

ORDINANCE

of the form and content of the documents, necessary for the issue of a permit for providing the market of biocide or a group of biocides under art. 18 of the Law for the Protection from the Harmful Impact of the Chemical Substances and Mixtures

Art. 1. With the ordinance are defined:

1. the form and the content of the technical record and the documents, which the applicant provides for the issue of a permit for providing the market of biocide or a group of biocides under art. 18 from the Law for the Protection from Harmful Impact of the Chemical Substances and Mixtures (LPHICSM);

2. the form and the content of the issued permits for the providing of the market of biocides or a group of biocides under art. 18 of LPHICSM;

3. the conditions and the order for the maintaining of the register of the permitted biocides under art. 18 and of LPHICSM.

Art. 2. (1) For issue of permits under art. 18 of LPHICSM, the person, who provides on the market biocide or a group of biocides, or his representative submits in the Ministry of Health an application in Bulgarian according to Annex No. 1, to which he/she attaches:

1. data for the unified identification code under art. 23 of the Law for the Trade Register and the Register for legal persons not-for-profit or a document for an equivalent registration in the sense of the legislation of the country member-state of the European Union, or under the legislation of another member-state under the Agreement of the European Economic Area;

2. documents in compliance with art. 95 (2) of the Regulation (EU) No.528/2012 of the European Parliament and of the Council from 22 May 2012 concerning the providing of the market and the use of biocides (OB, L 167 from 27.06.2012), further referred as “Regulation (EC) No.528/2012“;

3. technical record of the biocide or the group of biocides;

4. information leaflet for safety, prepared according to the requirements of Annex II to Regulation (EC) No. 1907/2006 of the European Parliament and the Council from 18 December 2006 concerning the registration, assessment, the permission and the limitation of chemicals (REACH), for the establishment of a European Agency for chemicals, for amendment of Directive 1999/45/EC) and for repealing of Regulation (EEC) No. 793/93 of the Council and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission, (special Bulgarian edition, 2007, chapter 13, volume 60), referred to below as “Regulation (EC) No.1907/2007 (REACH)”;

5. a document for paid state fee under art. 19, par.1, sec.18 of LPHICSM;

6. declaration for identity of the provided on a paper and on an electronic media information under s. 3 and 4.

(2) The documents under par.1, s. 3 and 4 are provided in Bulgarian, one copy – on a paper and three copies – on an electronic media.

(3) The provided on a paper media documents under par. 1, s. 3 and 4 are provided in original, signed on each page by the applicant, while the documents under par. 1, s.2, as well as the information leaflets for safety of the chemical substances, included in the content of the biocide/the group of biocides, and the protocols from tests – on a certified by the applicant copy with caption “True to the original”.

Art. 3. (1) For biocide or a group of biocides with active substance, which is a chemical substance, the technical record under art. 2, s. 3 is prepared according to Annex 2.

(2) For biocide or a group of biocides with active substance, which is a microorganism,

including viruses and fungi, the technical record under art. 2, s. 3 is prepared according to Annex No.3.

Art. 4. The permit for providing on the market of biocide or a group of biocides is issued under sample according to Annex 4.

Art. 5. (1) At the Ministry of Health is maintained a register for the allowed biocides or groups of biocides under art. 18 of LPHICSM.

(2) The register contains:

1. number and date of the permission for the providing on the market of the biocide/the group of biocides;
2. validity term of the issued permit, when there is such;
3. data of the person who provides on the market the biocide/the group of biocides – name, seat and management address;
4. name of the biocide/the group of biocides;
5. name and concentration of the active substance/active substances, contained in the biocide/the group of biocides;
6. type of the biocide/the group of biocides and area of application;
7. category of use;
8. date of repealing the permit;
9. changes in the circumstances under s. 1-7.

(3) Each biocide/group of biocides, for which is issued a permit for providing on the market, receives a subsequent number in the register, under which all the inscriptions in terms of the circumstances are applied under par. 2.

(4) The inscriptions in the register under par.1 are performed within 10 days after the date of the issue or the amendment of a permit for providing on the market a biocide/ group of biocides.

(5) In the register under par. 1 is formed a separate section, which contains information of the submitted applications for issue of permits for providing on the market of the biocide/group of biocides. The section contains the following paragraphs:

1. order number;
2. data of the person who has submitted an application – name, seat and management address;
3. number and type of the attached to the application documents;
4. movement of the file, formed under the application.

(6) The data under par. 5 are registered in the register in the order of submission of the applications.

