not sufficient, e.g. if

	the composition or the application technique of the product influence the mobility and adsorption properties considerably.
6.1.2 Degradation and transformation	See 6.1.1.
6.1.3 Other studies	See 6.1.1. Other information and studies on the product concerning the fate of the substance than those mentioned above if such are available (e.g. bioavailability).
6.2 Effects on terrestrial organisms	Possible studies conducted with the product concerning toxicity or other effects on terrestrial organisms (micro-organisms, invertebrates, birds, mammals etc.), if such are available. The species, type, duration, and result of test must be mentioned on the form.
6.3 Effects on aquatic organisms	
6.3.1 Acute toxicity to Daphnia (water flea)	The species and the EC_{50} (48 h) value with its 95% confidence interval should be given on the form. E.g. EC method number C.2. or OECD guideline number 202 (Daphnia sp. acute immobilisation test and reproduction test) in which the test can be combined with the study in A 6.3.2.
6.3.2 Effect on the reproduction of Daphnia	Always required. The species and the duration and the EC_{50} or NOEC value with its 95% confidence interval should be given on the form. E.g. OECD guideline number 202 or 211.
6.3.3 Other studies	Studies with e.g. other water organisms like fish or algae, if such are available. The species, test type, duration and result should be given on the form.
6.4 Evaluation of the environmental effects of other ingredients in the product	A short evaluation of the fate of ingredients other than the active substances and their toxicity to different organisms must be attached to the application. The sources (literature references) of the information presented have to be given in the evaluation. The original studies do not have to be attached.

A 7 PHYSICAL, CHEMICAL, AND TECHNICAL PROPERTIES OF THE PRODUCT

7.1 pH	State if possible.
7.2 Density	Must always be stated.
7.3 Particle size	State if the product is powder or granular.

7.4 Suspension and emulsification properties	State if possible.
7.5 Storage stability	Must always be stated. The compounds which are generated in the decomposition due to storage, aging, light, warming etc. must also be given.
7.6 Corrosive properties	State if possible.
7.7 Vapour pressure	In pascals (Pa). State if possible (calculated or measured).
7.8 Flash point	State if possible.
7.9 Inflammability and explosivity	Must always be stated.
7.10 Other possible data	Information on other physical, chemical and technical properties of the product should be stated, if available.

A 8 CLASSIFICATION ACCORDING TO SPECIAL REGULATIONS

8.1 Transport classification	Must always be stated. National (e.g. VAK-classification) and possibly international transport classifications (by land, by sea, by air; e.g. RID, ADR classifications) and possible UN-number.
8.2 Other regulations	State on request.

A 9 WASTE DISPOSAL

If the waste disposal method suggested is burning, the compounds generated by burning, recommended burning conditions (temperature, reaction time and oxygen content) and other information needed for the safe disposal of the waste must be mentioned in the appendix. If a landfill is recommended for disposal, information about the necessary preliminary treatment, the fate of the waste in the landfill, the release of active substances from the waste etc. must be given.

Information necessary for safe disposal must also be given regarding other disposal methods. If preliminary treatment of the waste is necessary, information about it must also be given. If the substance is considered to be hazardous waste (see the Waste Act, 646/2011 and Waste Decree (179/2012) appendix 4 the list of hazardous wastes), this has to be mentioned separately. The possibilities for recycling or reuse must also be presented.

In Finland the classification of hazardous wastes is regulated with Ministry of the Environment Decree on list of wastes and hazardous wastes (179/2012). For the purpose of this classification “hazardous substance” is defined as chemical classified as hazardous according to the Chemicals Act. Limit values has been set for the concentration of a chemical in the waste in Council of State Decree 179/2012 according to which the waste is classified as hazardous. The regulations on handling of hazardous waste should be taken into account when preparing instructions for treatment of hazardous waste. The most essential regulations are:

- Council of State Decision on waste dumps (861/1997). It bans the dumping of hazardous waste on municipal waste landfill
- Council of State Decree on incineration of waste (151/2013)
- Council of State Decree on waste (179/2012) where it is regulated e.g. that each transfer of hazardous waste must be accompanied with an obligatory transfer document.

9.1 Product

Must always be stated. A chemical or other disposal method for the product.

