

Republic of Latvia
Cabinet
Regulation No. 628
Adopted 27 August 2013

Requirements in Relation to Activities with Biocidal Products

*Issued pursuant to
Section 9, Paragraph seven
of the Chemical Substances Law*

1. This Regulation prescribes the procedures to be conformed to in relation to activities with biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (hereinafter – Regulation No 528/2012).

2. The State limited liability company “Latvian Environment, Geology and Meteorology Centre” (hereinafter – Centre) shall issue an inventory number of a biocidal product (hereinafter – inventory number) and:

2.1. in accordance with Articles 7 and 8 of Regulation No 528/2012 shall evaluate the application of an active substance;

2.2. in accordance with Articles 13 and 14 of Regulation No 528/2012 shall evaluate the application for renewal of an active substance;

2.3. in accordance with Article 17 of Regulation No 528/2012 shall issue a national authorisation for making available on the market and use of biocidal products in the territory of Latvia (hereinafter – national authorisation);

2.4. in accordance with Article 23 of Regulation No 528/2012 shall perform comparative assessment of biocidal products;

2.5. in accordance with Article 26 of Regulation No 528/2012 shall issue an authorisation according to simplified procedure;

2.6. in accordance with Article 27 of Regulation No 528/2012 shall examine notifications regarding authorisations granted according to simplified procedure;

2.7. in accordance with Articles 33 and 34 of Regulation No 528/2012 shall issue an authorisation granted as a result of proceedings of mutual recognition;

2.8. in accordance with Articles 43 and 44 of Regulation No 528/2012 shall evaluate an application in order to receive an authorisation issued by the European Commission for making available on the market and use of biocidal products in the territory of the European Union (hereinafter – Union authorisation);

2.9. in accordance with Article 45 of Regulation No 528/2012 shall evaluate the application for renewal of the Union authorisation;

2.10. in accordance with Articles 48, 49 and 50 of Regulation No 528/2012 shall cancel, revise or amend the national authorisation;

2.11. in accordance with Article 53 of Regulation No 528/2012 shall issue a parallel trade authorisation;

2.12. perform other functions laid down for the competent authority in accordance with Regulation No 528/2012.

3. The Centre shall assign inventory numbers within the time period laid down in Article 89(1) of Regulation No 528/2012 to biocidal products which conform to the criteria referred to in Article 89(2) of Regulation No 528/2012 and which are intended to be placed on the market of Latvia.

4. In order to receive an inventory number, a legal person or natural person who imports biocidal products into Latvia or a manufacturer (hereinafter – applicant) shall submit a relevant application to the Centre.

5. The information to be included in the application is indicated in Annex 1 to this Regulation.

6. The label of the biocidal product in accordance with Article 69 of Regulation No 528/2012 and the safety data sheet in accordance with Article 70 of Regulation No 528/2012 shall be attached to the application.

7. The Centre shall refuse to assign an inventory number if:

7.1. the information submitted regarding the biocidal product does not conform to the definition of the biocidal product referred to in Article 3(1) of Regulation No 528/2012;

7.2. any of the procedures referred to in Regulation No 528/2012 is applicable to the biocidal product;

7.3. a chemical substance, which is included in Annex 2 to this Regulation, is indicated in the application as the active substance;

7.4. complete information, which is indicated in Paragraph 6 of and Annex 1 to this Regulation has not been submitted within 14 days upon request of the Centre.

8. The inventory number of a biocidal product assigned by the Centre shall be indicated on the packaging label of the biocidal product.

9. The term of validity of the inventory number assigned shall not exceed that laid down in Article 89(2) of Regulation No 528/2012.

10. If information which has been indicated in the application referred to in Paragraph 4 of this Regulation has changed, the applicant shall notify the Centre thereof within 14 working days from the day when changes were made, in printed form or in the form of an electronic document. The Centre shall evaluate the conformity of changes with the requirements referred to in this Regulation and Regulation No 528/2012 and, if necessary, shall update the publicly available information on the Centre website regarding biocidal products, which have been granted an inventory number.

11. Cabinet Regulation No. 184 of 15 April 2003, Requirements for Activities with Biocidal Products (*Latvijas Vēstnesis*, 2003, No. 83; 2005, No. 102; 2007, No. 121; 2008, No. 49, 157; 2009, No. 60, 102; 2010, No. 58, 120; 2011, No. 60, 102, 175; No. 2012, No. 72, 184; 2013, No. 65, 103), is repealed.

12. This Regulation shall come into force on 1 September 2013.

Prime Minister

Valdis Dombrovskis

Minister for Environmental Protection and
Regional Development

Edmunds Sprūdžs

Information to be Included in the Application for Receipt of an Inventory Number of a Biocidal Product

1. Information regarding the applicant:
 - 1.1. the name of the applicant;
 - 1.2. the registration number with the Commercial Register;
 - 1.3. the code of the payer of the value added tax (VAT);
 - 1.4. legal address;
 - 1.5. actual address
 - 1.6. telephone number;
 - 1.7. fax number;
 - 1.8. e-mail address.

2. Person responsible for the provision of information:
 - 2.1. given name, surname;
 - 2.2. position;
 - 2.3. telephone number;
 - 2.4. e-mail address.

3. Information regarding the manufacturer of a biocidal product, if the biocidal product is imported into the territory of Latvia:
 - 3.1. the name of the manufacturer;
 - 3.2. the location of the manufacturing plant.

4. Information regarding the distributor, if the applicant is established outside Latvia:
 - 4.1. the name of the distributor;
 - 4.2. legal address;
 - 4.3. actual address;
 - 4.4. telephone number;
 - 4.5. fax number;
 - 4.6. e-mail address.

5. Trade name of the biocidal product.

6. Names of the active substances in the composition of biocidal product and their concentration.

No.	Name of the substance ¹	CAS number ²	EC number ³	Concentration	Unit of measurement

Notes.

¹ Generally accepted (trivial) name of the substance or name according to the nomenclature of the International Union of Pure and Applied Chemistry (IUPAC).

² Number of the substance in the register of chemical substances *Chemical Abstracts Service* (CAS number), if available.

³ Number of the European Community (EC number), if available.

7. Product type according to Annex 5 to Regulation No 528/2012.

8. Other information.

Minister for Environmental Protection and
Regional Development

Edmunds Sprūdžs