# COSMETIC PRODUCT SAFETY ASSESSMENT

Manufacturer: 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

#### **COSMETIC PRODUCTS:**

Intimate Care Deodorant Gel "SIBERIAN WELLNESS"

### PRODUCT CATEGORY:

Level 1 — Skin products

Level 2 — Skin cosmetics

Level 3 — Intimate care cosmetics (for external use)

## **Composition name:**

Cosmetics for intimate care (for external use)

Dossier code: 004

Revision: 01, Date: October 15, 2019

Safety assessment is made in accordance with Item 1 Article 10 of Regulations (EU) 1223 of the European Parliament and the EU Council of October 30, 2009.

### Risk assessment covers:

- physical and chemical characteristics and microbiological properties;
- specific characteristics and toxicological indicators of the cosmetic products and their compositions;
- product presentation;
- conditions of application;
- cosmetic products impact;
- package (purity and stability);
- labeling (including particular cautions and instructions for use in accordance with Item 1 Article 10) Regulations (EU) 1223/2009;
- probability of adverse effects on the human health.
- The assessment was made in accordance with the principles of Good Laboratory Practice and Good Manufacturing Practice (GLP, GMP), the conditions for manufacturing and storage without causing any damage to the consumer's health in normal and predictable use and if the cautionary notes and instructions for use are followed.

Chemical signs, toxicological parameter, and level of raw materials used in the end product composition were considered.

The cosmetic products do not contain any ingredients classified as carcinogenic, mutagenic, or toxic for reproductive system (CMR) and classified as Categories 1A, 1B, and 2 according to Regulations (EU) No. 1272/2008.

The cosmetic products do not contain any ingredients obtained from genetically modified

plants and animal-derived products.

The cosmetic products have not been tested on animals.

Based on the available information on the impact of the products and their ingredients, they are considered safe for the health. The product is considered SAFE if it is used in normal and reasonably predictable conditions of application.

The exception includes the consumers with marked reaction, which may very rarely cause an undesirable effect.

The data sources and the report on the cosmetic product safety assessment are available in the importing company.

The human health safety assessment was made for the following cosmetic products: Intimate Care Deodorant Gel "SIBERIAN WELLNESS" and was generated on the basis of the provided information as of the indicated date.

Revision and updating of this assessment are performed upon condition of changes in the products compositions or other characteristics thereof, changes in the used raw materials and their percentage content provided in Regulations 1223/2009 and amendments thereof, or in the cases of confirmed adverse effects and the respective information that is essential and that has become available after the products' release to the market.

Seal: SPECIALIST FOR COSMETIC PRODUCTS SAFETY ASSESSMENT EMIL YAMALIEV, Research Fellow, M. Sc., Pharmacist Certificate No. 608015570/April 22, 2004 Signature:

City of Plovdiv
Address: 274, Trakiya
Community, entrance "B", floor 2,
apt. 4, city of Plovdiv

Qualified safety assessment specialist: /signature/

/Emil Georgiev Yamaliev, Research Fellow, M. Sc., Pharmacist/

Qualification: Diploma No. 001608 series OII of June 25, 1979 of Medical Academy, Department of Pharmaceutics, Sofia Certificate of assessment specialist No. 608015570 of April 22, 2004