Art. 6. (1) The register under art. 5 is a database, which is maintained on an electronic media.

(2) The register is public and the access to it is performed by the official website of the Ministry of Health.

(3) The Minister of Health defines with an ordinance employees, who perform the registrations in the register.

Art. 7. The documents for issue, change or repealing of the permits for providing on the market of biocides/groups of biocides under art. 18 b, 18d and 18e of LPHICSM are preserved within a term of 20 years.

FINAL PROVISION

Paragraph only. The ordinance is issued on the grounds of art. 18i of the Law for Protection of the Harmful Impact of the Chemical Substances and Mixtures.

Annex No. 1
to art. 2, par. 1

Incoming No./.....year

TO THE MINISTER OF HEALTH

APPLICATION

for issue/amendment of a permit for providing the market of a biocide/group of biocides,

By.....
(th e three names)
in his/her capacity of
.....
(owner, manager, CEO, representative under proxy – number and data of the notary certified proxy)
of
(name of the legal entity/trader)
with a seat and management address: town/village.
....., residential area/street
....., No., bl., entr., apt.,
phone., UIC.....

On the grounds of art. 18/18d of LPHICSM I request to be issued/amended a permit for
(the unnecessary is crossed off) (the unnecessary is crossed off)
providing on the market of biocide/group of biocides with the following trade name:
(the unnecessary is crossed off)
.....

I attach the following documents:

1. data for the unified identification code under art. 23 of the Law for the trade register and the register of the legal entities with non-profit-use or a document for an equivalent registration in the sense of legislation of a EU member state, or under the legislation of another member-state under the Agreement of the European Economic Area;
2. documents in compliance with art. 95 (2) of Regulation (EU) No. 528/2012 of the European Parliament and the Council from 22 May 2012 concerning the providing of the market and the use of biocides;
3. technical record of the biocide/the group of biocides;
4. information leaflet for safety, prepared under the requirements of the Annex II to Regulation (EC) No.1907/2006 of the European Parliament and the Council from 18 December 2006 concerning the registration, assessment, permission and limitation of chemicals (REACH)
5. document for paid state fee under art. 19, par. 1, s. 18 of LPHICSM;
6. declaration for identity of the submitted on paper and on electronic media information under s. 3 and 4.

Date:

Signature:

**Technical record of the biocide or the group of biocides with active substance/substances –
chemical substance/substances**

I. Data of the person, who provides on the market the biocide/the group of the biocides, and of the producer of the biocide and the active substance.

1. Name, address, phone number and email of the person, who provides on the market the biocide/the group of biocides.
2. Name and address of the producer of the biocide/the group of biocides and address of the production enterprise.
3. Name and address of the producer of the active substance and address of the production enterprise.

II. Identity of the biocide/the group of biocides.

1. Trade name of the biocide/the group of biocides and production code, where necessary.
2. Detailed quantitative and qualitative data of the composition of the biocide/the group of biocides.
 - 2.1. Data of the active substance.
 - 2.1.1. Trade name.
 - 2.1.2. Identifier of the active substance according to art. 18 (2) from 1 (OB L 353, 31.12.2008), referred to below as „Regulation (EC) No. 1272/2008 (CLP)“, information leaflet for safety, prepared according to the requirements of Annex 2 to Regulation (EC) No. 1907/2006 (REACH).
 - 2.1.3. Concentration in metric units in the composition of the biocide/the group of biocides.
 - 2.1.4. Efficiency and resistance in terms of the organisms, which are a subject of the offered use, application area.
 - 2.1.4.1. Efficiency under data from test protocols* and/or literature data**, when applicable.
 - 2.1.4.1.1. Spectrum of activity, for example, fungicide, rodenticide, insecticide, bactericide.
 - 2.1.4.1.2. Organisms subject to the offered use, and products, organisms and objects, which should be protected.
 - 2.1.4.1.3. Effects on organisms, which are subject to the offered use, and recommended concentrations of the use of the active substance.
 - 2.1.4.1.4. Manner of use, including the time for impact.
 - 2.1.4.2. Information for established cases or possibility for the development of resistance and suitable measures for avoiding the development when there are available data.
 - 2.1.4.3. The intended use of application and category of the users in the sense of na § 1, s. 17 from the additional provisions of LPHICSM.
 - 2.1.5. Resume of the physical-chemical, toxicological and ecotoxicological data for the active substance.
 - 2.1.5.1. Physical-chemical, toxicological and ecotoxicological data, connected with the classification of the active substance as dangerous, including classes and categories of danger, warnings for danger and recommendations for safety, according to Annex 1 of Regulation (EC) No. 1272/2008 (CLP). When the active substance is not classified as dangerous according to Regulation (EC) No. 1272/2008 (CLP), this is explicitly stated.
 - 2.1.5.2. Physical-chemical, toxicological and ecotoxicological data, which lead to specific requirements and/or limitations during use (for example, in persons from risk groups, in cases of significant skin resorption, and etc.). When for the active substance no specific requirements and/or limitations are applied, this is explicitly stated.
 - 2.1.6. Classification of the active substance, including classes and categories of danger,