9.2 Waste generated from the application

Must always be stated. Disposal methods for the waste generated when using the product (e.g. for wood preservatives precipitate generated by dipping, spreading instruments etc. and for slimicides pulp residues treated with the product).

9.3 Empty packages

Must always be stated. Information must be given on how the package is emptied and cleaned and the recycling or disposal method for empty packages.

9.4 Waste from treated product

Must always be stated. Disposal methods for the waste generated from a treated product (e.g. wood) and in the processing of the treated product (sawing, planing or other such treatment waste) and for products no longer used (e.g. impregnated wood).

Waste wood containing hazardous substances has been classified as hazardous in the EU since 1 January 2002. A statement based on detailed calculations should submitted on whether waste wood containing the wood preservative (both waste from woodworking and treated wood after its service life when becoming waste) is classified as hazardous waste according to Council of State Decree 179/2012. Classification of substances in the product as hazardous for health or the environment based on CLP Regulation. Concentration limits given in Decree 807/2001, changes 687/2005, 206/2007, 655/2008 and 6/2010 can be used in the hazardous waste classification based on environmental hazard if no study results are available on the ecotoxicity of treated wood. CLP Regulation contains concentration limits for hazardous waste classification based health hazard. Other information needed for hazardous waste classification are e.g. concentration of the wood preservative in the treated wood and its leaching or other disappearance during the service life, and duration of service life of the wood treated for different protection/use classes. It can be assumed that the service life of wood treated for the Nordic class A is 20 years and 10 years for classes AB and B.

A 10 METHODS OF ANALYSIS

10.1 Analysis of the active substance in the product

A qualitative and quantitative method for defining the active substance in the product must always be stated.

A 11 SAFETY PRECAUTIONS

11.1 Handling

Must always be stated. Technical safety precautions when handling the product, during different stages of the process and when handling material treated with the product. Precaution measures during service should be especially considered. Personal protective equipment during different stages of the process. Prevention of environmental effects and measures to be taken when the product is released to the environment due to an accident or misuse. The information can be given in the safety data sheet or in the instructions for use, which must be attached to the application (see A 16 and A 17).

11.2 Storage

See A 11.1. Safety precautions during storage.

11.3 Transportation

See A 11.1. Safety precautions while being transported.

11.4 Fire risks

See A 11.1. Safety precautions for preventing fire risks.

A 12 TOXICITY TO HUMANS

12.1 Information on known intoxications and exposure during manufacture and use

State if empirical information on the effects in humans is available.

12.2 Exposure studies on industrial hygiene

State if information is available. E.g. information on concentrations in workplace air or on biological monitoring. The original studies or the sources of the information (literature references) must be supplied.

A 13 FIRST AID INSTRUCTIONS IN CASES OF POISONING

Must always be stated. Possible antidote and other measures. The information can be given in the safety data sheet (A 16) or instructions for use (A 17).

A 14 USE OF THE PRODUCT IN OTHER COUNTRIES

In which countries and for what purposes the protective chemical is used and in which of these countries has advance approval by authorities been required. Possible restrictions for use in other countries should be stated in A 3.8.

A 15 OTHER INFORMATION

15.1 Names of institutions or companies that are responsible for the studies referred to in this application	A list of institutions etc. that have conducted the studies should be given on request.
15.2 Other information on the product and literature references not given before	State on request.

A 16 SAFETY DATA SHEET

A proposal for a safety data sheet is attached to the application. The safety data sheet must be made according to REACH regulation Annex II. The applicant must separately submit for registration information on chemicals causing hazards to the Chemical Products Register of Tukes according to decree 553/2008 of the Ministry of Social Affairs and Health. It is recommended that the registration notification is submitted after the decision on advance approval is made.

A 17 INSTRUCTIONS FOR USE

A proposal for the instructions for use of the product for e.g. working places has to be attached to the application in Finnish or Swedish. The instructions for use should be also written in the other national language when necessary. It must comprise the intended use of the product, limitations of use, labelling, summary of health and environmental effects, technical instructions for use, occupational safety instructions for different work stages, environmental protection instructions, first aid instructions, instructions in case of accidents, and waste disposal instructions (see paragraph 4 of the decision by the Ministry of the Environment 256/1994). See more detailed instructions in the Guide "How to prepare instructions for the use of slimicides and wood preservatives".

