



## Internet document

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Contact for further information:

Notification Authority for Chemicals

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# Explanatory notes on applications for authorisation $A_N$ for a biocidal product

(Art. 7.a, section 3, Annex 8 OBP, RS 813.12)

## Introduction

In order to obtain an authorisation  $A_N$  pursuant to the Ordinance on Biocidal Products (OBP), the following conditions must be satisfied:

- At least one active substance in the product is notified (i.e. included in the [list of notified active substances](#)), but the decision on whether to include it in Lists I/IA (Annexes 1 and 2 OBP) is still pending.
- In addition to the notified active substances, the product may contain active substances specified in Lists I and/or IA (Annexes 1 and 2 OBP).

For products containing other active substances, an application for a different type of authorisation must be submitted (see Art. 7 OBP).

**The OBP Ordinance can be viewed on the internet on the website of the Notification Authority for Chemicals (NACHEM) [www.notificationauthoritychem.admin.ch](http://www.notificationauthoritychem.admin.ch) or directly in the Classified Compilation of Federal Legislation <http://www.admin.ch/ch/e/rs/rs.html> Otherwise, it may be ordered from the following site: [www.bundespublikationen.admin.ch](http://www.bundespublikationen.admin.ch)**

The form "Application for authorisation  $A_N$  for a biocidal product" must be sent to Bundesamt für Gesundheit, Direktionsbereich Verbraucherschutz, Anmeldestelle Chemikalien, Postfach, 3003 Bern.

Disclaimer : [www.disclaimer.admin.ch/terms\\_and\\_conditions.html](http://www.disclaimer.admin.ch/terms_and_conditions.html)

**Further information:**

<b>1 Identity of the product</b>	
<b>1.1 Trade name</b> The trade name under which the product is sold in Switzerland must be stated. If the product is marketed under several trade names, then several authorisations are required accordingly. An application for authorisation of an identical product (formerly a frame formulation) can be submitted for the additional names (see Art. 15 VBP).	
<b>2 Contact addresses</b>	
<b>2.1 Applicant</b> The full name and address of the applicant and the name of the contact person must be provided. An e-mail address is desirable. The applicant must be domiciled in Switzerland or have a registered office or branch in Switzerland	
<b>2.2 Manufacturer of the product</b> Since a distinction is made between the manufacturer of the product and the applicant, the full name and address of the manufacturer has to be stated. The contact person's only needs to be provided if it is known to the applicant.	
<b>3 Uses</b>	
<b>3.1 Product types (PTs) and their uses</b> The active substances in the biocidal product must be notified for the corresponding product type. If the biocidal product can be classified under more than one product type, all the types concerned should be ticked.  The product types and subtypes are described in greater detail below. Further details can be found in the following documents: <ul style="list-style-type: none"> <li>• "Manual of decisions for implementation of Directive 98/8/EC" <a href="https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp">https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp</a></li> <li>• Technical Notes for Guidance; Human Exposure to biocidal products, part 2" <a href="http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/guidance-documents">http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/guidance-documents</a></li> </ul>	
PT 1	Human hygiene biocidal products <ul style="list-style-type: none"> <li>• Disinfectants for skin cleaning; e.g. hand disinfectants, disinfectant soap, antimicrobial cleaning gel, wet wipes for hands (for food companies, hospitals, babies, in toilets).</li> <li>• Antiseptic mouthwash.</li> </ul>
PT 2	Private area and public health area disinfectants and other public health area biocidal products <ul style="list-style-type: none"> <li>• Disinfectants for medical equipment and flooring, biocidal products for use in the home or for industrial areas: For disinfecting floors, walls, solaria, other surfaces, medical devices; use by cleaning staff, medical staff, swimming pool attendants, or in private households (disinfectant cleaning agent for baths, toilets; disinfectant toilet bars).</li> <li>• Products for combatting mould.</li> <li>• For preventing algal growth in ornamental fountains or aquaria.</li> <li>• Detergent or detergent additive with intended disinfectant activity.</li> <li>• Biocidal products for use in swimming pools, etc.: For disinfecting private or public open-air or indoor swimming pools; users include swimming pool attendants and private users.</li> </ul>

**Further information:**

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	<ul style="list-style-type: none"> <li>• Biocidal products for use in air conditioning systems: Disinfectants for use in humidifiers or condenser components in air-conditioning systems; overlaps with PT 11 are possible.</li> <li>• Biocidal products for chemical toilets, treatment of wastewater or hospital waste.</li> <li>• Other PT 2 biocidal products.</li> </ul> <p>Applicants should provide details of this subcategory.</p>
PT 3	<p>Veterinary hygiene biocidal products</p> <ul style="list-style-type: none"> <li>• Preventive disinfection of teats (no therapeutic claim).</li> <li>• Products for use in regular disinfection to prevent diseases in animal husbandry and during animal transport. Typical applications include lightly soiled surfaces (thoroughly cleaned animal housing and facilities for the disposal of animal by-products, vehicles, boots), equipment, ventilation systems.</li> <li>• Footbaths for animals and water additives for the control of fish parasites [neither with a therapeutic claim]).</li> <li>• Products for use in the prevention and control of epizootic disease. Typical applications include heavily soiled surfaces (pre-disinfected and briefly cleaned passageways and slaughter areas, vehicle tyres or boots), slurry pits, manure pits, contaminated equipment and materials suitable for immersion.</li> </ul>
PT 4	<p>Food and feed area disinfectants</p> <ul style="list-style-type: none"> <li>• Products used to disinfect equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food, feed or drink (including drinking water) for humans and animals.</li> <li>• Professional use in food companies, slaughterhouses, the processing of poultry meat, fruit, vegetables and bakery products, and food retailing (disinfection of tables and work surfaces). Disinfection of feed areas. See PT 11 for disinfectants for water supply systems.</li> <li>• Disinfectants for private kitchens</li> <li>• Disinfection of greenhouses, agriculture [excluding plant treatment]</li> </ul>
PT 5	<p>Drinking water disinfectants</p> <p>Products used to disinfect drinking water (for both humans and animals).</p>
PT 6	<p>In-can preservatives</p> <ul style="list-style-type: none"> <li>• Preservatives for detergents and cleaning agents: Biocidal products for preserving cleaning agents for household or industrial use, and for preserving detergents, dishwashing liquids or liquid soaps.</li> <li>• Other in-can preservatives: For preserving all other chemical products: paints, adhesives, lubricants, fuels, enzyme solutions, concrete additives, etc.</li> </ul>
PT 7	<p>Film preservatives</p> <ul style="list-style-type: none"> <li>• Products used to preserve films and coatings by controlling microbial deterioration in order to protect the original properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, bindings, papers and art works.</li> <li>• The biocidal products are not intended to protect unused coatings, e.g. paints (see PT 6), but only the dried, hardened coatings. Preserved plastics are used e.g. for floor coverings, vehicles, toys. PVC is a commonly preserved plastic, for example.</li> <li>• Fungicides on the backs of carpets are classified under PT 9.</li> <li>• Biocidal products for paints, mortar or roughcast, for silicone sealants and other coatings on buildings can protect both the hardened product (PT 7) and the building</li> </ul>

