



Translation from Bulgarian into English

## MINISTRY OF HEALTH

### A U T H O R I Z A T I O N

## TO LAUNCH ON THE MARKET OF BIOCIDAL PRODUCT

**N. 1509-3/18.05.2017**

Sealed: Ministry of Health \* Sofia\* Republic of Bulgaria

Pursuant to Art. 14 and Art. 18g, para. 1 pt. 2 and para. 3 in conjunction with Art. 15, para. 4 pt. 17 of the Law on Protection from the Harmful impact of the chemical substances and mixtures, with reference to the submitted Application Ref. № 2 6 - 0 0 - 6 1 /17.03.2014 and Order № 0 1 - 5 4 /27.03.2014 of the Minister of Health

I HEREBY AUTHORIZE THE LAUNCHING ON THE MARKET OF:

- I. Trade name of the Biocidal Product  
LEKO WITH SILVER IONS
- II Name and address of the person launching the Biocidal Product on the market  
“Orgachim” AD  
21, “Treti Mart” Blvd  
Town of Ruse  
Republic of Bulgaria
- III. Name and address of the manufacturer of the Biocidal Product  
“Orgachim” AD  
21, “Treti Mart” Blvd  
Town of Ruse  
Republic of Bulgaria
- IV. Type of Biocidal Product in accordance with Annex № V of Regulation (EC) 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  
Major Group 2 - Preservatives.  
Product Type 10 - Construction material preservatives

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V Type of the Biocidal Product (granular, liquid, powder, etc.).  
Liquid

VI. Data about the active substance / substances contained in the Biocidal Product  
A. Chemical substance

N.°	Chemical Name	CAS № and EC №, if any are defined	Concentrations of the active substance in metric units
1.	Reaction mass of silver chloride and titanium dioxide	CAS № EC N.	0.1 g/100 g
2.	Zinc Pyrithione	CAS № 13463-41-7 EC №236-671-3	0.11 -0.22 g/100 g

VII. Scope of application

Biocidal Product with bactericidal and fungicidal action

Scope of application: protection of surfaces in households, residential buildings, healthcare institutions, sites of public use, food production and commercial sites, residential premises and wet rooms.

VIII. Use

Biocidal Product ready for use. A dilution is not usually necessary. If necessary, dilute with water up to 5-7%.

First, disinfect the surface with a Surfaces Biocide (Disinfectant), let dry and then apply two layers of paint.

Apply the Biocidal Product by brush, roller or airless spraying.

Consumption: 1 L of Biocidal Product for 6-7 m<sup>2</sup>.

IX. Classification and Labelling Data of the Biocidal Product

A. Biocidal product with active substance/substances - chemical substance/ substances

Classification and Labelling according to Regulation (EC) № 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the Classification, Labelling and Packaging of substances and mixtures:

Hazard Classes and Categories

n.a.

Labelling

Pictograms

Not required.

Signal statement:

n.a.

Hazard statements:

n.a.

Authorization №1509-3/ 18<sup>th</sup> May 2017 to launch on the market a biocidal Product "LEKO WITH SILVER IONS"

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Precautionary Statements:

P101: If medical advice is needed, have product container or label at hand.

P102: Keep out of reach of children.

P260: Do not breathe dust/fume/gas/mist/vapours/ spray.

P262: Do not get in eyes, on skin, or on clothing.

P271: Use only outdoors or in a well-ventilated area.

P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

X. Packing Data (type of package, capacity/volume)

Plastic buckets of 2.5, 4, 8.5 and 15 liters.

XI. Types of Users

Mass and professional.

XII. Specific requirements or restrictions

1. MSDS and label should be executed in accordance with the issued Authorization and subject to the requirements of the Law on Protection from the Harmful impact of the chemical substances and mixtures, Chapter IV and Annex II of Regulation (EC) № 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
2. Comply with the requirements of Art. 5 para. 1 of the Ordinance on the Packing and Waste Packaging (published in SG Issue No. 85/2012), by placing the necessary markings.
3. Complete the Declaration of Conformity in accordance with Art. 4 para. 3 and art. 6 para. 2 of the Ordinance on the Packing and Waste Packaging.

This Authorization shall cancel the Authorization № 1509-2 / 02.03.2016

Biocidal Products launched on the market on the basis of Authorization №. 1509-2/18.03.2016, can be marketed until stocks are exhausted but not later than 1" June 2017

CHIEF STATE  
HEALTH INSPECTOR

DR. ANGEL KUNCHEV *feigned ill.*>

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The undersigned Tsvetelina Bogomilova Bogdanova do hereby certify that this is a true and correct translation I have made from Bulgarian into English of the document attached hereto. The translation includes 3 pages.

Translbr:.....Tsvet

va Bogd va