A 18 NUMBERED LIST OF APPENDIXES

A separate, numbered list of appendixes should be attached to the application. The list must include the name of the study, performer, research laboratory, date, report number and the bibliographical information of scientific publications. **The numbering of the list must follow the same numbering scheme as that used on the application form**. **An updated list of appendixes must be attached when submitting new data to Tukes.**

PART B - INFORMATION ON THE ACTIVE SUBSTANCE (This information is included in the active substance dossier for which the applicant provides a letter of access)

B 1 GENERAL INFORMATION

1.1 Name of the product which is related to the information on active substance	Must always be stated. If several products for which approval is applied for have the same active substance, all the names should be given.
1.2 Name, address and telephone number of the Finnish manufacturer or importer of the active substance	Must always be stated.
1.3 Name of the foreign manufacturer of the active substance	Must always be stated, if the application deals with an active substance manufactured abroad.
1.4 Authorisation from the manufacturer of the active substance	The right to use the documents concerning the active substance must be shown, if the applicant himself has not had the studies done.

B 2 IDENTIFICATION

2.1 Chemical name	Must always be stated according to IUPAC.
2.2 Other names	The common name accepted or suggested by ISO and other generally known names, trade names, abbreviations, manufacturing codes etc.
2.3 Trade names of other products containing the active substance	State if the active substance is also used in other traded products.
2.4 CAS number and EINECS or ELINCS number	Must always be stated, if the active substance has a CAS number and a EINECS or ELINCS number (see page 8).
2.5 Empirical formula	The empirical formula should always be stated.
2.6 Structural formula and optical isomers	Must always be stated, optical isomers as well.
2.7 Molecular weight	Must always be stated.
2.8 Spectral data	UV, IR and other spectral data.

B 3 INFORMATION ON THE TECHNICAL ACTIVE SUBSTANCE

3.1 Purity	The purity of the technical active substance should always be given as a percentage (w/w).
3.2 Type and quantity of impurities	Must always be stated. The chemical names according to IUPAC or CA and possible CAS-numbers of impurities, e.g. optical isomers, by-products of synthesis, degradation products etc. Concentrations should be given as percentages (w/w).
3.3 Additives to the active substance	Must always be stated. E.g. stabilisers, inhibitors etc. and their amounts as a percentage per weight or concentration (mg/kg).

B 4 INFORMATION FOR DETERMINATION OF THE ACTIVE SUBSTANCE

Quantitative and qualitative analytical methods with the necessary preliminary treatments for the determination of the active substance in soil (wood preserving chemicals), water and biological material, and the recoveries and the detection limits of the methods must always be given.

If information is available, the analytical methods with necessary preliminary treatments, recoveries and detection limits should be also given for the impurities of the technical active substance and for the main degradation products and metabolites.

B 5 DESCRIPTION OF THE PRODUCTION PROCESS OF THE ACTIVE SUBSTANCE

A general description of the synthesis of the active substance, the chemical reactions occurring in it, initial products and substances generated in the synthesis etc. should always be presented in the application or an appendix to it.

B 6 PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

Information on the state of aggregation, melting and boiling points, vapour pressure and solubility has to given both regarding the technical active substance and the chemically pure active substance. It has to be mentioned under other items as well if the tests have been performed with pure or technical active substances. The purity and composition of a technical active substance have to be the same as stated in B 3.

6.1 State and colour	Must always be stated.
6.2 Refraction index	State if available.
6.3 Melting point	Must always be stated, if it can be defined. If not, the sublimation or decomposition temperature should be given. E.g. EC method number A.1. or OECD guideline number 102 (Melting point/Melting range).
6.4 Boiling point	See 6.3 E.g. EC method number A.2. or OECD guideline number 103 (Boiling point/Boiling range).