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	(PT 10) from moss, algae or lichen. Products for indoor use tend to be classified under PT 7, while those for outdoor use tend to be regarded as PT 10 (Manual of Decisions for Implementation of Directive 98/8/EC).
PT 8	<p>Wood preservatives</p> <ul style="list-style-type: none"> <li>• Products used to preserve wood from the saw-mill stage onwards or to preserve wood products by controlling wood-destroying or wood-disfiguring organisms. This product type includes both preventive and curative products.</li> <li>• Products to be used on felled timber in forests are regarded as plant protection agents and must be authorised as such (applications should be submitted to the Federal Office for Agriculture).</li> </ul>
PT 9	<p>Preservatives for fibre, leather, rubber and polymerised materials</p> <ul style="list-style-type: none"> <li>• Preservatives for textiles and leather: Preservation protects textiles and leather during storage, transport and use. Preservatives include, for example, insecticides and fungicides for protecting carpets, as well as fungicides for tents and outdoor textiles or shower curtains. Fungicides in the leather tanning process.</li> <li>• Paper preservatives: These include products for protecting non-food packaging materials, for example. They should be distinguished from PT 12: Slimicides for paper pulp.</li> <li>• Preservatives for rubber and polymerised materials and other biocidal products classified under PT 9: For preserving rubber or plastic (e.g. rubber or plastic that comes into contact with the ground or water, such as pond liners).</li> </ul>
PT 10	<p>Masonry preservatives</p> <ul style="list-style-type: none"> <li>• Products used to preserve and remedially treat masonry or other construction materials other than wood by controlling microbiological and algal attack.</li> <li>• Agents for protecting against algae, fungi or lichen on masonry (concrete, stones), pathways or roofs; also for the curative treatment of affected masonry during remedial work; for cleaning gravestones, etc.</li> <li>• Products for preserving concrete additives are covered by PT 6. Products for removing plants from concrete are not regarded as biocidal products but plant protection agents (herbicides).</li> </ul>
PT 11	<p>Preservatives for liquid-cooling and processing systems</p> <ul style="list-style-type: none"> <li>• Preservatives used in once-through systems: These products are used to ensure the supply of microbiologically pure water to production facilities, e.g. in food companies, in paper factories and in certain cooling systems e.g. in power plants. Products for the shock disinfection of water systems (including systems for drinking water) are included in this group. Products for disinfecting drinking water are classified as PT 5. Overlaps with PT 16 are possible.</li> <li>• Preservatives used in recirculation systems: e.g. for cooling towers or evaporation condensers in air conditioning systems, for industrial cooling systems.</li> </ul>
PT 12	<p>Slimicides</p> <p>Products used to prevent or control slime growth on materials, equipment and structures used in industrial processes.</p> <ul style="list-style-type: none"> <li>• Slimicides for paper pulp: Biocidal products control the bacteria and fungi that occur in paper pulp (made of</li> </ul>

