COSMETIC PRODUCT SAFETY REPORT

drawn up in compliance with the Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, as amended (hereinafter the Regulation)

Name of the product:

argan oil peeling mask 300 mg CBD 50 ml

Responsible person:

REAKIRO POLAND Sp. z o.o.

Jana Kilinskiego No.2

35-005 Rzeszow

Poland

Part A – Information on cosmetic product safety

1. Quantitative and qualitative composition of the cosmetic product

See annex no. 1, table 1. Quantitative and qualitative composition of the cosmetic product.

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

2.1.1 Physical/chemical characteristics of substances or mixtures

(in compliance with the Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU), section 3.2.1)

Specifications substance or mixture contained in the cosmetic product, see section 1, annexed to the report or are deposited with the responsible person.

See annex no. 2, Ingredients.

2.1.2 Physical/chemical characteristics of the finished cosmetic product

Organoleptic properties

Appearance: emulsion with small particles

Colour: white - yellow

Aroma: odourless

Physical and chemical properties

pH: -

Viscosity: -

2.2 Stability of the cosmetic product

Both the product and the ingredients are stable under normal use and storage conditions (e.g. in dry, sheltered and clean space at the temperature 5 - 25 degrees centigrade), during declared shelf life for 24 months.

Durability and PaO (period-after-opening), including compatibility of the product with packaging material, are determined on the basis of market experience and manufacturer´s experience with similar products.

Results of preservation challenge test are given in section 3.2

3. Microbiological quality

3.1.1 Microbiological quality of substances and mixtures

(in compliance with the Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU), section 3.3.1)

Based on available information from the ingredient specification (see section 2.1.1), the ingredients used can be assessed as microbiologically harmless.

3.1.2 Microbiological quality of the finished cosmetic product

Cosmetic product can be regarded as microbiologically safe for consumers' health according to standards ISO 21148 Cosmetics - Microbiology - General instructions for microbiological testing, ISO 21149 Cosmetics - Microbiology - Enumeration and detection of aerobic mesophilic bacteria and ISO 18415 Cosmetics - Microbiology - Detection of specific and non-specific microorganisms and according to COLIPA Guidelines for microbiological quality control (MQM) or according to the requirements of the Czech Pharmacopoeia or European Pharmacopoeia (European Pharmacopoeia 8.0, Ph. Eur.).

3.2 Results of preservation challenge test

Preservative efficacy is evaluated as satisfactory according to ISO 11930 Cosmetics - Microbiology - Evaluation of the antimicrobial protection of cosmetic product or according to the European Pharmacopoeia (European Pharmacopoeia 8.0, Ph. Eur.) or KOKO test Schülke.

For safety assessment were used results of the preservative efficacy study on the similar product called "REAKIRO moisturizing cream" (in compliance with the Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU), section 3. Part A — Cosmetic product safety information).

See annex no. 3, Tests - Protocol of preservation challenge test.

4. Impurities, traces, information about the packaging material

4.1 Impurities and traces of prohibited substances

In the final cosmetic product, the prohibited substance THC is present as an impurity, the source of the substance is the ingredient Cannabis Sativa Stem/Flower Oil (see Annex no. 1, table 1. Quantitative and qualitative composition of the cosmetic product).

The ingredient comes from the cannabis plant varieties authorized for industrial cultivation in Europe, for which the THC content does not exceed 0.2% (in compliance with Commission Regulation (EC) no. 145/2008 of 19 February 2008 in Annex II.). THC content in the ingredients derived from these varieties of cannabis plant is technically unavoidable - hemp oil contains trace amounts of cannabinoids including THC that get into the oil during the course of stamping of the outer skins of seeds. The unintended presence of trace amounts of a prohibited substance THC in the product is

therefore technically unavoidable (in compliance with the Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU), section 3.4.2).

See annex no. 2, Ingredients.

