Application for authorisation ANas a biocidal product family

(Art. 2, para 2 let. b and Art. 13 of the Ordinance on Biocidal Products OBP – SR 813.12)

**Definitions:**

A biocidal product family is a group of biocidal products that have the following common characteristics:

* similar uses,
* same active substances,
* similar composition with specified deviations,
* similar risk potential,
* similar efficacy.

The risk assessment for humans, animals and the environment as well as the efficacy is based on the same requirements as for an authorisation AN.

A biocidal product family contains a defined concentration range of the specified ingredients. After prior notification to the Notification Authority for Chemicals, additional members of the biocidal product family whose composition lies within the deviations defined in the authorisation are subsequently allowed to be placed on the market. The notification has to be made at least 30 days before placing the additional member of the biocidal product family (in analogy with Art. 13*d* para. 1 OBP). Notification is not required if the deviation relates only to pigments, fragrances and/or colorants within the permitted deviations of the authorisation, unless the deviation is linked to a modification of the trade name (in analogy with Art. 13*d* para. 3 let. b OBP).

A biocidal product family can consist of a several sub-families that can differ in product type, use, method of use, categories of use, preparation and/or packaging. Members of a sub-family must have the same classification and labelling (If the biocidal product family consists of a several sub-families please tick the fourth box under “please tick as appropriate” on the next page and follow the instructions). If anything is not clear you can contact the Notification Authority for Chemicals.

*Proof of efficacy (in analogy with Art. 13 let. b and Annex no. 1.1 m OBP).*

*For product types 1-4 (disinfectants) and for product type 8 (wood preservatives) each claimed method of use requires a proof of efficacy to be submitted for the least effective member of the biocidal product family or sub-family, or an explanation of why a proof of efficacy has not been submitted for a specific application. To provide the proof of efficacy please fill out Annex 2 or Annex 3 of the application form.*

**Please tick as appropriate:**

I.

[ ]  I would like to integrate an already authorised biocidal product (transitional authorisation AN) into a biocidal product family. Please fill out the complete form.

II.

[ ]  I would like to submit an application for an authorisation AN for a biocidal product family with new biocidal products (i.e. members) whose members within the family or sub-family do **not** differ (i.e. also not in the use, type of application etc.) other than by the concentration of pigments, colorants or fragrances. Please take note that the active substance concentration, solvent concentration and total content of pigments, colorants or fragrances within the family or sub-family have to be the same (constant) for all biocidal products (members). Please fill out the form without no. 3, and for the family or sub-family enter a product example that carries the name of the biocidal product family or sub-family into the product register and state the concentration range for the pigments, colorants or fragrances. After the electronic form has been sent over the internet, the form has to be printed, signed and submitted by post with the remaining documents of the application to the Notification Authority for Chemicals.

III.

[ ]  I would like to apply for an authorisation AN for a biocidal product family with new biocidal products (i.e. members) whose members differ not only in pigments, colorants or fragrances (differentiation from point II.). Please fill out the form without no. 3. An electronic form has also to be filled out in the product register for each member of the biocidal product family ([www.rpc.admin.ch](http://www.rpc.admin.ch)). After the web form has been sent over the internet, the form has to be printed, signed and submitted by post with the remaining documents of the application to the Notification Authority for Chemicals.

IV.

[ ]  The biocidal product family consists of various sub-families. A form has to be filled out for each sub-family.

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| Identity of the biocidal product family |
| Trade name of the biocidal product family:       |
| Contact addresses |
| Applicant:Company:      Address:      Tel. / Fax / e-mail:      Contact person:      Tel. / Fax / e-mail:       |
| Manufacturer of the product (if not identical with 2.1):Company name:      Address:      Country:      Tel. / Fax / e-mail:      Contact person:      Tel. / Fax / e-mail:       |

1. **Table with the individual members of the biocidal product family**

(only to be filled out for the integration of already authorised biocidal products into a biocidal product family)