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	<p>raw fibre or recycled paper). These products do not include fungicides applied to the surface of finished paper (PA 9).</p> <ul style="list-style-type: none"> <li>• Slimicides for crude oil production: These products control organisms in drilling sludge, boreholes and pipelines.</li> <li>• Other slimicides: these must be described by the applicant.</li> </ul>
PT 13	<p>Metalworking-fluid preservatives</p> <ul style="list-style-type: none"> <li>• Biocidal products for preserving metalworking fluids (fluids used as coolants, lubricants or agents for transporting the abrasive / cut material). Biocidal products may be contained in the finished metalworking fluid or added at intervals during metalworking.</li> </ul>
PT 14	<p>Rodenticides</p> <ul style="list-style-type: none"> <li>• Products used to control mice, rats and other rodents outside plant cultivation areas (agricultural fields, greenhouses, forests), for example in cities, industrial premises, etc. and not used to protect plants or plant products inside plant cultivation areas (for example to control of rats that can spread in areas of human settlement). Demarcation according to the Manual of Decisions for implementation of Directive 98/8/EC).</li> </ul>
PT 15	<p>Avicides</p> <p>Authorisation not possible (Art. 4 OBP).</p>
PT 16	<p>Molluscicides</p> <p>Products used to control molluscs. Products for controlling snails in gardens are regarded as plant protection agents.</p>
PT 17	<p>Piscicides</p> <p>Authorisation not possible (Art. 4 OBP).</p>
PT 18	<p>Insecticides, acaricides and products to control other arthropods</p> <ul style="list-style-type: none"> <li>• Products used to control insects, arachnids and crustaceans.</li> <li>• To protect stored goods (e.g. textiles), to treat storage areas or other commercial or private (residential) areas or means of transport. Articles that release the biocidal active substance are also included: e.g. vaporiser chips, insecticide strips. Overlaps are possible with plant protection agents for protecting food crops (treatment of grain silos). Insecticides for wood treatment are regarded as wood preservatives (PT 8). Insecticides for animal parasite control are veterinary products. Insecticides for protecting food products are classified under PT 20.</li> </ul>
PT 19	<p>Repellents and attractants</p> <ul style="list-style-type: none"> <li>• Products used to repel or entice harmful organisms (invertebrates such as mosquitoes, vertebrates such as birds).</li> <li>• Repellents that are applied directly to human or animal skin: This subcategory was subject to the Cosmetics Ordinance until chemicals legislation came into force on 1 August 2005. Certain biocidal products are also cosmetics, including, in particular, combined insect-repellent and sunscreen products. In their function as insect repellents they are regarded as biocidal products, but as sunscreen products they are covered by the Cosmetics Ordinance (Vkos). This means that they require authorisation pursuant to the OBP (like insect repellents, see above). The provisions of the Cosmetics Ordinance apply to the use of UV filters in these products (see also section 7.2) (see further explanations under</li> </ul>

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	<p><a href="http://www.bag.admin.ch/anmeldestelle/13604/13869/13888/index.html?lang=en">http://www.bag.admin.ch/anmeldestelle/13604/13869/13888/index.html?lang=en</a>)</p> <ul style="list-style-type: none"> <li>• Attractants and repellents that are not applied directly to human or animal skin: These include, for example, repellents (e.g. essential oils) that are diffused (from vaporisers or candles) to repel mosquitoes, repellents to protect textiles from moths (provided that the moths are not killed but merely kept away), but also natural products such as lavender oil or repellents in flea collars for animals or in treated mosquito-repellent sleeping bags. Attractants (e.g. pheromones) in insect traps.</li> <li>• Repellents to control vertebrates (dogs, cats, martens).</li> </ul>
PT 20	<p>Preservatives for food or feedstocks</p> <p>Products used to preserve food or animal feed by controlling harmful organisms.</p>
PT 21	<p>Antifouling products</p> <ul style="list-style-type: none"> <li>• Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.</li> </ul>
PT 22	<p>Embalming and taxidermist fluids</p> <p>Products used to disinfect and preserve human or animal corpses or parts thereof.</p>
PT 23	<p>Control of other vertebrates</p> <p>Authorisation not possible (Art. 4 OBP).</p>

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### **3.2 Area of use**

All areas in which the product is to be used must be ticked.

Use in milk rooms: This includes sites where milk or milk-based products are produced, stored or processed.

### **3.3 Type of application**

Tick the box stating how the product is used. If "other" is ticked, the type of use must be specified. If the biocidal product is to be used with a device, the device and the complete process must be described in detail.

If the product is incorporated partly or wholly in materials (fibres, plastics, etc.), the uses of these materials or items containing them must be described.

Fact sheets should be enclosed.

### **3.4 Aim of use**

State whether the product is used for preventive and/or control purposes.

### **3.5 In situ generation**

State whether the active substance or substances are produced in situ, i.e. whether the actual active substance is produced only during use by mixing in other substances. Specify the substances in question.

### **3.6 Dilution**

State whether, and if so how, the product should be diluted during use.

### **3.7 Dose rates**

Details of dosages (e.g. per treated surface or as a concentration in a water system) and the number and duration of treatments should be provided.

## **4 Category of use**

If the product is intended for both professional and non-professional use, please check both boxes.

## **5 Packaging and physical state**

Under "Packaging", state the type of packaging, for example PVC bottle or cardboard box.

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## **6 Composition and proposals for classification and labelling**

### **6.1 Composition of the product and classification of the substances according to Directive 67/548/EEC and Regulation 1272/2008/EC (GHS)**

State the complete (100%) composition of the product, and with exact concentrations for all substances (no concentration ranges). Additionally, state the information requested in the table for each substance contained in the product that possesses dangerous properties according to Article 3 ChemO.

The composition of the product will be treated as confidential in all cases. The active substances, their concentrations and the substances to be declared are not regarded as confidential. If the applicant is not the manufacturer of the product, the manufacturer can submit the composition separately.

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**Name of the product (*state trade name*):** State the trade name under which the product is sold in Switzerland.

(a)	(b)	(c)	(d)	(e)		(f)			(g)
Chemical name (e.g. ISO common name).	CAS number and EC number	Content in the biocidal product in % (w/w)	Function in the biocidal product	Classification according to Directive 67/548/EEC		Classification according to Regulation 1272/2008/EC (CLP Regulation)			Manufacturer of the active substance (name, town, country)
				Danger symbols	R phrases	Hazard pictograms	Hazard class and hazard category	Hazard statements ("H phrases")	

(a): Chemical name:

- Active substances or precursors of active substances: ISO common name or name according to the list of notified active substances.
- Components other than active substances: State the chemical name according to e.g. ISO common name, IUPAC or EINECS.

(b): The CAS number **must** be given to ensure unambiguous identification.

(c) Content in the product: State precise content in % by weight (or ppm). For mixtures (solutions) and hypochlorite solution: see remarks 3 and 4 on the form. If the product contains perfumed substance mixtures, state the individual components (e.g. according to manufacturer's SDS).

(d) Function in the product: described by terms such as active substance, solvent, emulsifier, thickener, antifoam agent, stabiliser, preservative, fragrance, etc.