pictograms, signal word, warnings for dangers and recommendations for safety, according to Annex 1 of Regulation (EC) No. 1272/2008 (CLP).

2.2. Data for each of the rest chemical substances, included in the contents of the biocide/the group of biocides.

2.2.1. Identifier of the substance according to art. 18 (2) Regulation (EC) 1272/2008 (CLP).

2.2.2. Information leaflets for safety, prepared according to the requirements of Annex 2 to Regulation (EC) 1907/2006 (REACH).

2.2.3. Percentage contents in the content of the biocide.

2.2.4. Classes and categories of danger, pictograms, signal word, warnings for danger and recommendations for safety according to Annex 1 of Regulation (EC) 1272/2008 (CLP). When the substances are not classified as dangerous according to Regulation (EC) 1272/2008 (CLP) and/ or no specific requirements are needed, this is explicitly stated.

III. Physical and chemical characteristics of the biocide/the group of biocides.

1. External appearance (the aggregate state and the colour are indicated).

2. Explosive characteristics.

3. Oxidizing characteristics.

4. Temperatures of explosion, firing and ignition.

5. Acidity/alkalinity(pH). In case of water solution, the concentration is indicated.

6. Relative density.

7. Stability of storage, expiry date. It is indicated if in the usual or foreseeable conditions, connected with the temperature and the pressure, the biocide/the group of biocides are stable or unstable if stored or operated with it, including the influence of the light, the temperature and the humidity on the technical characteristics of the biocide/the group of biocides. Reactivity in terms of the material, of which the package is made.

8. Technical characteristics of the biocide/the group of biocides (for example, foamliness, possibility for watering and dust formation).

9. Physical and chemical compatibility with other products, including other biocides, with which it is applied together.

If necessary other physical and chemical parameters are indicated, such as blending capacity, solubility in fats (the oil solvent is indicated), conductivity or gas group. The suitable available information for safety is indicated concerning the redoxy potential, capacity for formation of radicals and photo-catalytic properties.

IV. Analytical method for defining the concentration of the active substance in the biocide/the group of biocides.

1. Analytical method for defining the concentration of the active substance/substances in the biocide/the group of biocides.

2. If necessary, analytical methods for defining of significant from toxicological and ecotoxicological point of view ingredients of the biocide/the group of biocides in soils, air, waters, foods and fodder.

V. Type of the biocide/the group of biocides and areas of application.

1. Type of the biocides/the group of biocides (liquid, powdery, granules, and etc.)

2. Type of the biocide/the group of biocides according to Annex 5 of Regulation (EU) 528/2012.

3. Spectrum of action, for example, bactericide, fungicide, insecticide, rodenticide, and etc.

4. Area of application.

5. Organisms, which are subject to the offered use, and products, organisms or objects, which should be protected, when there are such.

6. Category of the users in the sense of § 1, s. 17 of the additional provisions of LPHICSM.

VI. Efficiency and resistance under data from protocols of the tests* and/or literature

data, when applicable.**

1. Data for the biological efficiency, with regards to the offered areas of application and methods of use, including geographic and climatic conditions.

1.1. Effects on the organisms, which are subject to the offered use.

1.2. Manner of action and time of impact.

2. Data for resistance if there are such.

VII. Manner of use.

1. Description of the manner of use, including description of the systems and the equipment for application, when such are provided.

2. Concentration of the operational solution and expense norm.

3. Number and duration of the treatment, as well as, if necessary, additional information for the specific requirements in connection with the geographical and climatic peculiarities.

4. End concentration of the biocide/the group of biocides and of the active substance in the treated object, if necessary (for example, waters in cooling and heating systems, surface waters).

