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643862/21/JSHS

CPSR/153/03/22/EN

COSMETICS PRODUCT SAFETY REPORT

Name of the product:

NAUTUBONE GEL 100 ml

Placing on the market:

MONADON, marketinške
storitve d.o.o.
Meškova ulica 4
1000 Ljubljana

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:
February 18, 2022

Created by:
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Approved by:
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TABLE OF CONTENTS:

PART 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.

COMPONENTS	INCI NAME	CONCENTRATION [%]	CAS NUMBER	FUNCTION	DISTRIBUTOR
DEMINERALIZED WATER	AQUA	70.05	7732-18-5	SOLVENT	CYDONIA BIH
PROPYLENE GLYCOL	PROPYLENE GLYCOL	3.6	57-55-6	SKIN CONDITIONING	FAGRON
GLICEROL	GLYCERIN	1.4	56-81-5	HUMECTANT	FAGRON
SODIUM HYDROXIDE	SODIUM HYDROXIDE	0.2	1310-73-2	BUFFERING	FAGRON
ETHYL ALCOHOL	ALCOHOL	22.0	64-17-5	SOLVENT	ETANOL LAB
GERANIUM OIL	PELARGONIUM GRAVEOLENS OIL	0.3	90082-51-2	SKIN CONDITIONING	AETHEREAL LTD
COMFREY ROOT EXTRACT	SYMPHYTUM OFFICINALE ROOT EXTRACT	0.55	84696-05-9	SKIN CONDITIONING	CYDONIA D.O.O.
CLARY SAGE OIL	SALVIA SCLAREA OIL	0.2	8016-63-5 / 84775-83-7	SKIN CONDITIONING	AETHEREAL LTD
CHAMOMILE ROMAN OIL	ANTHEMIS NOBILIS FLOWER OIL	0.1	84649-86-5 / 8015-92-7	SKIN CONDITIONING	AETHEREAL LTD
SYNTHALEN K	CARBOMER	0.6	9007-20-9 / 9003-01-4 / 76050-42-5 / 9062-04-8 / 9007-16-3 / 9007-17-4	GEL FORMING	FAGRON
MICROCARE MHB	METHYLPARABEN	0.1	99-76-3	PRESERVATIVE	FAGRON
MICROCARE OHB	PROPYLPARABEN	0.04	94-13-3	PRESERVATIVE	FAGRON
INDIGOTINE	CI 73015	0.1	860-22-0	COLOURANT	FAGRON

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 gel without mechanical impurities
Colour: dark green
Fragrance: characteristic for the raw materials used

2.2 The stability of the cosmetics product

Physicochemical stability test showed the product to be stable under varying temperature conditions. It was subjected to 12 weeks of stability under varying temperature conditions. No organoleptic changes were observed. Taking into account the all above, we confirm that the product remained stable and compatible with its packaging at temperature below 40°C. The result of the test is included in report no. 643831/21/JSHS dated 17.02.2022 - Annex 3.

Shelf life of the cosmetic product is more than 24 months from date of manufacture. Product should be stored under room conditions in a cool, dry place, away from direct sunlight and high temperature.

Shelf life was determined on the basis of:

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

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 field of research	Culture test results	Requirements
The total number of yeasts and molds	< 1,0 x 10^1 jtk/g	PN-EN ISO 16212:2017-08
The total number of aerobic mesophilic	< 5,0 x 10^2 jtk/g	PN-EN ISO 21149:2017-07
Pseudomonas aeruginosa	Not detected	PN-EN ISO 22717:2016-01
Candida albicans	Not detected	PN-EN ISO 18416:2016-01
Staphylococcus aureus	Not detected	PN-EN ISO 22718:2016-01
Escherichia coli	Not detected	PN-EN ISO 21150:2016-01

Quantity requirements

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

CATHEGORY 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))

CATHEGORY II

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

Quality requirements

In 0.1ml /0.1g sample of the product microorganisms such as

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

must not be detectable in cosmetic product.

The product meets the quality and quantity requirements for microbiological purity.
Results of microbiological tests were performed in HAMILTON laboratory – report no. 643866/21/JSHS, dated 05.01.2022 (Annex 3).

Challenge Test - report 643889/21/JSHS dated 02.02.2022 conducted HAMILTON laboratory confirm the proper selection of the preservation of cosmetics product under development has to be assessed experimentally in order the ensure microbiological stability and preservation during storage and use.

4. Impurities, traces, information about the packaging material

4.1 The content of traces of prohibited substances

Component / INCI name	Name of prohibited substances	Amount of non-authorised substances in trace amounts per product (ppm)
NAUTUBONE GEL 100 ml	Arsenic Cadmium Mercury Lead Antimony Iron Nickel	0.018 not detected not detected 0.011 not detected 8.2 0.64

SUMMARY:

In the absence of binding specific regulations for heavy metals, many of the institutions for the protection of human health and the environment have been unable to find a solution. In order to ensure the safety of trace amounts of heavy metals in cosmetics, the World Health Organisation has developed, on the basis of sound scientific toxicological analysis, its own criteria for assessing the safety of trace amounts of heavy metals in cosmetics. Due to internal regulations introduced by some Member States, it is recommended that the content of heavy metals in the finished product does not exceed the following values: Arsenic, Cadmium – 5ppm, Mercury – 1 ppm, Antimony and Lead – 10ppm.

