

## **COSMETICS PRODUCT SAFETY REPORT**

Name of the product:

**SIBERIAN WELLNESS TONYFYING CREAM FOR PERFECT LEGS**

Placing on the market:

**SIBERIAN HEALTH S.R.O.**

**Blanická 590/3,**

**120 00 Praha 2 – Vinohrady, Czech Republic**

In compliance with Regulation (EC) No 1223/2009 of The European Parliament and of The Council  
of 30 November 2009 on cosmetic products

Creation Date:

**October 06, 2020**

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## CHAPTER A – Information about the safety of the product

### 1. Qualitative and quantitative composition of the cosmetic product

The person ordering the execution of the report is responsible for the information on the qualitative and quantitative composition of the product, taking into account trade names of raw materials, information about the suppliers.

The manufacturer declares that the final product as well as all cosmetic ingredients have not been tested on animals in accordance with the Art. 18 of the Regulation 1223/2009/EC, as well as the cosmetic product does not contain CMR 1A and 1B and 2 under the Regulation 1272/2008/EC.

The manufacturer confirms that cosmetic is manufactured according to GMP quality system.

TRADE NAME	INCI Name	Concentration [%]	CAS Number	Function	SUPPLIER
WATER	AQUA	87.15	7732-18-5	SOLVENT	-
NATURA-TEC PLANTSILTM	HYDROGENATED ETHYLHEXYL OLIVATE	3.00	-	SKIN CONDITIONING	CERATEC SARL - INCORPORATING NATURA-TEC DIVISION
	HYDROGENATED OLIVE OIL UNSAPONIFIABLES		-		
NIO-TROX	TROXERUTIN	3.00	7085-55-4 / 31511-30-5	SKIN CONDITIONING	NATURALIS SRL
	MAGNOLOL		528-43-8		
	HONOKIOL		35354-74-6		
	POLYGLYCERYL-10 LAURATE		34406-66-1		
	POLYGLYCERYL-6 OLEATE		9007-48-1 / 79665-92-2		
	SORBITAN PALMITATE		26266-57-9		
UREA	UREA	2.00	57-13-6	HUMECTANT	MOSREAKTIV LLC
TECHNICAL GRANULATED CAUSTIC SODA (SODIUM HYDROXIDE)	SODIUM HYDROXIDE	0.15	1310-73-2	BUFFERING	CAUSTIC JOINT-STOCK COMPANY
	SODIUM CARBONATE		497-19-8		
EUXYL® PE 9010	PHENOXYETHANOL	1.00	122-99-6	PRESERVATIVE	SCHÜLKE & MAYR GMBH
	ETHYLHEXYLGLYCERIN		70445-33-9		
TEGO CARBOMER 340 FD	CARBOMER	0.60	9007-20-9 / 9003-01-4 / 76050-42-5 / 9062-04-8 / 9007-16-3 / 9007-17-4	GEL FORMING	EVONIK NUTRITION & CARE GMBH
ARNICA OIL CLR	GLYCINE SOJA OIL	0.50	8001-22-7	SKIN CONDITIONING	CLR CHEMISCHES LABORATORIUM DR. KURT RICHTER GMBH
	ARNICA MONTANA EXTRACT		-		
	TOCOPHEROL		54-28-4 (GAMMA) / 16698-35-4 (BETA) / 10191-41-0 (DL) / 119-13-1 / 1406-18-4 / 1406-66-2 / 2074-53-5 (DL) / 59-02-9 (D) / 7616-22-0		
BLEND OF HYDROGLYCERIC EXTRACTS "TIRED LEGS, MODIFIED"	GLYCERIN	0.50	56-81-5	SKIN CONDITIONING	OOO "2D-FARMA"
	AQUA		7732-18-5		
	AESCLUS HIPPOCASTANUM FRUIT POWDER		8053-39-2		
	HIRUDINEA EXTRACT		-		