4.1. For disinfectants of drinking waters and waters in swimming pools are provided additionally data for:

4.1.1. recommended time of impact for reaching the disinfection effect;

4.1.2. recommended concentration of residual quantities of disinfectant in the processed drinking water/water in the swimming pool, if applicable;

4.1.3. concentration of residual quantities of dangerous for the help ingredients of the disinfectant as well as other ingredients, which impact the quality of the drinking water/the water in the swimming pool;

4.1.4. side products, which may be formed in the process of disinfection, and their type;

4.1.5. practically applicable method for control of the residual quantity of the disinfectant in the drinking water/the water in the swimming pool;

4.1.6. technical instruments and equipment for the practical application of the disinfectant.

5. Interval of time, which should be observed between:

5.1. the separate applications of the biocide/the group of biocides, and/or

5.2. application of the biocide/the group of biocides and the use of the treated products, and/or

5.3. the use of the biocide/the group of the biocides and the access to people or animals to the treated areas, while the instruments and measures for neutralization are provided, the time for airing out of these zones, the guidelines for the cleaning of the equipment.

6. Protection measures in the use, special requirements in the transportation and storage as means of collective and personal protection, fire prevention measures, covering of the furniture or the equipment, removal of food for people and/or animals, guidelines for avoiding the exposition of animals.

7. Measures for rendering first aid, including antidotes, if such are known.

8. Type of the formed gases and the reactive products in the case of fire.

9. Procedures for waste management of the biocide/the group of biocides and their packaging according to the Law for the Waste Management.

10. Data for specific dangers for the environment, including undesired or unforeseeable side effects, for example on useful or other organisms, which are not subject to the offered use.

11. Data for every repellent or means of protection, contained in the biocide/the group of biocides, intended to avoid the unfavorable effects on organisms, which are not subject to the offered use (if there are such).

VIII. Toxicological and ecotoxicological data of the biocide/ the group of biocides.

1. Toxicological and ecotoxicological data, connected with the classification of the biocide/the group of biocides as dangerous and recommendations for safety, according to Annex 1 of the Regulation (EC) 1272/2008 (CLP). When the biocide/the group of biocides is not classified as

dangerous according to Regulation (EC) 1272/2008 (CLP), this is explicitly stated.

2. Toxicological and ecotoxicological data, which lead to specific requirements and/or limitations in use (for example, in cases of persons of risk groups, in case of significant skin resorption, and etc.). When for the biocide/the group of biocides no specific requirements are needed and/or limitations in use, this is explicitly stated.

IX. Classification of the biocide/the group of biocides, including classes and categories of danger, warnings for danger and recommendations for safety, according to the requirements of Annex 1 of Regulation (EC) No. 1272/2008 (CLP).

X. Data for the packaging of the biocide/the group of biocides.

1. Material, type, form, graphic design, and etc.

2. Compatibility of the material of the package with the biocide/the group of biocides.

3. Capacity (mass or volume).

XI. Project of the label, prepared according to the requirements of art. 69 of the Regulation No. 528/2012.

* When the provided data are on the grounds of protocols of tests, copies of the protocols are provided.

** When literature data are provided, the resource is indicated and a copy of the literature data is provided.

Annex 3
to art. 3, par. 2

Technical record of the biocide/the group of biocides with active substance/substances – microorganism/ microorganisms, including viruses and fungi

I. Data of the person, who provides on the market the biocide/the group of the biocides, and of the producer of the biocide/the group of biocides and the active substance.

1. Name, address, phone number and email of the person who provides the biocide/the group of biocides.

2. Name and address of the producer of the biocide/the group of biocides and the address of the production enterprise.

3. Name and address of the producer of the active substance and address of the production enterprise.

II. Identity of the biocide/ the group of biocides.

1. Trade name of the biocide/the group of biocides, trade code, when this is necessary.

2. Detailed quantitative and qualitative data of the contents of the biocide/the group of biocides.

2.1. Data of the active substance.

2.1.1. Conventional name and synonyms.

2.1.2. Taxonomic name of the print with data and if a print or a mutant of the print is concerned.

2.1.3. Microbe collection and referent number of the print, under which it is stored.

2.1.4. Methods, procedures, criteria for proving the availability and the identification of the active substance (for example morphological, biochemical, serological and etc.).

2.1.5. Biological properties of the active substance.

2.1.5.1. Characteristics of the organism and its use, including origin, and if necessary geographical distribution.

2.1.5.2. Effects on organisms, which are object of the offered use. Pathology or type of the antagonism of the host. Description of the specific for the active organism hosts.

2.1.5.3. Manner of transmission, infecting dose, manner of action, including information of

presence, absence or formation of toxins. In case of presence or formation of toxins – information of the type, characteristics, the chemical structure, the stability and the biological effects of the toxins.