The safety evaluation of a cosmetic product in terms of THC content is based on acute reference dose (ARfD) established for THC by scientific opinion EFSA 2015. The ARfD was established on the 0,001 mg/kg of body weight for a person weighing 60 kg, it is therefore **0,060 mg THC** (Scientific Opinion on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin. EFSA 2015.).

In the cosmetic product the systematic daily exposure (SED) of THC was calculated $1{,}7 \cdot 10^{-5}$ mg/kg bw/day, i.e. for a human weighing 60 kg this value is **0,001017 mg of THC. This value is 58 times lower than the ARfD (0,060 mg THC) - the THC content is toxicologically acceptable and the product is still safe for human health.** (in compliance with the Regulation (EC) No 1223/2009, article 17)

4.2 The relevant characteristics of packaging material

Description of the packaging: plastic jar with a screw cap.

The packaging material applied is suitable for the given type of cosmetic product and meets the hygienic requirements on products intended for contact with foodstuffs and meals and / or cosmetic products.

See annex no. 4, Packaging.

5. Normal and reasonably foreseeable use

(in compliance with the Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU), section 3.5)

The safety assessor has determined a relevant exposure scenario see Annex no. 1, table 6. Exposure to the cosmetic product.

The intended use of the product is appropriately communicated to the consumer by a text on the packaging.

There are no additional warnings or other explanations stated on the product.

See annex no. 5, Text of the product packaging.

6. Exposure to the cosmetic product

(in compliance with the Commission Implementing Decision of 25 November 2013 on Guidelines on

Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU), section 3.6 and The SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation 10TH revision, sections 3-3)

$A = m*(m/m_{\odot})*R*F*1000/60$

Calculated relative daily exposure (mg/kg bw/day)	A
Estimated quantity of the product applied (g)	m
The total amount of diluted product (g)	$m_{\odot}$
Estimated retention factor	R
Frequency of application per day (day^{-1})	F
default human body weight (kg)	60

See annex no. 1, table 6. Exposure to the cosmetic product.

The estimated amount of the product per an application was indicated by the responsible person. The value was determined experimentally by repeated application of the product. (The product in the original package was weighed, an application of the product was performed under normal or reasonably foreseeable conditions of use and then the product was weighed again. The measurement was repeated 10 times.) 10 results for the amount of the product per one application were determined from the weight losses. The maximal measured value was used for the safety assessment of the product.

7. Exposure to substances

(in compliance with the Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU), sections 3.7 and 3.8.3)

$SED = A*C*D_p$

Systemic Exposure Dosage (mg/kg bw/day)	SED
Calculated relative daily exposure (mg/kg bw/day)	A
Concentration (%/100)	C
Skin permeability (%/100)	D_p

See annex no. 1, table 7. Exposure to the substances.

8. Toxicological profile of the substances

(in compliance with the Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU), section 3.8.4)

MoS = NOAEL / SED

Margin of Safety	MoS
The No Observed (Adverse) Effect Level (mg/kg bw/den)	NOAEL
Systemic Exposure Dosage (mg/kg bw/den)	SED

See annex no. 1, table 8. Toxicological profile of the substances.

It was an assessment of the toxicological profile of substances of all relevant toxicological effects, including local toxicity evaluation (skin and eye irritation, sensitization, phototoxicity) and calculation of MoS (Margin of Safety).

The safety of ingredients listed in the Annexes II, III, IV, V and VI of Regulation EC No. 1223/2009 fall under the responsibility of the SCCS. The safety assessor does not assess its toxicological properties (MoS) - these ingredients are considered safe if they meet the requirements of the relevant Annexes of the Guidance and if they are not assessed as dangerous as well as in cases when SCCS issued its opinion (in compliance with The SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation 10TH revision, section 3-1).