6.5 Density	Must always be stated, if it can be determined. E.g. EC method number A.3. or OECD guideline number 109 (Density of liquids and solids).
6.6 Volatility	
6.6.1 Vapour pressure	Must always be stated, if it can be determined. Vapour pressure (in pascals, Pa) at two temperatures or as a vapour pressure curve. E.g. EC method number A.4. or OECD guideline number 104 (Vapour pressure curve).
6.6.2 Henry's law constant	Must always be stated, if it can be calculated. A parameter which depends on the water solubility and vapour pressure of a substance, and expresses the tendency of a substance to evaporate from aqueous solutions. The unit of Henry's law constant (H) should be stated as Pa x m^3 x mol^{-1} or as atm x m^3 x mol^{-1}.
6.7 Surface tension	Must always be stated for liquids. E.g. EC method number A.5. or OECD guideline number 115 (Surface tension of aqueous solutions).
6.8 Water solubility	Must always be stated. E.g. EC method number A.6. or OECD guideline number 105 (Water solubility).
6.9 Fat solubility	Must always be stated. E.g. OECD guideline number 116 (Fat solubility of solid and liquid substances).
6.10 Partition coefficient n-octanol/water	Must always be stated. E.g. EC method number A.8. or OECD guidelines number 107 (Partition coefficient n-octanol/water) or 117.
6.11 Solubility in organic solvents	Must always be stated. Must be examined with at least two common solvents with different polarities. Results should be given as mg/100 ml of the solvent.
6.12 Hydrolysis as a function of pH	Must always be stated. Must be examined at least at three different pH-values. E.g. EC method number C.7. or OECD guideline number 111 (Hydrolysis as a function of pH).
6.13 Thermal and photolyti-cal stability	Must always be stated. As for photochemical degradation, it can be referred to B 22.2. E.g. OECD guideline number 113 (Screening test for thermal stability and stability in air) or US-EPA guideline OPPTS 835.2210.
6.14 Flash point	State if it can be defined. E.g. EC method number A.9.
6.15 Flammability	Must always be stated. E.g. EC methods number A.10. - A.12.
6.16 Oxidising properties	Must always be stated. E.g. EC method number A.17.

6.17 Decomposition or other reaction during combustion	Must always be stated.
6.18 Dissociation constant	The acid-base constant (pK_a, pK_b) or other such constant should always be given if it can be determined. E.g. OECD guideline number 112 (Dissociation constants in water).
6.19 Other physical and chemical properties	State other physical and chemical properties that have been examined.

HEALTH EFFECTS OF THE ACTIVE SUBSTANCE

B 7 ACUTE TOXICITY, IRRITATION, AND SENSITIZATION

Under each item it has to be stated if the test has been performed with pure or technical substances. The purity and composition of a technical active substance must be the same as in item B.3. In addition, all the dosages must be given in the same way, e.g. calculated as pure active substance.

7.1 Acute oral toxicity	Always required. The animal species used in the test, the effects observed, adverse effects in organs etc. and the LD_{50} (mg/kg) value with its 95% confidence interval must be stated. If the acute oral toxicity of the active substance is found to be low in the limit test, i.e. the LD_{50} value is over 2 000 mg/kg, an exact LD_{50} value does not have to be defined. The rat is the preferred test species. E.g. EC method number B.1.bis or EC B.1. tris or OECD 420 (Acute oral toxicity - fixed dose method) or OECD guideline number 423 (Acute toxic class method). Available older study reports made according to EC method number B.1 or OECD guideline number 401 are also accepted.
7.2 Acute dermal toxicity	Always required. The animal species used in the test, the effects observed, adverse effects in organs etc. and the LD_{50} (mg/kg) value with its 95% confidence interval must be stated. If the acute dermal toxicity of the active substance is found to be low in the limit test, i.e. the LD_{50} value is over 2 000 mg/kg, an exact LD_{50} value does not have to be defined. The rat and the rabbit are the preferred test species. E.g. EC method number B.3. or OECD guideline number 402 (Acute dermal toxicity).
7.3 Acute inhalation toxicity	Always required. The animal species used in the test, method of exposure (e.g. gas, solid or liquid aerosol), exposure period, the effects observed, adverse effects in organs etc. and the LC_{50} (mg/l) value with its 95% confidence interval must be stated. If the acute inhalation toxicity of the active substance is found to be low in the limit test, i.e. the LC_{50} value is over 5 mg/l in a 4-hour study, an exact LC_{50} value does not have to be defined. The rat is the preferred test species. E.g. EC method number B.2. or OECD guideline number 403 (Acute inhalation toxicity).