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| **Trade name of the biocidal product** | **Approval number** |
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| Uses |
| Product types (PTs) and their uses*More than one box may be checked.* |
| [ ]  PT 1: Human hygiene biocidal products[ ]  Hygienic hand disinfection[ ]  Surgical hand disinfection[ ]  Hygienic hand washing[ ]  Mouth wash[ ]  PT 2: Disinfectants and algaecides not intended for direct application to humans or animals[ ]  Disinfectants: Althlete's foot prophylaxis[ ]  Instrument disinfection[ ]  Disinfectants: Sterilisation[ ]  Surface disinfection general[ ]  Disinfectants: Surfaces for medical use, schools, pharmaceuticals, etc.[ ]  Industrial surface disinfection[ ]  Surface disinfection: Air conditioning, refrigeration, ventilation[ ]  Surface disinfection for solariums[ ]  Household disinfection (exclusively)[ ]  Surface disinfection: Other (specify):      [ ]  Disinfectants: Odour inhibition / inhibitors[ ]  Disinfectants: Automobile air conditioning[ ]  Disinfectants: Anti-mould[ ]  Swimming pool disinfection: Surface/plumbing[ ]  Private swimming pool: Water disinfection[ ]  Algicide for swimming pool water[ ]  Algicide: Other (ponds, aquariums, etc.)[ ]  Treatment of waste water, waste, chemical toilet[ ]  Laundry disinfection[ ]  Public and private swimming pool: Water disinfection[ ]  PT 3: Veterinary hygiene biocidal products [ ]  Animal husbandry: Preventive disinfection[ ]  Teat disinfection[ ]  Preventive immersion baths, disinfection[ ]  Official animal epidemic control[ ]  Veterinary hygiene biocidal products: Animals, animal husbandry: other (specify):      [ ]  PT 4: Food and feed area disinfectants[ ]  Disinfectants for food industry (incl. kitchens, restaurants, canteens): Surfaces[ ]  Food and feed area disinfectants: CIP (cleaning in place)[ ]  Disinfectants for beverage industry and brewery[ ]  Disinfectants for dairy, milk processing[ ]  Disinfectants for milking machines[ ]  Surface disinfection: Greenhouses, agriculture[ ]  Disinfection of private kitchens[ ]  Storage of feed disinfectants[ ]  Food and feed area disinfectants      [ ]  PT 5: Drinking water disinfectants[ ]  Drinking water disinfection[ ]  Drinking water disinfectants for communities, large facilities[ ]  Drinking water disinfectants additives for buildings[ ]  Drinking water disinfectants for travel, baby bottles, etc.[ ]  Filter membrane disinfection[ ]  Drinking water disinfectants      [ ]  PT 6: Preservatives for products during storage[ ]  In-can preservatives for detergents[ ]  In-can preservatives for other detergents[ ]  In-can preservatives for paint[ ]  in-can preservatives for paper production[ ]  In-can preservatives for fuel[ ]  In-can preservatives for glue[ ]  Other in-can preservatives[ ]  PT 7: Film preservatives[ ]  Film preservatives for paint[ ]  Film preservatives for plastic[ ]  Film preservatives for glue[ ]  Film preservatives for paper, textile and leather[ ]  Film preservatives for sealants and filling materials[ ]  other film preservatives[ ]  PT 8: Wood preservatives[ ]  Wood preservatives in general[ ]  PT 9: Preservatives for fibre, leather, rubber and polymerised materials[ ]  Preservatives for paper[ ]  Preservatives for rubber and polymerised materials and other biocidal products covered by product type 9[ ]  Preservatives for textiles and leather[ ]  PT 10: Construction material preservatives[ ]  PT 11: Preservatives for liquid-cooling and processing systems[ ]  Preservatives used in once-through systems[ ]  Preservatives used in recirculation systems[ ]  Preservatives for liquid-cooling and processing systems[ ]  PT 12: Slimicides[ ]  Slimicides for oil extraction[ ]  Slimicides for paper pulp[ ]  Other slimicides[ ]  PT 13: Working or cutting fluid preservatives[ ]  PT 14: Rodenticides[ ]  Bait[ ]  Contact powder[ ]  Other (specify):      [ ]  PT 15: Avicides[[1]](#footnote-1)[ ]  PT 16: Molluscicides[ ]  PT 17: Piscicides 1[ ]  PT 18: Insecticides, acaricides and products to control other arthropods[ ]  Insecticides etc.: Application in private and public spaces (living areas, restaurants, homes, etc.)[ ]  Insecticides etc.: Fly (larvae) control in stables[ ]  Insecticides etc.: Application on horses and livestock[ ]  Insecticides etc.: Application on dogs and cats[ ]  Insecticides etc.: For nebulising or spraying from a nebuliser or a programmable device[ ]  Insecticides etc.: For evaporation from strips or electric vaporisers[ ]  Insecticides etc.: Fumigants[ ]  Insecticides etc.: Use in farms[ ]  Insecticides etc.: Other (specify):      [ ]  PT 19: Repellents and attractants[ ]  Repellents: Human application (skin, hair, clothing)[ ]  Repellents: Application on horses and livestock[ ]  Repellents: Application on dogs and cats[ ]  Repellents and attractants for evaporation from strips or electric vaporisers[ ]  Repellents for vertebrate control (e.g. dogs, cats, martens)[ ]  Attractants[ ]  Repellents and attractants: Other (specify):      [ ]  PT 20: Control of other vertebrates1[ ]  PT 21: Antifouling products[ ]  Antifouling products: Soluble matrix[ ]  Antifouling products: Insoluble matrix[ ]  Antifouling-products: Self-polishing[ ]  Antifouling products[ ]  PT 22: Embalming and taxidermist fluids |