	VITIS VINIFERA LEAF EXTRACT		85594-37-2 / 84929-27-1		
	RUSCUS ACULEATUS ROOT EXTRACT		84012-38-4		
	POTASSIUM SORBATE		24634-61-5 / 590-00-1		
	SODIUM BENZOATE		532-32-1		
	CITRIC ACID		77-92-9 / 5949-29-1		
<b>MENTHOL CRYSTAL</b>	MENTHOL	0.50	1490-04-6 / 2216-51-5 / 89-78-1 / 15356-70-4	SOOTHING	ARORA AROMATICS PVT. LTD.
<b>NIACINAMIDE</b>	NIACINAMIDE	0.50	98-92-0	SMOOTHING	JUBILANT LIFE SCIENCES LTD
<b>CAFFEINE (ANHYDROUS)</b>	CAFFEINE	0.50	58-08-2	SKIN CONDITIONING	AARTI INDUSTRIES LIMITED
<b>PEPPERMINT OIL INDIA</b>	MENTHA PIPERITA OIL	0.20	8006-90-4 / 84082-70-2	REFRESHING	JOHANN VÖGELE KG
<b>BEAUPLEX™ VH</b>	NIACINAMIDE	0.20	98-92-0	SKIN CONDITIONING	DSM NUTRITIONAL PRODUCTS LTD.
	CALCIUM PANTOTHENATE		137-08-6		
	TOCOPHERYL ACETATE		7695-91-2 / 58-95-7		
	SODIUM ASCORBYL PHOSPHATE		66170-10-3		
	PYRIDOXINE HCL		58-56-0 / 12001-77-3		
	SODIUM STARCH OCTENYLSUCCINATE		66829-29-6 / 52906-93-1 / 70714-61-3		
	MALTODEXTRIN		9050-36-6		
	SILICA		7631-86-9 / 112945-52-5 / 60676-86-0		
<b>LEMON OIL</b>	CITRUS LIMON PEEL OIL	0.10	8008-56-8 / 84929-31-7	SKIN CONDITIONING	JOHANN VÖGELE KG
<b>CYPRESS OIL</b>	CUPRESSUS SEMPERVIRENS OIL	0.05	84696-07-1 / 8013-86-3		
<b>LIME OIL DISTILLED</b>	CITRUS AURANTIFOLIA OIL	0.05	8008-26-2 / 90063-52-8		

Safety data sheets of supplied raw materials and certificates of analysis allow for the identification of the substances used as well as a detailed description of their properties, together with any needed data on contamination. The information contained in the SDS of individual raw materials allows us to assess toxicological properties.

Identification of substances used in the manufacture of cosmetics is given in Annex 2.

## 2. Physical / chemical characteristics and stability of the cosmetic product

### 2.1 Physical / chemical characteristics

Appearance: homogeneous creamy mass that does not contain foreign impurities  
 Colour: light yellow to yellow  
 Fragrance: characteristic of fragrance – fresh mint scent with woody and citrus notes  
 pH: 5.0 – 9.0

### 2.2 The stability of the cosmetics product

The physicochemical stability test showed that the product is stable under varying temperature conditions. No organoleptic changes were observed. Results are included in Report from August 5, 2019 (Annex 3).

The manufacturer has set the product validity period to 18 months from the date of manufacture. Store at a temperature from 5°C to 25°C.

Shelf life was determined on the basis of:

- composition of the finished product
- the results of stability tests
- Challenge Test results
- estimated time of use of a cosmetic product by the consumer.

### 3. Microbiological quality

#### 3.1 Microbiological quality of substances and mixtures

Used raw materials do not raise objections from the microbiological point of view. For materials with low microbiological risk, the assessment of microbiological purity was not conducted. Other raw materials in terms of quantity and quality meet the microbiological requirements that allow their use in the production of cosmetics.

#### 3.2 Microbiological quality of the finished product

The product meets the quality and quantity requirements for microbiological purity. The test report can be found in Report No. 281391/20/CGDA (Annex 3).