(e) Classification according to Directive 67/548/EEC:

- For all dangerous ingredients, provide the danger symbols (symbols abbreviated as Xn, Xi, T, etc.) and corresponding R phrases.
- For substances listed in Table 3.2 of Annex VI of Regulation (EC) no. 1272/2008 (CLP Regulation), provide the official classification (see: <http://esis.jrc.ec.europa.eu/index.php?PGM=cla>), if necessary with the manufacturer's supplementary classification. If the manufacturer possesses data concerning other endpoints not covered in Annex VI, the classification under Annex VI must be supplemented accordingly. For supplementary classifications, please attach the relevant documents (e.g. SDS).
- For substances with no official classification, give the classification defined by the manufacturer of the substance (see, for example, the manufacturer's SDS).

(f) Classification according to Regulation 1272/2008/EC (CLP Regulation):

- For all hazardous substances contained in the product, provide the hazard pictograms (e.g. GHS01, GHS02, etc.), the hazard classes and hazard categories and the hazard statements ("H phrases").

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- For substances listed in Table 3.1 of Annex VI of Regulation (EC) no. 1272/2008, provide the official classification (see: <http://esis.jrc.ec.europa.eu/index.php?PGM=cla>), if necessary with the manufacturer's supplementary classification. If the manufacturer possesses data concerning other endpoints not covered in Annex VI, the classification under Annex VI must be supplemented accordingly. For supplementary classifications, please attach the relevant documents (e.g. SDS).
- For substances with no official classification, give the classification defined by the manufacturer of the substance (see, for example, the manufacturer's SDS).

(g) State the name and address of the manufacturer of **each individual active substance**.

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**Example:**

**Composition of product: Exinsect-Spray Z**

Chemical name (ISO common name). For active substances: ISO common name or name according to the list of notified active substances.	CAS no. and EC no.	Content in biocidal product in % (w/w)	Function in the biocidal product	Classification (according to Directive 67/548/EEC)		Classification according to Regulation 1272/2008/EC (CLP Regulation)			Manufacturer of the active substance (name, town, country)
				Danger symbols	R phrases	Hazard pictograms	Hazard class and hazard category	Hazard statements ("H phrases")	
Extract/lavandin oil	CAS 91722-69-9 EC 294-470-6	0.8	Active substance	Xi	R 38 R 52/53	GHS07	Skin Irrit. 2 Aqu. Chron. 3	H315, H412	Biozides AG, Hauptstr. 3, 00000 Ort, D
Stoddard solvent (benzene content <0.1%)	CAS 8052-41-3 EC 232-489-3	45	Solvent	Xn	R 65	GHS08	Asp. Tox. 1	H304	
Ethanol	CAS 64-17-5 EC 200-578-6	8	Solvent	F	R 11	GHS02	Flam. Liq. 2	H225	
Acetone	CAS 67-64-1 EC	0.5	Solvent	F Xi	R 11 R 36 R 66	GHS02 GHS07	Flam. Liq. 2 Eye Irrit. 2 STOT SE 3	H225 H319 H336	

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	200-662-2				R 67				
1-Methoxy-2-propanol	CAS 107-98-2 EC 203-539-1	5	Solvent		R 10 R 67	GHS02 GHS07	Flam. Liq. 3 STOT SE 3	H226 H336	
Formaldehyde	CAS 50-00-0 EC 200-001-8	0.05	Preservative	Carc. Cat. 3 T C	R 40  R23/24/ 25 R 34 R 43	GHS05 GHS06 GHS08	Carc. 2 Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 Skin Corr. 1B Skin Sens. 1	H351 H331 H311 H301 H314 H317	
Propane/butane	CAS 74-98-6/106-97-8 EC 200-827-9/203-448-7	40.6	Propellant	F+	R12	GHS02 GHS04	Flam. Gas 1 Press. Gas	H220	

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## 6.2 Ecotoxicological data for ingredients

Ecotoxicity tests should be carried out in accordance with Commission Regulation (EC) no 440/2008<sup>1</sup> of 30 May 2008. If tests not specified in this Regulation have been carried out, or in the event of any deviations from the tests specified therein (e.g. different test period, different test species), the deviations should be stated here. Please note that according to CLP, both new and chronic data, where available, must be used to classify substances. M factors for classifying mixtures containing highly toxic substances should be derived from the chronic data for highly toxic substances if these were classified on the basis of chronic data.

## 6.3 Physicochemical data relevant to classification

To permit classification of a preparation / mixture in respect of its physicochemical hazards, the corresponding test data should be submitted where relevant. Since the Directive 67/548/EEC and CLP Regulation have different test requirements as regards physicochemical properties, the method by which data were obtained and the corresponding classification used should be stated.

### Classification according to Directive 67/548/EEC

- Flash point °C;
- Initial boiling point °C (e.g. according to Commission Regulation (EC) no 440/2008 of 30 May 2008 [Test Method Regulation according to REACH], Method A.2).
- Oxidising properties  
The following should be stated here, if relevant and available: Test results for the product in respect of oxidising properties according to Commission Regulation (EC) no 440/2008 of 30 May 2008 (Test Method Regulation according to REACH), Method A.17 (Solids) or according to Method A.21 (Liquid substances).
- Organic peroxides (e.g. peracetic acid):
  - o Preparations that are not classified as explosive and contain organic peroxides are classified by means of a calculation based on their active oxygen content (see section 9.5 in Annex VI of Directive 67/548/EEC). Tests to determine the oxidising properties of organic peroxides are not envisaged.
  - o Briefly, calculation-based classification is conducted as follows: Any organic peroxide and any preparation that contains an organic peroxide and is not classified as explosive should be classified as oxidising if either the peroxide or the preparation contains the following components:
    - over 5 % organic peroxides or
    - over 0.5 % reactive oxygen from organic peroxides and more than 5 % hydrogen peroxide.
- Aerosols (compressed gas containers):  
The following should be stated here, if relevant and available: Tests according to Directive 2008/47/EC (Aerosol Directive), Annex, number 6.3 and the heat of combustion (see CLP Regulation (EC) no. 1272/2008 Annex I 2.3.4 for the determination of the heat of combustion). Aerosol containers containing flammable components can only be accurately classified if test data are available. If no test data are submitted to the notification authority data for aerosol containers with over 1% flammable components (liquids with flash point  $\leq 93^{\circ}\text{C}$ , flammable gases and

