

SAFETY

ASSESSMENT OF COSMETIC PRODUCT

Manufacturer: Laboratory of Modern Health, LLC.,
11/20 Khimzavodskaya St., Berdsk, Novosibirsk
Region, Siberia, Russia 633004

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

COSMETIC PRODUCT:

MARINE CALCIUM Extra Rich Botanical Toothpaste ENAMEL CARE

PRODUCT RANGE:

Level 1 – Oral cavity care products

Level 2 – Dental care products

Level 3 – Toothpaste

Composition name:

Toothpaste

Code of record: 030

Edition: 01

The safety assessment was carried out in accordance with Article 1 Paragraph 10 of EU Regulation 1223 of the European Parliament and of the Council of 30.10.2009.

Risk assessment is relating to:

- physical and chemical characteristics and microbiological properties
- specific characteristics and toxicological indicators of cosmetic product and its composition
- product presentation
- conditions of use
- effects of cosmetic product
- package (purity and stability)
- labelling (including specific warnings and instructions for use in accordance with Article 19 Paragraph 1) – EU Regulation 1223/2009
- probability 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): conditions of production and storage without harm to the health of the consumer under normal and foreseeable use, and in compliance with the cautionary notes and instructions for use.

The chemical characteristic, toxicological parameter and the level of raw material used in the final product were considered.

Cosmetic product does not contain ingredients classified as carcinogenic, mutagenic and toxic by reproduction (CMR) and classified as categories 1A, 1B and 2 according to EU Regulation No 1272/2008

Cosmetic product does not contain ingredients derived from genetically modified plants or products of animal origin.

Cosmetic product was not tested on animals.

According to the available information on the effects of the product and its ingredients, they are considered harmless for health. Products are considered SAFE when used under normal and reasonably foreseeable conditions of use.

Except for users with strong allergic reactions, that rarely may cause undesirable effects.

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

A public health safety assessment has been carried out for cosmetic product: **MARINE CALCIUM Extra Rich Botanical Toothpaste ENAMEL CARE** and based on the information provided on a specified date.

This assessment shall be reviewed and updated if the changes of the product composition or other characteristics, **changes of used raw material and its percentage took place in Regulation 1223/2009 and its amendments** or in case of proven undesirable effects and relevant information, which is significant and which occurred after the placing the product on the market.

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Plovdiv

Address: app. 2, floor 1, entrance B,
46 Trakia microdistrict,
Plovdiv

Safety assessor:
/Dr. Stefanova Todorka Gospodinova/

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