The field of research	Culture test results	Requirements
The total number of yeasts and molds	< 1.0 x 10 <sup>1</sup> cfu/g	PN-EN ISO 16212:2017-08
The total number of aerobic mesophilic	< 1.0 x 10 <sup>1</sup> cfu/g	PN-EN ISO 21149:2017-07
<i>Pseudomonas aeruginosa</i>	Not detected	PN-EN ISO 22717:2016-01
<i>Candida albicans</i>	Not detected	PN-EN ISO 18416:2016-01
<i>Staphylococcus aureus</i>	Not detected	PN-EN ISO 22718:2016-01
<i>Escherichia coli</i>	Not detected	PN-EN ISO 21150:2016-01

##### **Quantity requirements**

*The minimum sample size for the study 1g or 1ml*

##### **CATEGORY I**

*(for children under 3 and the eyes area)*

*The total number of aerobic mesophilic: cannot exceed 200 cfu/g or ml  
(CFU – colony-forming units)*

##### **CATEGORY II**

*The total number of aerobic mesophilic: cannot exceed 2000 cfu/g or ml*

##### **Quality requirements**

*In 1ml / 1g sample of the product microorganisms such as*

- *Pseudomonas aeruginosa*
- *Staphylococcus aureus*
- *Candida albicans*
- *Escherichia coli*

*must not be detectable in cosmetic product.*

Challenge Test were performed in the laboratory J.S. HAMILTON POLAND S.A. and confirm the proper selection of the preservation of cosmetics product. Results are investigated in report No. 281578/20/CGDA (Annex 3).

#### 4. Impurities, traces, information about the packaging material

##### 4.1 The content of traces of prohibited substances

INCI name	Name of prohibited substances in trace amount	Amount of prohibited substances in trace amount (ppm)
TEGO CARBOMER 340 FD / CARBOMER	HEAVY METALS	<20
	As	<1
	Cd	<1
	Co	<1
	Cr	<1
	Hg	<1
	Ni	<1
	Pb	<1
NIO-TROX / TROXERUTIN, MAGNOLOL, HONOKIOL, POLYGLYCERYL-10 LAURATE, POLYGLYCERYL-6 OLEATE, SORBITAN PALMITATE, AQUA	Sb	<1
	Ni	<0.04
	Cd	<0.04
	Cr	<0.04
	Hg	<0.04
As	<0.04	

Avoiding trace contaminants is impossible for technical reasons. No other impurities and traces of unauthorized substances that are likely to affect product safety are expected.

The use of these ingredients is permitted in accordance with Regulation 1223/2009/EC.

##### 4.2 Relevant material properties of packaging

Type of packaging	Manufacturer
Tube 75 ml; material: 50% HDPE + 50% LDPE	ALBEA

The results of tests of the mass-packaging compatibility test confirmed the lack of interaction between the mass and packaging. Results are investigated in Report from August 5, 2019 (Annex 3).

To sum up: the type of used packaging does not affect the stability of the product.

#### 5. Normal and reasonably foreseeable use

##### SIBERIAN WELLNESS TONYFYING CREAM FOR PERFECT LEGS

###### How to use:

Lightly massage a small amount of cream into your legs, once in the morning and one in the evening. The product is intended for adults that are not allergic to any of the ingredients.

#### 6. Exposure to the cosmetic product <sup>(1)</sup>

Application place:	body skin ( excluding face skin )
Skin surface area of application:	5530 cm <sup>2</sup> determined in accordance with the guidelines for the average consumer, area female legs in according to RIVM
Estimated daily amount applied:	5.5 g determined in accordance with the guidelines for the average consumer
Frequency of application:	2 / day determined in accordance with the manufacturer's recommendation
Population or exposed:	adults
Body weight:	60 kg
Retention Factor:	1

(1) SCCS/1602/18

(2) RIVM report 320104001/2006

## 7. Exposure to the substance

### 7.1 Calculate the margin of safety

On the basis of test results on exposure to cosmetic product in accordance with the guidelines of the SCCS/1602/18 and using data from the manufacturers of the substance, opinions of the Scientific Committees SCCS, EFSA, toxicological data base (reference to the data can be found in Annex 2) the margin of safety was calculated.

The concentration of the individual components was given in the concentration range, the exact contents of which were checked during the expert's evaluation. For calculations of the safety margins, the maximal values given in the range are assumed.

Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application

$$E_{\text{product}} = 183.33 \text{ mg/kg}\cdot\text{bw/day}$$

Systemic exposure dose for the components of the product was calculated from the formula:

$$SED = E_{\text{product}}(\text{mg/kg bw/day}) \times C(\%)/100 \times DAp(\%)/100$$

Where:

C – the maximum concentration of the ingredient under study in the finished cosmetic product on the application site

DAp – dermal absorption expressed as a percentage of the dose assumed to be applied in real-life conditions, if it is not known shall be 100%

The margin of safety

$$MoS = POD_{\text{sys}}/SED$$

INCI name	Max Concentration in cosmetics (%)	Dermal Absorption (%)	SED	MoS
<b>HYDROGENATED ETHYLHEXYL OLIVATE</b>	3	not applicable, substances considered safe by CIR		
<b>UREA</b>	2	not applicable, substance is recognized as GRAS		
<b>PHENOXYETHANOL</b>	0.915	used in a concentration complied with the Regulation 1223/2009/WE		
<b>POLYGLYCERYL-6 OLEATE</b>	0.72	not applicable, substances considered safe by CIR		
<b>CARBOMER</b>	0.6	not applicable, does not penetrate through skin		
<b>HYDROGENATED OLIVE OIL UNSAPONIFIABLES</b>	0.6	not applicable, substances considered safe by CIR		
<b>ARNICA MONTANA EXTRACT</b>	0.5	not applicable, substance used in folk medicine		
<b>CAFFEINE</b>	0.5	not applicable, substance is recognized as GRAS		
<b>GLYCINE SOJA OIL</b>	0.5	not applicable, substance is not toxic, may be part of human diet		
<b>MENTHOL</b>	0.5	100	9.1665·10 <sup>-1</sup>	>100
<b>NIACINAMIDE</b>	0.6	not applicable, substance is recognized as GRAS		

<b>TOCOPHEROL</b>	0.5			
<b>POLYGLYCERYL-10 LAURATE</b>	0.36	not applicable, substances considered safe by CIR		
<b>TROXERUTIN</b>	0.3	100	$5.5 \cdot 10^{-1}$	-
<b>GLYCERIN</b>	0.25	not applicable, substance is recognized as GRAS		
<b>MENTHA PIPERITA OIL</b>	0.20	50	$1.83 \cdot 10^{-1}$	>100
		the substance has the GRAS status as a food additive, according to CIR the maximum safe concentration in the cosmetic product is 5%, dried herb is used in folk medicine and as drinking herbs		
<b>SORBITAN PALMITATE</b>	0.15	not applicable, substance is recognized as GRAS		
<b>SODIUM HYDROXIDE</b>	0.14925	used complied with the Regulation 1223/2009/WE		
<b>ETHYLHEXYLGLYCERIN</b>	0.115	not applicable, dermal absorption is very low 0.02% DAp in according to ECHA, systemic exposure dose very low		
<b>CITRUS LIMON PEEL OIL</b>	0.1	100	$1.83 \cdot 10^{-1}$	-
<b>HONOKIOL</b>	0.09	100	$1.65 \cdot 10^{-1}$	-
<b>MAGNOLOL</b>	0.09	100	$1.65 \cdot 10^{-1}$	-
<b>MALTODEXTRIN</b>	0.06	not applicable, substance is recognized as GRAS		
<b>CALCIUM PANTOTHENATE</b>	0.05			
<b>CUPRESSUS SEMPERVIRENS OIL</b>	0.05	100	$9.17 \cdot 10^{-2}$	-
<b>SODIUM STARCH OCTENYLSUCCINATE</b>	0.05	not applicable, may be part of human diet		
<b>TOCOPHERYL ACETATE</b>	0.02	not applicable, substance is recognized as GRAS		
<b>PYRIDOXINE HCL</b>	0.01	not applicable, the substance is a soluble form of vitamin B <sub>6</sub> ( important role in the human body )		
<b>SODIUM ASCORBYL PHOSPHATE</b>	0.01	50	$9.17 \cdot 10^{-3}$	-
<b>AESULUS HIPPOCASTANUM FRUIT POWDER</b>	0.0075	100	$1.37 \cdot 10^{-2}$	-
<b>HIRUDINEA EXTRACT</b>	0.0075	100	$1.37 \cdot 10^{-2}$	-
<b>RUSCUS ACULEATUS ROOT EXTRACT</b>	0.0075	not applicable, substance used in folk medicine		
<b>VITIS VINIFERA LEAF EXTRACT</b>	0.0075	not applicable, may be part of human diet		
<b>POTASSIUM SORBATE</b>	0.005	used in a concentration complied with the Regulation 1223/2009/WE		
<b>SODIUM BENZOATE</b>	0.005			
<b>SODIUM CARBONATE</b>	0.0015	not applicable, substance is recognized as GRAS		
<b>SILICA</b>	0.0004			
<b>CITRIC ACID</b>	0.00015			

## 8. Toxicological profile of substance

Toxicological profile of the substances contained in the cosmetic product, together with data on the source of the information is set out in Annex 2.