<sup>1</sup> Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 142 of 31.5.2008, P. 1; last amended by Regulation (EC) no. 761/2009, OJ L 220 of 24 August 2009, P. 1. This text can be found on the following website: [www.notificationauthoritychem.admin.ch](http://www.notificationauthoritychem.admin.ch)  
The Notification Authority for Chemicals is the common authority for the FOEN, FOPH and SECO for the notification and authorisation of chemicals.  
**Further information:**  
Federal Office of Public Health, Consumer Protection Directorate, Notification Authority for Chemicals, 3003 Berne, tel. +41 (0)31 322 73 05, [cheminfo@bag.admin.ch](mailto:cheminfo@bag.admin.ch), [www.notificationauthoritychem.admin.ch](http://www.notificationauthoritychem.admin.ch)  
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flammable solids), the "highly flammable" classification must be used. Aerosols with  $\leq 1\%$  flammable components and a heat of combustion  $< 20$  kJ/g are not classified as flammable and tests do not need to be submitted. Aerosols with  $\geq 85\%$  flammable components and a heat of combustion  $\geq 30$  kJ/g must always be classified as highly flammable.

- Explosive properties:

The following should be stated here, if relevant and available: Tests according to Commission Regulation (EC) no 440/2008 of 30 May 2008 (Test Method Regulation according to REACH), Method A.14 (e.g. for products containing troclosene sodium (CAS 2893-78-9)).

- Other classification-related data should be provided if available.

### **Classification according to CLP Regulation**

- Flash point °C;

- Initial boiling point °C (e.g. according to Commission Regulation (EC) no 440/2008 of 30 May 2008 (Test Method Regulation according to REACH), Method A.2).

- Oxidising properties:

The results of tests of the product's oxidising properties should be provided here if they are relevant and available:

- For solids according to test O.2 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part III, Subsection 34.4.1
- For liquids: according to test O.2 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part III, Subsection 34.4.2

- Organic peroxides (e.g. peracetic acid):

The following should be stated here, if relevant and available: Test results for the product according to the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part II

- The test results should be used to assign all organic peroxides / mixtures containing organic peroxides should be assigned to a type in the "Organic peroxides" class unless:

- they contain no more than 1.0 % active oxygen (for calculation see Annex 1 of the CLP Regulation, section 2.15.2.1) and a maximum of 1.0 % hydrogen peroxide, or
- they contain no more than 0.5 % active oxygen (for calculation see Annex 1 of the CLP Regulation, section 2.15.2.1) and more than 1.0 % but no more than 7.0% hydrogen peroxide.

- Aerosols (compressed gas containers):

The following should be stated here, if relevant and available: Test according to Part III, sections 31.4, 31.5 and 31.6 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria or tests according to Directive 2008/47/EC (Aerosol Directive), Annex, number 6.3 (the tests are identical) and the heat of combustion (for determination of the heat of combustion see CLP Regulation (EC) no. 1272/2008 Annex I 2.3.4). Aerosol containers containing flammable components can only be accurately classified if test data are available. If no test data are submitted to the notification authority data for aerosol containers with over 1% flammable components (liquids with flash point  $\leq 93^\circ\text{C}$ , flammable gases and flammable solids), the "highly flammable" classification must be used. Aerosols with  $\leq 1\%$  flammable components and a heat of combustion  $< 20$  kJ/g are not classified as flammable and tests do not need to be submitted. Aerosols with  $\geq 85\%$  flammable components and a heat of combustion  $\geq 30$  kJ/g must always be classified as highly flammable.

- Explosive properties:

The following should be stated here, if relevant and available: Tests according to Part 1 of the Manual of Tests and Criteria of the UN Recommendations on the Transport of Dangerous Goods (e.g. for products containing troclosene sodium (CAS 2893-78-9)).

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- Corrosive to metals:

The following should be stated here, if relevant and available: Tests according to the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part III, Section 37, subsection 37.4.

- Other classification-related data should be provided if available.

#### **6.4 Proposal for classification and labelling according to Directive 67/548/EEC**

Notes:

You may choose only one classification/labelling.

If the applicant does not specify, the decision will be issued according to CLP Regulation.

##### **6.4.1 Classification of the biocidal product**

The danger symbol abbreviations and corresponding R phrases should be provided, for example:

Danger symbol:

F+

Xn

Corresponding R phrase:

R 12

R 65

The symbols (abbreviations such as Xn, Xi, T, etc.) and corresponding R phrases should be stated. Products should be classified in terms of properties that are dangerous to health/the environment using the calculation method specified in Annex II or III of Directive 1999/45/EC or on the basis of test results (Art. 12 and 13 ChemO). If biocidal products are being classified using test results, the appropriate test reports should be submitted.

#### **Further information:**

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## 6.4.2 Labelling of the biocidal product

Provide the labelling of the biocidal product as specified in Articles 39 and 40 ChemO: Hazard symbols, R and S phrases and, in certain cases, information about special risks (Annex 1 section 5 ChemO). Annex 1, section 4 ChemO should also be observed when selecting dangerous substances that have to appear on the labelling.

