

COSMETICS
SAFETY ASSESSMENT

Manufacturing company: **Baikal Natural Cosmetics LLC.,**
15 Bashilovskaya Street,
Moscow, 127287, Russia

Importing company, address: SIBERIAN HEALTH s.r.o.,
Blanická 590/3, 120 00 Praha 2, Vinohrady, CZ

COSMETICS:

Fresh Breath Mouthwash
“SIBERIAN WELLNESS”

PRODUCT CATEGORY:

Level 1 - Oral Care Products
Level 2 - Mouthwash/ Fresh Mouth Spray
Level 3 - Mouthwash

Composition:

Mouthwash

Dossier code: 025

Revision: 01 Date: 05/08/2020

The safety assessment was carried out in accordance with clause 1, Article 10 of Regulation (EU) 1223 of the European Parliament and Council dated 30.10.2009.

Risk assessment covers the following:

- physical and chemical characteristics and microbiological properties
- specific characteristics and toxicological indicators of cosmetic products and their composition
- product presentation
- conditions of use
- exposure of cosmetic products
- packaging (cleanliness and stability)
- Marking (including specific precautions and instructions for
in accordance with paragraph 1
of Article 19) - Regulation (EU) 1223/2009.
- likelihood of undesirable effects on public health.
- The assessment was carried out in accordance with the principles of good laboratory practice and good manufacturing practice (GLP, GMP) - the conditions of production and storage without harming the health of the consumer under normal and predictable use, as well as subject to observation of the warning notes and instructions for use.

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Chemical characteristics, toxicological parameter and level of raw material used in the final product composition were considered.

Cosmetic products do not contain ingredients classified as carcinogenic, mutagenic and

toxic to reproduction (CMR) and assigned to categories 1A, 1B and 2 in accordance with Regulation (EU) No 1272/2008.

Cosmetic products do not contain ingredients derived from genetically modified plants and animal products.

Cosmetic products have not been tested on animals.

Based on the available information on the effects of the product and its ingredients, they are considered harmless to health. The products are considered SAFE if used under normal and reasonably foreseeable conditions of use.

An exception may be consumers with a pronounced reaction, where the manifestation of an undesirable effect is possible in very rare cases.

Data sources and cosmetic product safety assessment report are available from the importing company.

A public health safety assessment was carried out in relation to the following cosmetic products: **Fresh Breath Mouthwash “SIBERIAN WELLNESS”** and compiled on the basis of the information provided as of the indicated date.

The revision and updating of this assessment is subject to changes in the composition of the product or its other characteristics, **changes in relation to the raw material invested and its percentage in Regulation 1223/2009 and amendments thereto**, or in case of proven undesirable effects and relevant information that is important and appeared after the release of products in the market.

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05/08/2020

Plovdiv

Safety Assessment Officer: _____ /signature/

/Dr. Stefanova Todorka Gospodinova/

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