## 9. Undesirable effects and serious undesirable effects

The product **SIBERIAN WELLNESS TONYFYING CREAM FOR PERFECT LEGS** is just placed on the market and the information regarding of any adverse reaction is not available.

In accordance with the requirements of Art. 23 of the Regulation 1223/2009/EC the chosen employee is required to document and report any adverse reactions caused by the product.

In case of serious undesirable effects, the responsible person notifies the relevant state authorities. In accordance with the Ordinance of the Minister of Health of February 20, 2019 on the center administering the System of Information on Serious Adverse Events Due to the Use of Cosmetic Products, the center administering the System of Information on Serious Adverse Events Due to the Use of Cosmetic Products is the Institute of Occupational Medicine. prof. dr. Jerzy Nofer in Łódź.

In case of a serious adverse event authorities shall be informed. The actions of the chosen employee along with the case solution is given in the guidelines provided by the European Commission website – Guidelines on reporting serious adverse events:

[http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/sue\\_reporting\\_guidelines\\_en.pdf](http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/sue_reporting_guidelines_en.pdf)

The response system to any reported information about cases of severe adverse reaction after using the product should be implemented.

Information on undesirable effects must be updated and made available to the person conducting the safety evaluation for the possible inclusion of changes in safety report (Art. 10 par. 1 p. C) of the Regulation 1223/2009/EC).

## 10. Information on the cosmetic product

In accordance with Art. 19, par. 1, p. G) of the Regulation 1223/2009/EC on cosmetic products: The list of ingredients shall be established in descending order of weight of the ingredients at the time they are added to the cosmetic product. Ingredients in concentrations of less than 1% may be listed in any order after those in concentrations of more than 1%.

Warning: The informations and content on the packaging should be adapted to the requirements of the packaging in Regulation 1223/2009/EC.

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## CHAPTER B – Cosmetics Product Safety Assessment

### 1. The conclusion of the assessment

The product **SIBERIAN WELLNESS TONYFYING CREAM FOR PERFECT LEGS** marketed by **SIBERIAN HEALTH S.R.O.** is **safe** and cannot create a risk to human health in normal and foreseeable conditions of use.

### 2. Labeled warnings and instructions of use

Taking into account the guidelines of Art. 19 of the Regulation 1223/2009/EC it is not required to provide the product label with any additional warnings and instruction of use.

### 3. Reasoning

The product which is the subject of this safety assessment is intended for legs skin care. The physicochemical stability under specified storage conditions of the final product, its compatibility with the packaging and established durability was confirmed in the course of tests carried out for the product.

The product **SIBERIAN WELLNESS TONYFYING CREAM FOR PERFECT LEGS** is just placed on the market and the information regarding of any irritant reaction is not available.

Ingredients were used within the allowed concentration and conditions that are set out in the Regulation 1223/2009/EC.

Risk assessment components were based on hazard analysis, toxicological data, component system analysis of the product, in justified cases designated safety margin.

For components with available systemic toxicity  $POD_{sys}$  safety margin was determined. In all cases MoS value was greater than 100.

Toxicological assessment of the components contained in the cosmetic product – Annex 2, based on data contained in:

1. the safety data sheet of the individual substances
2. the base of CIR cosmetic ingredients
3. database FDA
4. HSDB database
5. SCCS opinion
6. opinion ECHA (European Chemicals Agency).

#### 4. Assessor's credentials and approval of part B

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Signature

#### Proof of qualifications (CV) Safety Assessor – Annex 4

Cosmetic product safety assessment was made on the basis of currently available data concerning the product, experience and knowledge in this field by the manufacturer, and the valid legislation. In the event of any change in the chemical composition, scope and usage, manufacturing processes or other relevant data that may affect the safety of the product. Safety Report should again be verified and updated regularly.

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