The product label must provide all the information required by Articles 39 and 40, ChemO, and Article 38 OBP. This includes:

- Product name,
- Name, address and telephone number of the authorisation holder,
- The details specified in Article 38, paragraph 3 OBP:
  - active substances (designated by ISO common names) with concentrations in metric units (normally mg/g),
  - authorisation number,
  - preparation type (aerosol, liquid concentrate, granules, powder, etc.),
  - use, detailed directions for use, dose rates,
  - any side effects,
  - directions for first aid (not required if S phrases provide sufficient information),
  - if the product is accompanied by a leaflet: "Read attached instructions before use";
  - directions for disposal,
  - batch number or designation,
  - expiry date,
  - any relevant information on intervals to be observed, precautionary measures, etc.
- If applicable, the "for professional users only" user category,
- Specific dangers to the environment
- If applicable, specific designations for certain products according to the annexes of ChemRRV (e.g. specific directions relating to substances in detergents according to Annex 2.1).

The following should be observed for **insect repellents** specifically:

Allergenic perfumed substances contained in insect repellents that are applied to the skin must be specifically declared, taking account of the EU list according to Directive 2003/15/EC (obtainable from <http://www.bag.admin.ch/anmeldestelle/00928/00940/index.html?lang=en>). Allergenic perfumed substances that appear in this list must be declared on the product label if their concentration exceeds 0.001 % (= 10 ppm).

Reason: the risk of skin allergies when insect repellents are used on the skin is comparable to that arising from the use of cosmetics ("leave-on" products). Such possible side effects must be noted on the label in accordance with Article 38, paragraph 3 letter f of the OBP.

The following should be observed for **UV filters** specifically:

The provisions of the Cosmetics Ordinance apply to the use of UV filters in these products (positive list of UV filters according to Annex 2 of VKos; Annex 3 of VKos from January 2006). The UV filters should be declared on the label in addition to the labelling details required by the OBP.

### Further information:

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## 6.5 Proposal for classification and labelling according to Regulation 1272/2008/EC (CLP Regulation)

### 6.5.1 Classification of the biocidal product

The hazard class, hazard category and the corresponding hazard statements ("H phrases") should be provided, for example:

Hazard class and hazard category:	Hazard statements
Flamm. Aerosol 1	H222
Asp. Tox. 1	H304

The product is classified according to Art. 9 - 15 of Regulation (EC) no. 1272/2008. If the biocidal product's classification does not match the result of the calculation method<sup>2</sup>, the classification method used must be stated and if applicable supplemented by comments on the test methods (product data) or information on the reference product (bridging) [separate enclosure]. Any endpoints that produce a deviation from the result of the calculation method must be stated. Results of ecotoxicity tests for the product should be provided. Please note that under CLP, acute toxicity tests can no longer be used to assign products to the chronic water pollutant categories. Instead, it is possible to classify them on the basis of chronic tests. Moreover, the ECHA guidelines state that tests involving a product may be used for classification only if the test organism was exposed to the mixture in a composition that corresponds relatively to the composition of the product. It is not sufficient to use aqueous extracts.

### 6.5.2 Labelling of the biocidal product

Provide the labelling of the biocidal product as specified in Articles 56*d* ChemO and Articles 17 - 33 of Regulation (EC) no. 1272/2008 Hazard pictograms, signal words, hazard statements ("H phrases"), safety instructions ("P phrases") and supplementary hazard instructions.

See section 6.4.2

<sup>2</sup> Calculation method covers additive nature, formulas (M factors, ATE values) and concentration limits applied to the endpoints of the components of a product.

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## 7 Proof of efficacy

Proof of efficacy must be submitted with authorisation applications for all disinfectants (product types 1 - 4) and all wood preservatives (product type 8). Further details can be found in Annex 1 for disinfectants and in Annex 2 for wood preservatives.

## 8 Enclosures

The following documents should be enclosed:

- The safety data sheet, if compilation is required under Article 52 ChemO.
- The documents on the efficacy of wood preservatives and disinfectants; indicate the number of enclosed documents.
- Draft label.  
A finished label with a definitive design is not required. However, the **promotional claim** on the label is important, as this provides the notification authority with important information for its dossier review, e.g. whether it is in fact a biocidal product and, if so, of what product type.
- **Directions for use.**  
According to Art. 38, para. 5 OBP, instructions for use need not be shown on the label. In cases where the instructions for use are contained in a separate leaflet, this leaflet must be enclosed.
- Letter of access. Applicants may refer to data from other biocidal products already approved by the competent authority, provided that they hold the relevant authorisation. If this is not the case, the applicant must submit a letter of access with the form. Without this letter, authorisation on the basis of reference data cannot be granted.

Other documents should be added if they facilitate understanding of the information given in the form. In particular, documents used to classify substances that have no official classification (e.g. safety data sheets) or to supplement an official classification or toxicological, environmental or physicochemical study report should be enclosed if the biocidal product is not classified using a calculation method (see sections 7.1.3, 7.2.3, 7.1.5, 7.2.5).

### Further information:

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# Annex 1 to applications for authorisation A<sub>N</sub> for a biocidal product

## Disinfectants (product types 1-4)

### 4 Intended uses

Disinfectants subject to other legislation:

Products covered by therapeutic products legislation and products intended solely to disinfect medical devices are not regulated by the Ordinance on Biocidal Products (OBP). However, products whose area of use extends beyond that of medical devices have to be authorised in accordance with the OBP (dual use).

Disinfectant soaps: soaps (liquid or solid) that are explicitly promoted as having disinfectant, antimicrobial or antibacterial characteristics are classed as disinfectants, i.e. they are subject to the OBP as product type 1. Conventional soaps or hand cleaning liquids are subject to the Cosmetics Ordinance. The differentiation between disinfectants and cosmetics is based on the promotional claims made for the products and their composition (active substances, efficacy).