The systemic effects and MoS were not assessed for substances whose presence in the cosmetic product is at a low level and the expected (worst case) exposure levels were below the appropriate threshold of toxicological concern (TTC) values or if that the substance is a food material for which a much higher innocuous ingestion level is known. (in compliance with the Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU), section 3.8.4)

For assessment of the toxicological profile of substances were taken into consideration available relevant information about the intrinsic properties of substances (in compliance with the Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU), section 3.8.2):

1) as the most valuable toxicity information, actual test data from in vivo or in vitro studies obtained in accordance with Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), recognised international guidelines, or standards (e.g.OECD Test Guidelines), and performed in accordance with good laboratory practice principles.

2) existing test data that have not been obtained in accordance with the latest adopted/accepted version of a test guideline or with good laboratory practice standards, but which are considered valid.

3) in vitro data or alternative data from valid test systems, to be used as a screening study to predict toxicity.

4) human data and/or experience. It is in general not acceptable to perform human toxicology studies for hazard identification, but, if data or experience exist, they should be included in the final assessment.

5) human (clinical) data, including data from clinical trials and applications in other industries such as food and medicinal products.

6) data gathered from post-marketing surveillance.

7) human volunteer compatibility studies, which should only be used to confirm safe levels of use for a relevant target population.

8) read-across approaches, based on the chemical structure and properties of related substances in order to predict the toxicity of the ingredient, grouping of substances, and non-testing data from QSAR model outputs.

For the assessment of the toxicological profile of each evaluated substance were considered these endpoints (in compliance with the Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU), section 3.8.2):

1) acute toxicity via relevant routes of exposure;
2) irritation and corrosivity;
3) skin irritation and skin corrosivity;
4) mucous membrane irritation (eye irritation);
5) skin sensitisation;
6) dermal/percutaneous absorption;
7) repeated dose toxicity (normally 28- or 90-day studies);
8) mutagenicity/genotoxicity;
9) carcinogenicity;
10) reproduction toxicity;
11) toxicokinetics (ADME studies);
12) photo-induced toxicity;

See annex no. 2, Ingredients.

At the appropriate endpoints were identified for further use in the process of risk characterization, the most relevant concentration of no observed adverse effect level (No Observed Adverse Effect Level, NOAEL) or lowest-observed-adverse effect level (Lowest Observed Adverse Effect Level, LOAEL).

Special attention was paid to the impacts on the toxicological profile due to particle size, possible presence of impurities in the substances used and possible matter interaction.

An ingredient is regarded safe if the calculated MoS of the ingredient is higher than 100.

Sources and justification for individual substances are listed in Annex no. 1, table 8. Toxicological profile of the substances.

9. Undesirable effects and serious undesirable effects

Based on this CPSR during normal and reasonably foreseeable use of a cosmetic product, no undesirable effects are expected.

After being placed on the market the cosmetic product will be further monitored by the responsible person.

If any undesirable effects on consumer health appear, the responsible person are to notify the competent authority about it without any delay and shall take corrective action in accordance with the Regulation.

At the same time, the responsible person is to notify the Safety Assessor about this fact who will update this CPSR based on the new findings and the adopted corrective action.

10. Information on the cosmetic product

No further information is available onto the given cosmetic product nor any additional studies have been performed.

11. List of Annexes

Annexes no. 1 – 6
Annex no. 1, Table
Annex no. 2, Ingredients
Annex no. 3, Tests
Annex no. 4, Packaging
Annex no. 5, Text of the product packaging
Annex no. 6, Proof of qualification

12. References

- Regulation (EC) No 1223/2009
- Commission implementing decision of 25 November 2013 (2013/674/EU)
- The SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation 10TH revision
- SCCS'S Opinions
- CosIng http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm#
- ECHA
- DBI (internal database of cosmetic ingredients, Naturfyt-Bio)
- MSDS and TDS of ingredients used
- Wikipedia (www.wikipedia.org)
- EFSA, NIH USA
- ChemIDPlus Light — http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp
- ChemIDPlus Advanced — http://chem.sis.nlm.nih.gov/chemidplus/
- Cosmetics Europe Recommendations — https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/recommendations.html
- IPCS Inchem — http://www.inchem.org/pages/jecfa.html

- PubMed — http://www.ncbi.nlm.nih.gov/pubmed
- ToxNet — http://toxnet.nlm.nih.gov/

Part B – Cosmetic product safety assessment

1. Assessment conclusion

The assessment conclusion is a statement on the safety of the cosmetic product in relation to the safety requirement of Article 3 of Regulation (EC) No 1223/2009.

