

Republic of Serbia
MINISTRY OF
ENVIRONMENTAL PROTECTION

Number: 532-01-1316/2021-03

Date: 19 April 2021

Nemanjina 22-26

Belgrade

Pursuant to Article 11 of the Law on Biocidal Products ("Official Gazette of RS", No. 36/09, 88/10, 92/11 and 25/15), Article 6 Paragraph 1. Item 11) of the Law on Chemicals ("Official Gazette of RS", No. 36/09, 88/10, 92/11, 93/12 and 25/15), Article 6 Paragraph 1 of the Law on Ministries (Official Gazette of RS" No. 128/20), Article 23 Paragraph 2, and Article 24 Paragraph 3 of the Law on State Administration ("Official Gazette of RS", No. 79/05, 101/07, 95/10, 99/14, 30/18 – other law and 47/18), Articles 136 and 141 Paragraph 2 of the Law on General Administrative Procedure ("Official Gazette of RS, No. 18/16 and 95/18 – authentic interpretation) and Article 2 of the Regulation on the amount of fees, taxpayers, as well as the method of payment of fees for the assessment and verification of data on biocidal products ("Official Gazette of RS" No. 90/15), deciding upon the request of the commercial company "DFC" d.o.o. ("DFC" Ltd.) from Belgrade, Zrenjaninski put Street 82i (Krnjača), for the inclusion of biocidal product in the Temporary List of Biocidal Products for the Submission of Technical Dossier, Mr. Branislav Atanasković, Acting Secretary of the Ministry of Environmental Protection, as per Resolution on Authorization issued by the Minister under the No 021-01-13/21-09 dated 26 February 2021, renders the following

RULING

1. The biocidal product is inscribed into the Temporary List of Biocidal Products for the Submission Technical Dossier:

Name of biocidal product:

- ANTI-MOSQUITO WET WIPES
- MOSQUITO REPELLENT WET WIPES;
- MOSQUITO&TICK REPELLENT WET WIPES;

Type of biocidal product: Repellents and Attractants (RT 19)

Manufacturer: "DFC" d.o.o. Srbija

Active substance contained in biocidal product: Ethyl butylacetylaminopropionate (manufacturer: Merck KGaA, Germany);

2. Biocidal product referred to in Paragraph 1 of this Ruling shall be marketed for general consumers' product and used for human protection from mosquitos and ticks as a repellent, in accordance with Instructions for Use.

3. The biocidal product referred to in Paragraph 1 of this Ruling shall be classified in accordance with the regulations governing chemicals, and shall be packaged, labeled and



advertised in accordance with those regulations and the specific requirements for the biocidal product.

4. The holder of the Ruling on entry of the biocidal product in the Temporary List of Biocidal Products for Submission of the Technical Dossier (hereinafter: the Holder of the Ruling) is obliged to comply with the conditions for placing the biocidal product on the market, to label the biocidal product and in the safety data sheet for the biocidal product state the ways and conditions of its use determined by this act.

5. The holder of the Ruling is obliged to keep records on the quantities of biocidal product placed on the market, total turnover of biocidal product realized in the previous year, quantities of stocks and quantities of biocidal product withdrawn from the market, as well as persons to whom the biocidal product was sold or transferred.

6. The holder of the Ruling is obliged to submit to the Ministry of Environmental Protection an application for the issuance of a marketing authorization for the biocidal product referred to in item 1 of this Ruling at latest until 19 April 2024.

7. If the holder of the Ruling does not act in accordance with the obligation specified in Paragraph. 2, 4. and 6. of this Ruling, the Ministry of Environmental Protection shall issue a decision on termination of the Ruling on entry of the biocidal product in the Temporary List of Biocidal Products for Submission of the Technical Dossier.

8. The holder of the Ruling is obliged to comply with all the obligations pursuant to the Law on Biocidal Products and Law on Chemicals, not stipulated by this Ruling.

Explanation

The Commercial Company "DFC" d.o.o. from Belgrade (Krnjača) submitted to the Ministry of Environmental Protection an application for entering the biocidal product, referred to in the wording of the Ruling, in the Temporary List of Biocidal Products for Submission of Technical Dossier. Along with this application the basic information on biocidal products and active substances contain in the biocidal product were submitted.