### 2 Efficacy

Proof of efficacy is not mandatory for every disinfectant. See details under

<http://www.bag.admin.ch/anmeldestelle/13604/13869/13880/index.html?lang=de>

Products are divided up as follows:

#### 2.1 Disinfectants for which complete documentation on efficacy is to be submitted with the form:

##### PT 1

- Disinfectants for skin cleaning; e.g. hand disinfectants, disinfectant soap, antimicrobial cleaning gel, wet wipes for hands (for food companies, hospitals, homes, veterinary use, in toilets, etc.).
- Antiseptic mouthwash.

##### PT 2

- Disinfectants for medical facilities, schools, old people's homes or for industrial activities. Products for disinfecting floors, walls and all other surfaces, medical equipment, solaria, etc. aero-disinfection (aerosols, steam, smoke, etc.). Application by cleaning staff, medical staff. Biocides for surface disinfection in indoor or outdoor public swimming pools. Use by swimming pool attendants. Disinfection of public swimming pool water with non-chlorinated substances (not recognised in SIA standard 385/9).

##### PT 3

- Disinfection for epizootic diseases, if disinfectant is not included in the DVG list
- Disinfectants for lightly soiled surfaces in animal husbandry and veterinary use (thoroughly precleaned, non-porous surfaces, devices, boots, facilities)
- Disinfectants for heavily soiled surfaces in animal husbandry and veterinary use (porous or only partly cleaned non-porous surfaces, vehicle bodywork and wheels, devices and boots)
- Disinfectants for immersion of contaminated (highly soiled) objects in veterinary applications
- Products used for epizootic disease prevention and control

##### PT 4

- Products used to disinfect equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food, feed or drink (including drinking water) for humans and animals.
- Professional use in food companies, slaughterhouses, the processing of poultry meat, fruit, vegetables and bakery products, and food retailing (disinfection of tables and other work surfaces). Disinfection of feed areas.
- Disinfectants for water supply systems.

#### Further information:

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## **2.2 Disinfectants for which documentation on efficacy is not required:**

### **PT 1**

- Proof of efficacy is always required for PT 1

### **PT 2**

- Disinfectants used exclusively in private households (disinfectant dishwashing products, disinfectant cleaning agents for kitchens, baths and toilets; disinfectant toilet bars). The restriction must be explicitly mentioned on the label. The product is only authorised for use in private households.
- Swimming pools, etc.: for disinfection of private swimming pools.
- Public baths: Disinfection of swimming pool water with chlorinated substances (apart from chloroisocyanurates).
- Biocidal products for chemical toilets, treatment of waste water or hospital waste
- Biocidal products for air-conditioning systems: Disinfectants for use in humidifier systems or condensers in air-conditioning systems.
- Detergent or detergent additive with intended disinfectant activity.
- Other biocidal products of PT 2

### **PT 3**

- Routine disinfection
- Use in areas where animals are housed, kept or transported. Application areas are to be specified, e.g. biocidal products (microbicidal or insecticidal) for use in footbaths for animals, for people in boots, for use in animal housing (e.g. chicken houses or pig sties). Products added to water to control fish parasites (no therapeutic claim).

### **PT 4**

Products for disinfecting private kitchens

### **PT 5**

- Professional drinking water treatment in water supply companies, mostly in industrial processes involving chlorine. Private use of biocidal products for disinfection of water for camping. In accordance with the positive list of the Food Safety Division.

In exceptional cases, the Notification Authority for Chemicals may require efficacy tests for all disinfectants, e.g. if there is doubt about the effect of the product.

#### **Further information:**

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For further information on the subject of "Disinfectant substances" see:

<http://www.bag.admin.ch/anmeldestelle/13604/13869/13880/index.html?lang=de> (only available in German, French or Italian)

The following proof of efficacy is to be submitted with the form for disinfectants if such documents are required:

Application area	Organisms	Quantitative suspension test (phase 2 / step 1)	Practical test (phase 2 / step 2)
Surface disinfection (If the product is marketed as a detergent offering simultaneous disinfection, it must be tested at an increased soiling level.	Bacteria (and mycobacteria)	EN 1276 or EN 13727 (and EN 14348) or DGHM quantitative suspension test or AFNOR NF T72-300/301	EN 13697 or DGHM practical surface disinfection or AFNOR NF T72-190
	Fungi	EN 1650 or EN 13624 or DGHM quantitative suspension test	EN 13697 or DGHM practical surface disinfection
	Spores (bacteria)	EN 13704	/
	Viruses	EN 14476 or DVV, poss. EN 13610 (bacteriophages)	/
	Air disinfection (automatic spraying)	Ditto (bactericide, fungicide, virucide)	AFNOR NF T 72-281 (bactericide, fungicide, sporicide – 2009 edition)
Instrument disinfection	Bacteria (and mycobacteria)	EN 13727 or EN 1276 (and EN 14348) or DGHM quantitative suspension test or AFNOR NF T72-300/301	EN 14561 and EN 14563 or DGHM quantitative carrier test or AFNOR NF T72-190
	Fungi	EN 1650 or EN13624 or DGHM quantitative suspension test	EN 14562 or DGHM quantitative carrier test
	Spores (bacteria)	EN 13704	/
	Viruses	EN 14476 or DVV	/
Hygienic hand disinfection (low-level soiling) or hygienic hand washing (high-level soiling)	Bacteria	EN 1276 or EN 13727 or DGHM quantitative suspension test or AFNOR NF T72-300/301	EN 1500 or DGHM hygienic hand disinfection (Hyg. hand washing: EN1499)
	Fungi	EN 1650 or EN 13624 or DGHM quantitative suspension test	/
	Viruses	EN 14476 or DVV	/
Surgical hand disinfection	Bacteria	EN 1276 or EN 13727 or DGHM quantitative suspension test or AFNOR NF T72-300/301	EN 12791 or DGHM surgical hand disinfection
	Fungi	EN 1650 or EN 13624 or DGHM quantitative	/