Conclusion: The content of heavy metals and substances prohibited as impurities in the evaluated cosmetic product, on the basis of the presented documentation of raw materials is within the limits mentioned above and does not pose a threat under normal and foreseeable conditions of use of the cosmetic product.

The avoidance of trace contamination is impossible for technical reasons. According to the information contained in the specification of the raw materials, other impurities and traces of prohibited substances that may affect the safety of the product are not expected. Acceptable to use these components in accordance with the Regulation 1223/2009/EC.

4.2 Relevant material properties of packaging

Type of packaging	Manufacturer
TUBE LDPE – 100 ml	Supplier data available from the manufacturer of the cosmetic product

The cosmetics product / package compatibility test was made by manufacturer's laboratory (Annex 3) and it has proved the lack of interaction with the package and cosmetic.

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

5. Normal and reasonably foreseeable use

NAUTUBONE GEL 100 ml

How to use:
Apply several times a day, rub lightly on the desired area as needed. The product is intended for adults that are not allergic to any of the ingredients.

6. Exposure to the cosmetic product [(1)(2)]

Application place:	body area
Skin surface area of application:	15 670 cm² determined in accordance with the guidelines for the average – SCCS, RIVM
Estimated daily amount applied:	7.82 g / day

Frequency of application:	2/28 day (like body balm)
Population or exposed:	adults, all skin types
Body weight:	60 kg
Retention Factor:	1.0

(1) *SCCS/1628/21*
(2) *RIVM report 320104001/2006*

The product was also tested dermatologically for irritation and sensitization (Annex 3), the conclusion of the tests is given in section 10 of the report.

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/1628/21 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.

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

and the frequency of application

$$\mathbf{E_{prod}= 123,2\ mg/kg\ bw/day}.$$

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

$$\mathbf{SED=E_{prod}(mg/kg\ bw/day)\ x\ C(\%)/100\ x\ Dap(\%)/100}$$

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

$$\mathbf{MoS= PODsys/SED}$$

INCI name	Max concentration in cosmetics (%)	Dermal absorption (%)	SED	MoS
PROPYLENE GLYCOL	3.06	50	1.88	>100
GLYCERIN	1.4	not applicable, substance is not toxic, according to FDA classified as a GRAS		
SODIUM HYDROXIDE	0.2	50	0.123	>100
ALCOHOL	22.0	20	5.42	>100
PELARGONIUM GRAVEOLENS OIL	0.3	not applicable, substances are not toxic, are common in nature		
SYMPHYTUM OFFICINALE ROOT EXTRACT	0.55			

SALVIA SCLAREA OIL	0.2	not applicable, substances are not toxic, are common in nature		
ANTHEMIS NOBILIS FLOWER OIL	0.1			
CARBOMER	0.6	not applicable, polymer, does not penetrate the epidermal barrier		
METHYLPARABEN	0.1	used in amounts consistent with Regulation 1223/2009/EC		
PROPYLPARABEN	0.04			
TOCOPHEROL	0.1	not applicable, substance is not toxic, according to FDA classified as a GRAS		
CI 73015	0.1	50	0.0616	>100
CITRAL	0.1087	50	0.067	>100
CITRONELLOL	0.0045	8.6	0.00046	>100
GERANIOL	0.0547	50	0.03369	>100
LIMONENE	0.008	50	0.0049	>100
LINALOOL	0.0263	12.7	0.000003	>100

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 **NAUTUBONE GEL 100 ml** is just placed on the market and the information regarding of any adverse reaction is not available.

Any objections to the used ingredients or any side effects are not expected – based on the data of the toxicological evaluation of the product.

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 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/cosmetcs/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

The cosmetic product has been tested for irritant sensitizing properties.
Dermatological studies have been carried out by HAMILTON laboratory. The results are contained in certificate no 643892/21/JSHS, dated 14.01.2022 (Annex 3).

Result: no positive reactions.

Conclusion: using the contact test, there was no irritant and allergenic properties of the formulation at a concentration for use.

Note:

1. The information on the packaging and the content shall be aligned with the requirements for packaging in Regulation 1223/2009/EC.

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Stara Iwiczna, February 18, 2022
Place and date

Signature

Paweł Wojtanowski
Safety Assessor

PART B – Cosmetics Product Safety Assessment

1. The conclusion of the assessment

The product **NAUTUBONE GEL 100 ml** marketed by **MONADON** is safe and does not create a risk to human health in normal and foreseeable conditions of use, including instructions for use, as well as taking into account the current state of knowledge.

The components and their quantities in the product are acceptable for using cosmetics in accordance with the Regulation 1223/2009/EC.

Ingredients limited by the Regulation 1223/2009/EC have been used in the concentration limits and conditions set out in Regulation applied.

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. Labelling must comply with the Aerosol Regulation.

3. Reasoning

The product which is the subject of this safety assessment is intended for body area care. The physicochemical stability of the final product, its compatibility with the packaging and established durability was confirmed in the course of tests carried out for the product. Dermatological examinations showing the lack of irritating and sensitizing properties were also carried out.

All the 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 PODsys 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).

Updating the report should be done each time:

- change of manufacturer's formulation
- new information on ingredients
- change of ingredient supplier
- change of packaging and supplier of packaging that is in direct contact with the cosmetic

4. Assessor's credentials and approval of part B

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Stara Iwiczna, February 18, 2022

Place and date

Signature

Paweł Wojtanowski
Safety Assessor

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.