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| Area of use*More than one box may be checked.*  |
| [ ]  Indoor[ ]  Outdoor[ ]  In closed system[ ]  In household[ ]  In stables[ ]  In milk chamber[ ]  In feed storerooms[ ]  Use on the skin[ ]  Industrial process[ ]  Ship hull[ ]  Fishing and aquaculture equipment | [ ]  Harbour infrastructure[ ]  Inlet pipes (into contact with the aquatic environment)[ ]  Offshore infrastructure[ ]  sewers[ ]  dumpsite[ ]  Use class 1 (only for PT8)[ ]  Use class 2 (only for PT8)[ ]  Use class 3 (only for PT8)[ ]  Use class 4 (only for PT8)[ ]  Other (specify):       |
| Type of application *More than one box may be checked.*  |
| [ ]  Spraying / aspersion[ ]  Dipping[ ]  Wiping[ ]  Fumigation[ ]  Nebulisation[ ]  Evaporation[ ]  Dissolved in liquid[ ]  Brush / roller [ ]  Impregnation through drill perforation / Inoculation | [ ]  Spray tunnel [ ]  Prolonged immersion[ ]  Boiler pressure impregnation / alternated vacuum and pressure impregnation[ ]  Bait[ ]  rubbing[ ]  Cleaning in Place[ ]  Incorporation in products, fibres, materials[ ]  With a device, describe (join information):      [ ]  Other (specify):       |
| Aim of use (*More than one box may be checked*)[ ]  Prevention [ ]  Treatment |
| In situ generation: |
| [ ]  Yes (describe):       | [ ]  No |
| Dilution: |
| [ ]  The product must be diluted for use with :       | [ ]  The product must be used undiluted |
| Dose rates:* Application concentration (for salts, emulsions, etc.):
* Recommended dose rate for ready-to-use product (g/m2, kg/m3, mg/l, etc.):
* Number of treatments:
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| Category of use |
| [ ]  Professional users  | [ ]  General public |

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| Packaging and type of preparation |
| Packaging:       |
| Fill quantity:       |
| Aggregate state: |
| [ ]  Aerosol (compressed gas dispenser) | [ ]  Aerosol (hand pump dispenser) | [ ]  Solid |
| [ ]  Fine grained | [ ]  Coarse grained | [ ]  Powdery |
| [ ]  Flaky | [ ]  Tablets | [ ]  Waxy |
| [ ]  Gas | [ ]  Liquid | [ ]  Gel |
| [ ]  Pasty | [ ]  Other:       |

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| 7 Composition and proposed classification of the biocidal product family (or sub-family) |
| 7.1 Concentration limits of the various ingredients of the biocidal product family (or sub-family) and their classification according to Regulation (EC) No 1272/2008 (GHS).The classification for each hazardous ingredient must be listed in the Table. |
| Chemical name (ISO common name)For active substances: ISO common name or name according to the list of the notified active substances[[2]](#footnote-2) | Cas-No.EG-No. | Low concentration limit in %3; (w/w)4 | Upper concentration limit in %[[3]](#footnote-3), (w/w)[[4]](#footnote-4) | Function in the biocidal product      | Classification according to Regulation 1272/2008/EC (CLP Regulation) | Manufacturer of the active substance(name, town, country) |
| Hazard pictograms | Hazard class and hazard category | Hazard statements (‘H phrases’) |  |
|       | CAS     EC      |       |       |       |       |       |       |       |
|       | CAS     EC      |       |       |       |       |       |       |       |
|       | CAS     EC      |       |       |       |       |       |       |       |
|       | CAS     EC      |       |       |       |       |       |       |       |
|       | CAS     EC      |       |       |       |       |       |       |       |
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|       | CAS     EC      |       |       |       |       |       |       |       |
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|       | CAS     EC      |       |       |       |       |       |       |       |
|       | CAS     EC      |       |       |       |       |       |       |       |
|       | CAS     EC      |       |       |       |       |       |       |       |
|       | CAS     EC      |       |       |       |       |       |       |       |