7.4 Acute toxicity by other routes of administration	State if the acute toxicity has been examined by using other routes of administration (e.g. intravenously).
7.5 Dermal irritation	Always required, if the active substance is not a strong acid or base (pH is not below 2 or above 11.5). The means of scores describing erythema, eschar formation and oedema should be given on the form. The rabbit is the preferred test species. E.g. EC method number B.4. or OECD guideline number 404 (Acute dermal irritation/corrosion).
7.6 Eye irritation	If the active substance irritates the skin, eye irritation does not have to be studied. The values describing the intensity of the effect regarding corneal opacity, injuries in the iris, redness and chemosis of the conjunctivae should be given on the form. The rabbit is the preferred test species. E.g. EC method number B.5. or OECD guideline number 405 (Acute eye irritation/corrosion).
7.7 Sensitisation	Always required. Usually the sensitising properties of a substance are recommended to be tested with a maximisation test using guinea pigs (GPMT). E.g. EC method number B.6. or OECD guideline number 406 (Skin sensitisation).

B 8 SUBACUTE AND SUBCHRONIC TOXICITY

8.1 Subchronic studies with rodents	Always required. At least the animal species used in the test, the route of administration, and the most important results (the target organs and the no effect level, etc.) should be stated on the form. E.g. a 90-day study in a rat, OECD guideline number 408 (Subchronic oral toxicity - Rodent: 90 day).
8.2 Subchronic studies with animals other than rodents	It is required that the subchronic toxicity of the active substance is studied with a non-rodent animal species. For information that should be given on the form, see B 8.1. E.g. OECD guideline number 409 (Subchronic oral toxicity - Non-rodent: 90-day).
8.3 Other studies on prolonged toxicity	State if studies with other routes of administration, other animals or other durations are available. E.g. EC method number B.7. or the OECD guideline number 407 (Repeated dose oral toxicity - Rodent: 28/14-day), EC B.9. or OECD 410 (Repeated dose dermal toxicity: 21/28-day), OECD 411 (Subchronic dermal toxicity: 90-day), EC B.8. or OECD 412 (Repeated dose inhalation toxicity: 28/14-day) or 413 (Subchronic inhalation toxicity: 90-day).

B 9 MUTAGENICITY

Always required. Mutagenicity studies at gene and chromosome level. At least two different *in vitro* tests, e.g. EC method number B.14. or OECD guideline number 471 (*Salmonella typhimurium*, Reverse mutation assay) **and** EC B.17. or OECD 476 (*In vitro* mammalian cell gene mutation test) **and** EC B.10. or OECD 473 (*In vitro* Mammalian Cytogenetic Test). In addition those *in vivo* studies considered necessary should be attached. For example, due to a positive result in an *in vitro* test, one of the following tests may be required: EC B.11. or OECD 475 (*In vivo*

Mammalian bone marrow cytogenetic test - chromosomal analysis) **or** EC B.12 or OECD 474 (Micronucleus test).

B 10 CHRONIC TOXICITY

Always required for wood preservatives. Required for slimicides when necessary, i.e. usually when the user is exposed to a substance repeatedly or for a longer period of time. Recommended to be tested both with a rodent and a non-rodent. New studies on chronic toxicity must be combined with the carcinogenicity study. E.g. OECD guideline number 453 (Combined chronic toxicity/carcinogenicity studies).

B 11 CARCINOGENICITY

Always required for wood preservatives. A carcinogenicity study is usually required for slimicides when the user is exposed to the substance repeatedly or for a longer period of time, there are suggestions for the mutagenicity of the active substance or if substances that resemble the active substance as to their chemical structure have been found carcinogenic or mutagenic. Recommended to be tested with two mammal species. Chronic toxicity studies and carcinogenicity studies can be combined. E.g. EC method number B.1. or OECD guideline number 451 (Carcinogenicity studies) or 453 (Combined chronic toxicity/carcinogenicity studies).