2.1.5.4. Possible effects on organisms, which are not subject to the offered use, but are tightly connected with the organisms, which are subject of the offered use (for example, with similar habitats, including infectiousness, pathogenicity, manner of transmission).

2.1.5.5. Manner of transmission to other organisms, which are not subject to the offered use, and data of possible biological effects on them.

2.1.5.6. Infectiousness and physical stability in the prescribed manner of use and in the expected conditions of the environment.

2.1.5.7. Pathogenicity and infectiousness for familiar parasites/predators, which are subject to the offered use.

2.1.6. Efficiency and area of application.

2.1.6.1. Organisms, which are subject to the offered use, and materials, substances, organisms or products, which must be treated or protected.

2.1.6.2. Spectrum of action.

2.1.6.3. Information on observations for desirable or undesirable side effects.

2.1.6.4. Information for cases or possibility for development of resistance and measures for its avoiding and control, when there are such.

2.1.6.5. Category of the users in the sense of par.1 s.17 of the additional provisions of LPHICSM.

2.1.7. Resume of the toxicological and ecotoxicological data for the active substance, pathogenicity and infectiousness under the data from protocols of tests* and/or literary data*.

2.1.8. Measures need for the protection of man, of the organisms, which are not subject of the offered use, of the environment.

2.1.8.1. Recommended protection measures in use, storage and transport, as well as in case of fire or other incidents.

2.1.8.2. Environmental conditions (climatic, geographic, meteorological, and etc.) or other circumstances, in which the active organism should not be used.

2.1.8.4. Consequences of the air pollution, the soil and the water, especially intended for use for drinking- household purposes.

2.1.8.5. Emergency measures in case of an accident or a failure.

2.1.8.6. Procedures for waste management of the active organism, including qualitative parameters of the waste waters after the landfill of waste.

2.1.8.7. Possibilities for destruction or disposal of the active organism when released in the air, waters, soils or other environments.

2.1.9. Data of the classification and labeling of the active organism – risk group and sign for bio-danger, according to Regulation No.4 from 2002 for the protection of the working from risks, connected with the exposition of biological agents in operation (published in State Gazette, issue 105 from 2002).

2.2. Data for each of the chemical substances, included in the content of the biocide/the group of biocides, different from the active substance/ substances.

2.2.1. Chemical name.

2.2.2. Identifier of the substance according to art. 18(2) of Regulation (EC) No. 1272/2008 (CLP).

2.2.3. Information leaflets for safety, prepared in compliance with the requirements f Annex 2 to Regulation (EC) No. 1907/2006 (REACH).

2.2.4. Percentage content in the content of the biocide/the group of biocides.

2.2.5. Classes and categories of danger, safety warnings and recommendations for safety according to Annex 1 of Regulation (EC) No. 1272/2008 (CLP).

III. Technical and biological properties of the biocide/the group of biocides.

1. External appearance (colour and odour).
2. Stability in storage, expiry date. Impact of the temperature, manner of packaging and storage and of other factors on the preservation of the biological activity.
3. Technical characteristics of the biocide/the group of biocides.
 - 3.1. Wetting.
 - 3.2. Stability of the foam formation.
 - 3.3. Formation and stability of the suspension.
 - 3.4. Formation of emulsion and re-emulsion, stability of the emulsion.
 - 3.5. Possibility for dust formation.
4. Physical, chemical and biological compliance with other products, including biocides, with which joint use is permitted.
5. Changes in the biological properties of the organism as a result of the formulation, including changes in the pathogenicity and the infectiousness.

V. Methods for identification and analysis.

1. Methods of analysis of the biocide/the group of biocides.
2. Methods for the defining and quantitative proof of the residual quantities.

V. Type of the biocide/the group of biocides and area of application.

1. Type the biocide/the group of biocides (liquid, dust, granulate, and etc.).
2. Вн Type the biocide/the group of biocides according to Annex 5 of the Regulation (EU) No.528/2012.
3. Spectrum of action.
4. Area of application – type of organisms, which are subject of the offered use, materials, which will be treated, and etc.

VI. Efficiency and resistance under data from tests and/or literary data.

1. Data for the biological efficiency, taking into account the offered areas of application and manner of use, including geographic and climatic conditions.
 - 1.1. Time of effect.
2. Data for resistance, if there are such.
3. Impact on the quality of the treated materials or products.