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| 7.2 Ecotoxicological data for ingredients*For each substance (active substance and other ingredients) classified under section 6.1 as acute aquatic cat. 1 with H400 or chronic aquatic cat. 1 with H410, the following values for* ***acute*** *aquatic toxicity must be stated:* |
| Chemical name of the ingredients dangerous fort the environment and CAS number. | Value (unit)48h EC50  (daphnia) | Value (unit)72h EC50  (algae) | Value (unit)96h LC50  (fish) |
|  | Method / species / further particulars |
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| *For each substance (active substance and other ingredients) classified under section 6.1 as acute aquatic cat. 1 with H400 or chronic aquatic cat. 1 with H 410, please state the following values for* ***chronic*** *aquatic toxicity (chronic NOEC or ECx) if available:* |
| Chemical name of the ingredients dangerous fort the environment and CAS number | Value (unit)NOEC / ECx(daphnia) | Value (unit)NOEC / ECx (algae) | Value (unit)NOEC / ECx (fish) | rapidly degradable Yes/No |
|  | Method / species / further particulars |
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| Physicochemical data relevant to classification *If ingredients of the product are classified in respect of the physicochemical properties (e.g. flammable or oxidising), the relevant data or test results which are required for the evaluation of the classification must be stated. Since the testing requirements for the physicochemical properties differ according to Directive 67/548/EEC and CLP Regulation, the method by which data are collected and for which classification they were used must be provided. These include e.g.:** Test results on oxidising properties
* Test results on flammability and combustion heat of aerosols (aerosol dispensers)
* Test results on flash point and boiling point
* Test results on explosive properties
* Test results on organic peroxides
* Test results on corrosiveness on metals
* Further classification-relevant data if available

It should be noted that the test requirements regarding physical-chemical properties in Directive 67/548 EEC and in the CLP Regulation are not identical. In many cases the results for classification under Directive 76/548 EEC are not applicable for classification under the CLP Regulation. However, methods to determine the physical-chemical properties under CLP and transport law. |
| 7.4 Proposal for classification and labelling according to Regulation 1272/2008/EC (CLP Regulation). |
| 7.4.1 Classification of the biocidal product family or sub-family[ ]  The classification of the biocidal product does not match the result of the calculation method[[5]](#footnote-5). In this case, 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.  |
| Hazard class and hazard category : | Hazard statements („H phrases“) |  |
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| [ ]  Classification not required |
| **Ecotoxicological data of the product** (if they have been collected)For the classification in the category acute aquatic cat 1: |
| 48h EC50  (daphnies)      | 72h EC50  (algae)      | 96h LC50  (fish)      |
| For the classification in the category chronic aquatic cat. 1 to 3: Please state the true value type (e.g. NOEC, EC10). In addition, the degradation of ecotoxicological relevant ingredients must be stated in section 6.2: |
| NOEC / ECx (daphnies)      | NOEC / ECx (algae)      | NOEC / ECx (fish)      |
| Labelling of the biocidal product family / sub-family |
| Hazard pictogram(s) | [ ]  01 | [ ]  02 | [ ]  03 | [ ]  04 | [ ]  05 | [ ]  06 | [ ]  07 | [ ]  08 | [ ]  09 |
| Signal word | [ ]  Danger | [ ]  Warning |
| Hazard statement („H phrases“):       |
| Precautionary statement („P phrases“):       |
| Dangerous components to declare([Regulation (EC) No 1272/2008; Art.18, para.3, let.b](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF)):       | Labelling of special risks([Regulation (EC) No 1272/2008, Annex II, part 2](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF)):       |
| Special labelling according to [Annexes ORRChem](http://www.admin.ch/ch/e/rs/814_81/app1.html):       |

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| 8. Enclosures |
| [ ]  Justification for the allocation of the biocidal products to the biocidal product family and sub-family. Please justify, based on the five characteristics listed on page one (art. 2, para 2, let. b OBP), why the biocidal products comply with the characteristics of a biocidal product family, and if applicable, sub-family. [ ]  Safety data sheet for each member of the biocidal product family (obligatory, if compilation is required under [Art. 19 and Art.21 ChemO](https://www.admin.ch/opc/en/classified-compilation/20141117/index.html#a19))[ ]  Documents on the efficacy for the least active biocidal product of the family or sub-family (only valid for product types 1-4 and 8; number of scientific opinions      ), see also Annex 1 and 2 of the application form) *or an explanation of why a proof of efficacy has not been submitted for a specific application.*[ ]  Draft label **(including promotional claims)**. Obligatory for all members of the biocidal product family[ ]  Instructions for use (if not on the label). Obligatory for all members of the biocidal product family[ ]  Justification for the classification (only for the highest possible risk of a biocidal product family or sub-families)[ ]  If you have ticked point III on page 2 of this form, the printed and signed forms (of the product register) of all biocidal products of the biocidal product family.[ ]  Others:       |