B 12 OTHER GENOTOXIC EFFECTS

Required when necessary. E.g. effects on DNA. E.g. OECD guideline number 479 (*In vitro* sister chromatic exchange assay in mammalian cells) or 482 (DNA damage and repair, unscheduled DNA synthesis in mammalian cells *in vitro*).

B 13 EFFECTS ON REPRODUCTION

Always required for wood preservatives. Required for slimicides when necessary, i.e. usually when the user is exposed to the substance repeatedly or for a longer period of time. A two-generation study with one species (male and female) is required. E.g. EC method number B.35. or OECD guideline number 416 (Two-generation reproduction toxicity).

B 14 TERATOGENICITY

Information about the teratogenicity of the substance is always required for wood preservatives. Required for slimicides when necessary, i.e. if the user is exposed to the substance repeatedly or for a longer period of time. Recommended to be tested with a rabbit and a rodent. E.g. EC method number B.31. or OECD guideline number 414 (Teratogenicity).

B 15 NEUROTOXICITY

Required when necessary regarding substances with which symptoms suggesting effects on the nervous system have been detected or with which these kinds of effects can be expected due to their chemical structure (for example organophosphorus substances). A test on delayed neurotoxicity is required when necessary. E.g. EC methods number B.35. or B.38 or OECD guidelines number 418 (Acute delayed neurotoxicity of organophosphorus substances) or 419 (Subchronic delayed neurotoxicity of organophosphorus substances: 90-day study).

B 16 TOXICITY OF OTHER INGREDIENTS IN THE ACTIVE SUBSTANCE

A short evaluation of the toxicological properties (acute toxicity, irritation, sensitization etc.) of the other substances (impurities, degradation products, metabolites etc.) in the active substance must be attached to the application when necessary. The sources (literature references) of the information presented have to be given in the evaluation. The original studies do not have to be attached.

B 17 METABOLISM IN ANIMALS

Always required for wood preservatives. Information on the kinetics of the active substance in mammals (absorption, distribution, metabolism, excretion). E.g. EC method number B.36 or OECD guideline number 417 (Toxicokinetics).

B 18 TOXICITY TO HUMANS

18.1 Information on known intoxications and exposure during manufacture and use	State if empirical information on the effects in humans is available.
18.2 Exposure studies on occupational safety	State if information is available (e.g. information on concentrations in workplace air or on biological monitoring. The original studies or the sources of the information (literature references) must be supplied

B 19 SUMMARY OF THE STUDIES ON HEALTH EFFECTS OF THE ACTIVE SUBSTANCE

A summary of all studies on health effects should always be attached to the application. The following information is presented regarding every study:

- reference to the application item
- performer of the study (institution)
- date of study
- a short description of the method (test conditions, numbers of animals, doses etc.) and a reference to e.g. the number of OECD guideline instruction
- report on the quality assurance of the test (e.g. a performance according to OECD's Good Laboratory Practice)
- a brief account of the results and conclusion of the study.

FATE AND EFFECTS OF THE ACTIVE SUBSTANCE IN THE ENVIRONMENT

B 20 RELEASE TO THE ENVIRONMENT

Information on how the substance can be released to the environment due to handling it etc., to which compartment of the environment (soil, water, air), and how large are the amounts released. Possible information on concentrations observed for example in waste water or in the environment.

B 21 MOBILITY IN THE ENVIRONMENT

21.1 Adsorption to the soil and sediment	A screening test on the adsorption and desorption of the substance to the soil is always required. E.g. an adsorption/desorption screening test with at least three different soil types. E.g. EC method number C.18 or OECD guideline number 106 (Adsorption/desorption).
21.2 Mobility in the soil	Required regarding wood preserving chemicals, if the active substance can be mobile in the soil (e.g. K_{oc} < 500) on the basis of the screening test in 21.1, and it is not readily degradable chemically or biologically. E.g. soil column, soil thin layer chromatography or lysimeter tests. A test with aged active substance is required when it is necessary to study the mobility of degradation products or metabolites.
21.3 Partition in the aquatic environment	Is required when necessary, i.e. if the study is necessary for understanding the fate of the substance. E.g. water/sediment partitioning test.
21.4 Other information and studies on mobility	State when applicable. E.g. evaporation from water.