Deciding on the request of the aforementioned commercial company, the Ministry of Environmental Protection, pursuant to Article 6, paragraph 1, item 11) of the Law on Chemicals, ("Official Gazette of RS", No. 36/09, 88/10, 92/11, 93/12 and 25/15), and in accordance with the provisions of Article 136 of the Law on General Administrative Procedure ("Official Gazette of RS", No. 18/16 and 95/18-authentic interpretation) and Article 11 of the Law on Biocidal Products ("Official gazette of RS ", No. 36/09, 88/10, 92/11 and 25/15), and on the basis of the submitted documentation, determined that the legally prescribed requirements for entering of a specific biocidal product in the Temporary List of Biocidal Products for Submission of the Technical Dossier were fulfilled, and rendered the decision as stipulated in the wording of this Ruling.

The obligations stipulated in Paragraph 2 of the wording of the of the decision is determined in accordance with Article 11, paragraph 3 and Article 39 of the Law on Biocidal Products, as well as in accordance of the requirements for marketing and using a biocidal



product which contains the aforementioned active substance, which are provided in Lista of Active Substances in Biocidal Products ("Official Gazette of RS" No. 7/19)..

The obligation stipulated in item 3 of the wording of the Ruling is determined in accordance with Article 37, paragraph 1. of the Law on Biocidal Products according to which the classification of a biocidal product is performed in line with the Law on Chemicals and bylaws governing the classification, labeling and packaging of chemicals, and packaging, labeling and advertising of biocidal products in accordance with these regulations and the Ordinance on specific requirements for packaging, labeling and advertising of biocidal products ("Official Gazette of RS", No. 59/10 and 26/11).

The obligations stipulated in Articles 4 and 5 of the wording of the Ruling are determined in accordance with Article 26 Par. 1 and 2 of the Law on Biocidal Products.

In the event that Holder of the Ruling does not proceed in accordance with the obligation set forth in Par. 2 and 4 of this Ruling, the Ministry of Environmental Protection shall, pursuant to Article 28 Paragraph 1 Items 4) and 6) of the Law on Biocidal Products, render a ruling on to cancel the validity of the ruling on inscription of biocidal product in a Temporary List of Biocidal Products for Submission of the Technical Dossier and set forth term and method of procedure with biocidal product referred to in this Ruling.

The obligations stipulated in Paragraph 6 of the wording of the Ruling are determined in accordance with Articles 6, 7 and 12, in relation with the Article 28 Paragraph 1 Item 1) of the Law on Biocidal Products.

The deadline referred to in Paragraph 6 of this Ruling is determined in accordance with Article 7, paragraph 3 of the Law on Biocidal Products, based on the evaluation that the provision of all necessary data and information for the purpose of completion of Technical Dossier for the biocidal product requires extended period of time.

If the holder of the Ruling does not act in accordance with the obligation specified in item 6 of this decision before the expiration of the deadline and does not submit an application for marketing authorization of the biocidal product in accordance with Article 12 of the Law on Biocidal Products, the Ministry of Environmental Protection shall, in accordance with the provision of Article 28, paragraph 1, item 1) of the Law on Biocidal Products, issue a decision on termination of the decision on entry of the biocidal product in the Temporary List of Biocidal Products for Submission of the Technical Dossier and determine the deadline and manner of handling the biocidal product based on this Ruling.

Taking into account that the biocidal product is a chemical, as well as that the Law on Chemicals is a general law in relation to the special Law on Biocidal Products, the holder of the Ruling is obliged to comply with all obligations set by the Law on Biocidal Products and the Law on Chemicals, and to proceed in all matters in accordance with the stated laws and bylaws rendered based on them.

The fee for the assessment of basic information for the purpose of rendering the ruling on the entry of a biocidal product in the Temporary List of Biocidal Products for Submission of the



Technical Dossier was charged pursuant to Article 11, paragraph 4 of the Law on Biocidal Products, and in accordance with Article 2 of the Regulation on the amount of fees, taxpayers, as well as the method of payment of fees for the assessment and verification of data on biocidal products ("Official Gazette of RS", No. 90/15).

INSTRUCTIONS ON LEGAL REMEDY: This Ruling may be appealed to the Government within the period of 15 days starting from the date of receipt of this Ruling. The Appeal shall be filed with the Ministry of Environmental Protection.

ACTING SECRETARY OF THE MINISTRY

Aleksandar Dujanović (sign.)

(Seal: Republic of Serbia

Ministry of Environmental Protection)

Communicate to:

- "DFC" d.o.o. Beograd (Krnjača)

- Archive

----- End of translation -----

The translation completely corresponds to the original document in Serbian Language.

Jasminka Baltić, sworn court translator for German and English Language

Reg. No. 740-06-858 / 98-04

Address: 11040 Belgrade, Ledi Pedžet 9a

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