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| I would like the decision of the notification authority for chemicals to be written in: |
| [ ]  German  | [ ]  French | [ ]  Italian |
| **Only one choice possible.** If the field above is not completed correctly, the decision will be written in German. |
| Place and date:       | Stamp and signature of the**applicant in Switzerland:** |
|  |       |
| The processing of applications is subject to costs as specified in annex II section 1.3 of the Ordinance on Charges for Enforcement of Chemicals Legislation ([ChemGebV](http://www.admin.ch/ch/d/sr/c813_153_1.html), SR 813.153.1). |
| Forms which have not been completed in full are subject to additional costs. |
| Please submit with enclosures and attachments to: | Federal Office of Public HealthNotification Authority for ChemicalsCH - 3003 BernTel. +41 (0)58 462 73 05Fax +41 (0)58 463 54 86[www.cheminfo.ch](http://www.cheminfo.ch)  |

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

Annex 1 to the application for authorisation AN for a biocidal product family or sub-family

Disinfectants (product types 1 - 4)

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| Claimed product efficacy: |
| [ ]  Levurocide (yeasts)[ ]  Fungicide (fungi and fungal spores)  | [ ]  Bactericide |
| [ ]  Limited spectrum virucidal effectiveness (EN Standards) | [ ]  Mycobactericide, Tuberculocide |
| [ ]  Virucidal action (enveloped and non-enveloped viruses) | [ ]  Sporicide (against bacterial spores) |
| [ ]  Other action, specify:      [ ]  The complete reports of the efficacy tests are enclosed and summarised below.  |
| **For each group of microorganisms, specify the tested types; e.g. *Staphylococcus aureus*, Polio virus, etc….:** | **Numbers of the Standards used (EN, DGHM, AFNOR, DVG)** | **Results: Application concentrations and minimum contact times** |
| [ ]  Bacteria:       |       |       |
| [ ]  Yeasts:       |       |       |
| [ ]  Fungi and Dermatophytes:       |       |       |
| [ ]  Mycobacteria:       |       |       |
| [ ]  Viruses: a) limited spectrum (according to EN Standards):       |       |       |
| [ ]  Viruses: b) action against enveloped and non-enveloped viruses; (according to EN Standards):       |       |       |
| [ ]  Bacterial spores:       |       |       |
| [ ]  Practical tests for nebulisation or evaporation:       | AFNOR NFT 72-281 |      Room size:       |
| [ ]  Tests for hygienic hand disinfection | EN1500 |       |
| [ ]  Tests for hygienic hand washing | EN1499 |       |
| [ ]  Tests for surgical hand disinfection | EN12791 |       |
| [ ]  Surface disinfection in animal husbandry for low-level or high-level soiling (specify).  |       |       |
| [ ]  Immersion of contaminated objects with high-level soiling in the veterinary field.  |       |       |
| [ ]  Test with other target organisms: specify:       |       |       |

 Annex 2 to the application for authorisation AN for a biocidal product family

Wood preservatives (product type 8)

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| 1. The wood preservative is applied as:  |
| [ ]  Impregnant | [ ]  Clear varnish |
| [ ]  Glaze | [ ]  Other:       |
| [ ]  Varnish paint |  |
| 2. The wood preservative is effective against the following insects: |
| [ ]  House longhorn beetle | [ ]  Powder post beetle |
| [ ]  Deathwatch beetle | [ ]  Other:       |
| 3. The wood preservative is effective against the following fungi: |
| [ ]  Wood-discolouring | [ ]  Dry rot |
| [ ]  Wood-destroying |  |

1. According to article 4 OBP, products of these types are not to be authorised in Switzerland. [↑](#footnote-ref-1)
2. [*Liste der notifizierten Wirkstoffe*](http://www.bag.admin.ch/anmeldestelle/13604/13869/13883/index.html?lang=de) [↑](#footnote-ref-2)
3. For biocides that contain **sodium hypochlorite solutions** and **calcium hypochlorite solutions**: The active chlorine content of the product must be given in % (sodium hypochlorite … % **active Cl**). [↑](#footnote-ref-3)
4. For solutions: the substance contents must be listed separately from the solvent. [↑](#footnote-ref-4)
5. Calculation method covers additive nature, formulas (M factors, ATE values) and concentration limits applied to the endpoints of the components of a product. [↑](#footnote-ref-5)