B 22 DEGRADATION AND TRANSFORMATION

22.1 Hydrolysis	Information is given under B 6.12. If hydrolysis is considered to be an important degradation route for the active substance, the quality and amount of degradation products should be studied.
22.2 Photolytical degradation	Information is given under B 6.13. If studies have been made separately e.g. in soil and in water, information is given here. If photolytical degradation is considered to be an important degradation route for the active substance, the quality and amount of degradation products should be studied.
22.3 Biodegradation	
22.3.1 Screening test on biodegradation	At least a screening test on biodegradation is always required of organic compounds. E.g. EC method number C.4-B or OECD guideline number 301 E (Modified OECD screening test) taking especially notice of the Annex "Evaluation of the Biodegradability of Chemicals Suspected to be Toxic to the Inoculum" to these test methods.
22.3.2 Additional studies on biodegradation	Additional studies are always required, if the compound is not readily degradable on the basis of the above mentioned tests. Simulation tests according to e.g. ISO standard method 14592 or a corresponding draft OECD test guideline or, if already available, reports according to e.g. EC methods number C.9 or C.12 or OECD guidelines number 302 A - C (Inherent biodegradability).

22.4 Degradation pathways	Degradation tests in soil (wood preserving chemicals) and in water (slime controlling chemicals) are required when necessary.
22.4.1 Degradation in soil	Required for wood preservatives when necessary, if the active substance is slowly degradable and may reach the soil. The degradation should be studied in at least three soil types. E.g. OECD guideline number 304 A (Inherent biodegradability test in soil).
22.4.2 Degradation in water/ sediment system	Required of slime controlling chemicals when necessary, if there are suggestions of the stability of the substance in aquatic environment (for example, if the substance is not readily biodegradable or if its half-life in hydrolysis is over 4 days). E.g. according to a draft OECD test guideline.
22.5 Other information and studies on degradation	E.g. BOD_5/COD, degradation in air (volatile substances) or in other types of environments, etc.

B 23 FIELD OR PLANT TESTS

Field or plant tests, tests, observations etc. in industrial plants regarding degradation, mobility etc., if such are available.

B 24 BIOACCUMULATION

24.1 Bioaccumulation in fish	Always required, if the partition coefficient n-octanol/water is over 1 000. E.g. OECD guideline number 305 (Flow-through fish test).
24.2 Additional studies on bioaccumulation	Always required if the bioaccumulation factor for fish is > 100. E.g. tests with other species or model ecosystem tests with several species.
24.3 Other studies	State when applicable. E.g. concentrations in organism samples, the metabolism of the substance in the organism, accumulation in food webs.

B 25 TOXICITY TO TERRESTRIAL ORGANISMS

State if other tests than those performed with laboratory mammals are available. E.g. soil arthropods, plants, birds etc.

B 26 TOXICITY TO AQUATIC ORGANISMS

26.1 Growth inhibition of algae	Always required. The species, test type, duration, and the EC_{50} value with its 95% confidence interval should be given on the form. E.g. EC method number C.3. or OECD guideline number 201 (Alga, growth inhibition test).

26.2 Other aquatic plants	State when information is available.
26.3 Water flea (Daphnia)	
26.3.1 Acute toxicity to Daphnia	Always required. The species, test type, duration, and the LC_{50} or EC_{50} value with its 95% confidence interval should be given on the form. E.g. EC method number C.2. or OECD guideline number 202 (Daphnia sp. acute immobilisation test and reproduction test) in which the test can be combined with the study in B 26.3.2.
26.3.2 Reproduction test on Daphnia	Always required. The species, test type, duration, and the EC_{50} value with its 95% confidence interval should be given on the form. E.g. OECD guideline number 202 (Daphnia sp. acute immobilisation test and reproduction test) or 211 (Daphnia magna reproduction test).
26.4 Acute toxicity to fish	Always required. The species, test type, duration, and the LC_{50} value with its 95% confidence interval should be given on the form. The study should primarily be done with a cold water species (e.g. with rainbow trout *Oncorhynchus mykiss/Salmo gairdneri*). E.g. EC method number C.1. or OECD guideline number 203 (Fish, acute toxicity test).
26.5 Effect on activated sludge	Always required for slimicides. The duration of the test and the EC_{50} value with its 95% confidence interval should be given on the form. E.g. EC method number C.11 or OECD guideline number 209 (Activated sludge, respiration inhibition test).
26.6 Other studies	State when applicable. E.g. prolonged toxicity to fish (e.g. OECD guideline number 204 Fish prolonged toxicity test: 14-day study), effect on early-life stages of fish (OECD guideline number 210 Fish early-life stage toxicity test), toxicity to other aquatic organisms.