Based on the information submitted, the cosmetic product can be evaluated as safe for human health if used at common or reasonably predictable conditions.

This conclusion can be only applied to such products which composition, properties, purpose and method of use comply with the documentation and laboratory test results attached to this assessment and the production and labelling of which meet the requirements of the EU legislation in force on the day of issue of this evaluation.

2. Labelled warnings and instructions of use

The cosmetic product does not have to have any indication on the label about any particular warnings regarding the use (in compliance with the Regulation (EC) No 1223/2009, article 19, paragraph 1, letter d).

See annex no. 5, Text on the product packaging.

3. Reasoning

(in compliance with the Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU), section 4.3):

Justification is based on:

A) The safety evaluation of substances and/or mixtures in terms of:

1) hazard characterization that substances and mixtures;

2) assessment of local and systemic exposure (considering the absorption data);

3) risk assessment of systemic effects (calculation of margin of safety - MoS) and risk assessment of local effects (e.g. skin allergy, skin irritation) - resources and justification for individual substances are listed in Annex of Part A , section 8 Toxicological profile of the substances.

B) The safety evaluation of the cosmetic product in terms of:

1) risk assessment summary on the basis of local and systemic effects of individual substances / mixtures

2) additional assessment of the safety of the product, which can not be assessed by assessing the substances/mixtures separately (e.g. skin compatibility to the formulation, assessment of the

potential effects of a combination of substances of potential effects that might arise from the interaction of the packaging material or possible effects due to chemical reactions between the substance/mixture in the product

3) other factors that influence the safety assessment, e.g. stability, microbiological quality, packaging and labelling, including instructions for use and safety precautions for use

If LOAEL values were used instead of a NOAEL or NOAEL was obtained by a 28-day toxicity test using repeated dose instead of 90-day toxicity test, use the appropriate value of an additional factor in the calculation of MoS, see Appendix Report No. 1, Table 8. Toxicological profile of the substances, an additional factor for MoS (LOAEL / NOAEL, 28-day or 90-day tests) (in compliance with The SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation 10TH revision, 3-4.8)

For determination of the minimum MOS value was taken into account the target group, see Report no. 1, Table 6. Exposure to the cosmetic product, minimum MoS value for the target group.

The assessment was made for cosmetic products intended for adults. (in compliance with The SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation 10TH revision, 3-6.9)

Based on the formulation of the given cosmetic product, its qualitative and quantitative composition according to the INCI, the physical, chemical and microbiology specifications of product and materials, available toxicological information, preservation challenge test, determining the type of cosmetic product, including its purpose and method of application and assessment of the properties of packaging materials has been assessed the cosmetic product safety for the consumer via evaluation of general toxicological profile of ingredients, their chemical structure and exposure level (MoS) depending on the purpose of their use in the cosmetic product.

The evaluation of the entire composition and applied ingredients concentrations imply that also as a whole the composition of the respective cosmetic product is in accordance with the requirements of the current legislation applicable for cosmetic products.

4. Assessor's credentials and approval of part B

Name and address of the safety assessor:

Rodan Hojgr
Havlíčkova 563
790 01 Jeseník
Czech Republic

Proof of qualification of safety assessor:

See annex no. 6, Proof of qualification.

Date and signature of safety assessor:

Date: 8. 6. 2020

Signature: PharmDr. Rodan Hojgr (electronic signature)