**Further information:**

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Application area	Organisms	Quantitative suspension test (phase 2 / step 1)	Practical test (phase 2 / step 2)
		suspension test	
	Viruses	EN 14476 or DVV	/
Surface disinfection, veterinary use Low-level soiling (epizootic diseases)	Bacteria	EN 1656 low-level soiling	EN 14349 low-level soiling of non-porous surfaces
	Fungi	EN 1657 low-level soiling	
	Yeasts	EN 1657 low-level soiling	
	Mycobacteria	prEN 14204 low-level soiling	
	Viruses	EN 14675 low-level soiling	
	Spores	EN13704 low-level soiling	
Surface disinfection, veterinary use High-level soiling (epizootic diseases)	Bacteria	EN 1656 high-level soiling	EN 14349 high-level soiling of non-porous surfaces or prEN 16437 porous surfaces without mechanical action
	Fungi	EN 1657 high-level soiling	
	Yeasts	EN 1656 high-level soiling	
	Mycobacteria	EN 14204 high-level soiling	
	Viruses	EN 14675 high-level soiling	
	Spores	EN13704 high-level soiling	
Immersion of contaminated objects, veterinary use (epizootic diseases)	Bacteria	EN 1656 high-level soiling	EN 14349 high-level soiling of non-porous surfaces
	Fungi	EN 1657 high-level soiling	<b>prEN 16438</b> non-porous surfaces
	Yeasts	EN 1657 high-level soiling	<b>prEN 16438</b> non-porous surfaces
	Mycobacteria	EN 14204 high-level soiling	
	Viruses	EN 14675 high-level soiling	
	Spores	EN13704 high-level soiling	

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## Annex 2 to applications for authorisation A<sub>N</sub> for a biocidal product

### Wood preservatives (PT 8)

The proof of efficacy on which authorisation is based relates in each case to the formulation submitted for a wood preservative. Technical queries should be addressed to the Swiss Federal Laboratories for Materials Testing and Research (EMPA). Please contact:

Dr Francis Schwarze  
EMPA St. Gallen  
Lerchenfeldstrasse 5  
CH-9014 St. Gallen  
Tel.: ++41 (0)71 274 72 47  
Fax: ++41 (0)71 274 76 94  
E-mail: [francis.schwarze@empa.ch](mailto:francis.schwarze@empa.ch)

### Proofs of efficacy to be submitted to confirm the claimed effects of a wood preservative.

Proofs of efficacy must be provided by testing laboratories that have been accredited under ISO/EC 17025 for the specific field. Furthermore, testing must be carried out in accordance with recognised standards. Complete copies of the reports must be submitted. The test reports must contain all data (individual values) required to interpret the results. All test and control data must be described and listed. The complete (i.e. 100%) composition of the product to be tested (including active substances and their concentrations) must be clearly indicated.

### Proof of efficacy against wood-discolouring and wood-destroying fungi

#### Wood-discolouring fungi: Blue-stain fungi and mould

- Preventive effect against secondary blue staining after outdoor weathering according to EN 152.1/EN 73.
- Determination of antimycotic action against blue stain and mould growth on green sawn lumber in field testing according to EMPA SOP 001'095.

#### Wood-destroying fungi: Basidiomycetes

- Determination of the limits of efficacy (cell process) against basidiomycetes according to EN 113 as per the preceding EN 73 and/or EN 84.
- Determination of fungicidal action against basidiomycetes after surface treatment according to modified EN 113 (RAL) and based on ENV 839 (EMPA SOP 002'514) after outdoor weathering and according to EN 73, alternatively according to the preceding EN 73 and/or EN 84.
- Field testing procedure for determining the relative protective effect of a wood preservative in soil contact according to EN 252.
- Anti-dry rot effect in masonry according to ENV 12404.

#### Soft rot

- Determination of the limits of efficacy (cell process) against soft rot and other soil-inhabiting micro-organisms according to ENV 807 as per the preceding EN 84.

#### Further information:

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## Proof of efficacy against wood-destroying insects

See standard 599-1 (2009) for an overview of proof of insecticidal effects.

### Determination of eradicator action (Ib) against:

(Insect species according to product declaration)

- Old-house borer (*Hylotrupes bajulus*): according to ENV 1390
- Furniture beetle (*Anobium punctatum*): according to EN 48, EN 370
- Powder post-beetle (*Lyctus brunneus*): according to EN 273

### Determination of preventive action (Iv) against:

(Insect species according to product declaration)

#### a) Products for surface treatment

Aging: according to EN 73

Biotest:

- Old-house borer (*Hylotrupes bajulus*): against instar larvae according to EN 46.1
- against eggs and instar larvae according to EN 46.2
- Furniture beetle (*Anobium punctatum*): according to EN 49.1
- Powder post-beetle (*Lyctus brunneus*): according to EN 20-1

#### b) Products for the cell process

Aging: according to EN 73

Biotest: Determination of toxic values for larvae of:

- Old-house borer (*Hylotrupes bajulus*): according to EN 47
- Furniture beetle (*Anobium punctatum*): according to EN 49-2
- Powder post-beetle (*Lyctus brunneus*): according to EN 20-2

Determination of the preventive action against termites:

- *Reticulitermes santonensis*: according to EN 117
- *Mastotermes darwiniensis*: according to EN 118

### Supplementary note:

Standard EN 73 has precedence in use classes 1 and 2, while standards EN 73 and EN 84 have precedence in use classes 3 and 4.

#### Further information:

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