B 27 STUDIES WITH ECOSYSTEM MODELS

State when applicable. Tests with ecosystem models with several species etc.

B 28 MODE OF ACTION IN TARGET ORGANISM; SELECTIVITY

State when applicable.

B 29 THE ENVIRONMENTAL FATE AND EFFECTS OF OTHER INGREDIENTS IN THE ACTIVE SUBSTANCE

A short evaluation of environmental fate and toxicity of the other substances (e.g. impurities and additives) in the active substance should be attached to the application when necessary. The sources (literature references) of the information presented have to be given in the evaluation. The original studies do not have to be attached.

B 30 SUMMARY OF STUDIES ON ENVIRONMENTAL FATE AND EFFECTS OF THE ACTIVE SUBSTANCE

A summary of all studies on environmental fate and effects should always be attached to the application. The following information should be presented regarding every study:

- reference to the item in the application,
- performer of the study (institution),
- date of study,
- a short description of the method (test conditions, numbers of animals, doses etc.) and a reference to e.g. the number of OECD guideline instruction,
- report on the quality assurance of the test (e.g. a performance according to OECD's GLP), and
- a brief account of the results and conclusion of the study.

OTHER INFORMATION

B 31 SAFETY PRECAUTIONS

31.1 Safety precautions when handling the active substance	State on request, e.g. if the active substance is transported, stored or handled separately in Finland e.g. during manufacture. Technical safety precautions when handling the active substance during different stages of the process. Precaution measures during service should especially be considered. Personal protective equipment during different stages of the process. Prevention of environmental effects and measures to be taken when the active substance is released to the environment due to an accident or misuse.
31.2 Safety precautions during the storage of the active substance	State on request (see B 31.1).
31.3 Safety precautions during the transportation of the active substance	State on request (see B 31.1).
31.4 Safety precautions for preventing fire risks	State on request (see B 31.1).

B 32 DISPOSAL METHOD FOR THE ACTIVE SUBSTANCE

State on request.

B 33 MEASURES RELATED TO THE RELEASE OF THE ACTIVE SUBSTANCE TO THE ENVIRONMENT DUE TO MISUSE OR ACCIDENT

State on request.

B 34 INFORMATION ON THE USE OF THE ACTIVE SUBSTANCE IN OTHER COUNTRIES

State when information is available. The restrictions etc. concerning the active substance.

B 35 OTHER INFORMATION

35.1 Names of institutions or companies that are responsible for the studies referred to in this application	State if the information differs from that given under A 15.1 of the A-form.
35.2 Other information and literature not cited previously	State on request.

B 36 NUMBERED LIST OF APPENDIXES

A separate, numbered list of appendixes should be attached to the application. The list must include the name of the study, performer, research laboratory, date, report number and the bibliographical information of scientific publications. **The numbering of the list must follow the same numbering scheme as that used on the application form**.

6 FURTHER INFORMATION

Further information can be obtained from:

Advance approval and notification procedures for wood preservatives and slimicides; classification and labelling of chemicals, health effects of chemicals, classification of chemicals hazardous for the environment

Finnish Safety and Chemicals Agency (Tukes)
Chemicals Products Surveillance
P.O. Box 66
FI-00521 Helsinki
Finland

e-mail: biosinfo@tukes.fi
www.tukes.fi/biocides

Submission of information on hazardous chemicals for registration

Finnish Safety and Chemicals Agency (Tukes)
Chemical Products Registe
Kalevantie 2
FI-33100 Tampere
Finland

e-mail: tuoterekisteri@tukes.fi
www.tukes.fi/en/Branches/Chemicals-biocides-plant-protection-products/Submitting-information-on-chemicals-/