VII. Manner of use.

1. Description of the manner of use, including description of application systems, if such are needed.
2. Expense norm.
3. Number and Duration of Treatments
4. In case of necessity information for specific conditions of the environment (for example, climatic, geographic, meteorological, and etc) or other circumstances, where the biocide/the group of biocides may or may not be used.
5. Time interval, which must be observed between:
 - 5.1. The separate applications of the biocide/ the group of biocides, and/or
 - 5.2. The application of the biocide/ the group of biocides and the use of the treated products, and/or
 - 5.3. The use of the biocide/ the group of biocides and the access of people or animals to the treated areas, while the instruments and measures for disposal, guidelines for cleaning of the equipment.
6. Recommended protective measures in the use, transport and storage as means of collective and personal protection, fire prevention measures, covering of the furniture or the equipment, removal of food for people and/or animals, guidelines for avoiding the exposition of animals.
7. Guidelines for harmless disposal of the biocide/the group of biocides and its packaging, as well as, if necessary, ban for recurrent use of the package.

VIII. Resume of the toxicological and ecotoxicological data of the biocide/the group of

biocides under protocols for tests or literary data, adding to the data reported for the active organism.

IX. Classification, packaging and labeling of the biocide/the group of biocides according to the requirements of Regulation (EC) No.1272/2008 (CLP).

1. Classification of the biocide/the group of biocides:

1.1. Classes and categories of danger, warnings for danger and recommendations for safety concerning the chemical contents, according to Annex 1 to Regulation (EC) No. 1272/2008 (CLP).

1.2. Risk group, in which the active organism is classified, and sign for bio danger according to Regulation No. 4 from 2002 for the protection of the working staff from risks, connected with the exposition of biological agents in the process of work.

2. Packaging.

2.1. Material, type, form and graphic design of the package.

2.2. Compliance of the material of the package with the biocide/the group of biocides.

2.3. Capacity (mass or volume).

3. Project of the label, prepared according to the requirements of art. 69 of Regulation (EU) No. 528/2012.

X. Category of the users – mass and/or professional in the sense of par. 1., s. 17 of the additional provisions of LPHICSM.

* When the data provided are on the grounds of protocols from tests, copies of the protocols are provided.

** When literary data are provided, the source is indicated and a copy of the literary data is provided.

Anex 4
to art. 4

PERMIT

for providing on the market of a biocide/a group of biocides

No./.....year

On the grounds of art. 14a and art.14 c, par. 5 in connection with art.15, par.4, s.16 of the Law for Protection of the Harmful Impact of the Chemical Substances and Mixtures and a submitted application with incoming number...../.....year

I permit the providing on the market of:

I. Trade name of the biocide/the group of biocides

.....

II. Name and address of the person, who provides on the market the biocide/the group of biocides

.....

III. Name and address of the producer of the biocide/the group of biocides

.....

IV. Producer of the active substance

.....

V. Type of the biocide/the group of biocides, according to Annex 5 of Regulation (EU) No. 528/2012 of the European Parliament and the Council dated 22 May 2012 concerning the providing on the market and the use of biocides (OB, L 167 from 27.06.2012)

.....

VI. Type of the biocide/the group of biocides (granulate, liquid, dust, and etc.)

.....

VII. Data for the active substance/substances in the content of the biocide/the group of biocides

A. Chemical substance

No.	Name	CAS No. and EC No. if such are defined	Concentration of the active substance in metric units

B. Microorganism/microorganisms

No.	Generally accepted name and synonyms	Taxonomic name	Strain	Concentration of the active organism in the content of the biocide/the group of biocides

VIII. Area/areas of application

.....

IX. Manner of use

.....

X. Data for classification and labeling of the biocide/the group of biocides according to Regulation (EC) No.1272/2008 of the European Parliament and the Council from 16 December 2008 concerning the classification, labeling and packaging of substances and mixtures, for amendment and for repealing of Directives 67/548/EEA and 1999/45/EC and for amendment of Regulation (EC) No.1907/2006 (OB L 353, 31.12.2008)

A. Biocide/group of biocides with active substance/substances – chemical substance/substances

Classes and categories of danger:

.....

Pictograms:

.....

Signal word:

.....

Danger warnings:

.....

Recommendations for safety:

.....

B. Biocide/group of biocides with active substance/substances – microorganisms, including viruses and fungi

Risk group, where the active organism is classified according to Ordinance No.4 from 2002 for protection of the working staff from risks, connected with exposition of biological agents (published in the State Gazette, issue 105, 2002)

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XI. Data of the package (type of the package, capacity/volume)

.....

XII. Category of the users

.....

XIII. Specific requirements and/or limitations

.....

Minister:

.....

(signature)