Mediator A/S

Cosmetic Product Safety Report

According to Annex I of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

For: Neurogan CBD Face Oil 4000
Performed on behalf of Natures Help

Content

1. Legal basis

The Cosmetic Product Safety Report

The present cosmetic product safety report has been compiled based on the legal requirements of Article 10 of Regulation (EC) No. 1223/2009:

"1. In order to demonstrate that a cosmetic product complies with Article 3, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annex I."

The Product Information File (PIF)

The PIF is to be compiled based on the requirements listed in Article 11 of Regulation (EC) No. 1223/2009:

"1. When a cosmetic product is placed on the market, the responsible person shall keep a product information file for it. The product information file shall be kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market.

2. The product information file shall contain the following information and data which shall be updated as necessary:

(a) a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product;

(b) the cosmetic product safety report referred to in Article 10(1);

(c) a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8;

(d) where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product;

(e) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries.

3. The responsible person shall make the product information file readily accessible in electronic or other format at his address indicated on the label to the competent authority of the Member State in which the file is kept."

2. Administrative information

Product name:	Neurogan CBD Face Oil 4000
Product no. / Formulation no.:	-
Produced for:	Natures Help, Skolevej 50B, 9490 Pandrup, Denmark
Production place:	Neurogan, 707 Broadway, suite 800, San Diego, California 92101
Responsible, product formulation:	Reference is made to the product summary file.
Responsible, placing on the market:	Natures Help, Skolevej 50B, 9490 Pandrup, Denmark CVR: 39740184
Responsible, packaging:	Reference is made to the product summary file.
EU/EEA Member states in which the product is to be placed on the market:	Reference is made to the product summary file.
Version:	1.1
Date of previous version:	October 12, 2020
Date of issue:	October 21, 2020
Date of expiry:	October 12, 2022

3. Part A - Cosmetic product safety information

3.1. Quantitative and qualitative composition of the cosmetic product

Reference is made to the information stored in the Product assessment file made available by Mediator A/S.

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

For information concerning the physical/chemical characteristics and stability of the cosmetic product reference is made to the Product summary file stored at Mediator A/S.

3.3. Microbiological quality

For information concerning the microbial quality of the cosmetic product and of the contained raw materials reference is made to the Product summary file stored at Mediator A/S.

3.4. Impurities, traces, information about the packaging material

For information concerning Impurities, traces and information about the packaging material of the cosmetic product reference is made to the Product summary file stored at Mediator A/S.

3.5. Normal and reasonably foreseeable use

Normal and reasonably foreseeable use	
Type of product:	Face Oil
Uses (primary/other foreseeable):	Daily use

3.6. Exposure to the cosmetic product

For information concerning consumer exposure to the cosmetic product (i.e. the exposure assessment) reference is made to the Product assessment file provided by Mediator A/S.

3.7. Exposure to the substances

For information concerning consumer exposure to the substances contained in the cosmetic product and the corresponding risk assessment reference is made to the MOS-calculations (Margin Of Safety) in the Product assessment file provided by Mediator A/S.

3.8. Toxicological profile of the substances

A toxicological profile of each of the substances contained in the cosmetic product is available in the Product assessment file provided by Mediator A/S.

3.9. Undesirable effects and serious undesirable effects

Undesirable effects and serious undesirable effects		
Date	Complaint (by intended use)	Action taken
-	-	-

The “person responsible for placing the cosmetic product on the market” has not delivered to Mediator A/S any data concerning undesirable effects and serious undesirable effects resulting from the use of the cosmetic product in the EU/EEA member states.

The information on undesirable effects is to be kept up-to-date and regularly made available to the safety assessor, who may consider it necessary to revise the safety assessment, suggest improvements to the formulation or use the information to establish the safety assessment for similar products.

The aim of this section of the cosmetic product safety report is to monitor the safety of the product after it has been placed on the market and to take corrective action, where necessary. *To this end, the responsible person (in collaboration with the distributors) is required to set up a system to collect, document, establish the causality of and manage the undesirable effects caused by the product after its use in the Union. When the undesirable effects are serious, the responsible person (and the distributors) are to notify the competent authority of the Member State where the effects occurred.*

The cosmetic product safety report is to include all the available data, including statistical data, on the undesirable effects and serious undesirable effects of the cosmetic product or, where relevant, other cosmetic products.

Information on serious undesirable effects which, according to the causality assessment, are found to be very likely, likely, not clearly attributable or unlikely to be attributable to the cosmetic product in question are to be included in the safety report in accordance with section 9 of Part A of Annex I to Regulation (EC) No 1223/2009, and notified to the national competent authorities, in accordance with Article 23 of the same Regulation. The notification forms sent to the competent authorities are therefore to be attached to the cosmetic product safety report.

The responsible person’s reaction to and handling of the reported serious undesirable effects is to be stated. The corrective and preventive measures taken, if any, should be described.

3.10. Information on the cosmetic product

No additional information provided.

4. Part B – Cosmetic product safety assessment

4.1. Assessment conclusion

The cosmetic product Neurogan CBD Face Oil 4000 is assessed as safe for normal and reasonably foreseeable use in accordance with the European Cosmetics Regulation (EC) No 1223/2009 but it is recommended by Mediator A/S that a storage stability test is conducted, to ensure compatibility between the product and the packaging, and making sure that the label complies with Article 19 of the European Cosmetics Regulation (EC) No 1223/2009.

4.2. Labelled warnings and instructions of use

The following warnings and instructions of use are mentioned on the packaging material/label of the product:

Instructions of use: Designated to promote healthy skin. To moisturize, calm and balance your skin. Apply 2-3 drops wherever and whenever needed on skin.

Ingredients (INCI): Cannabis Sativa Stem Extract, Caprylic/Capric Triglyceride

The product name includes the wording “Face Oil”. Therefore, further instructions of use are not needed as the product name is sufficient to define the use of the product as a face oil for daily use.

There are no other ingredients incorporated in the finished product, which require additional directions, specific indications or warnings in accordance to the relevant Annexes of the European Cosmetics Regulation (EC) No 1223/2009 (as amended) or due to their toxicological and/or physical-chemical properties or because of their concentrations in the finished product.

Mediator A/S recommends making sure that the label complies with Article 19 of the European Cosmetics Regulation (EC) No 1223/2009.

4.3. Reasoning

The safety assessment of Neurogan CBD Face Oil 4000 is based on the toxicological profile of each ingredient and evaluation of the data collected on the product. The product is manufactured in accordance with Good Manufacturing Practice (GMP) for cosmetics.

4.3.1. Physical/chemical characteristics, stability and microbiological quality of the cosmetic product

Neurogan CBD Face Oil 4000 is an oil-based formulation. No preservatives have been added. Microbial stability testing is not necessary for this kind of product. Mediator A/S recommends running a storage stability test to confirm the physical stability of the product.

4.3.2. Impurities, traces and information about the packaging material

According to the information provided no impurities and/or traces are expected to be present in the final product or in the ingredients at levels that may have an impact on the safety of the finished product.

No information on the packaging material has been provided. Mediator A/S recommends making sure that the container is compatible with the product and safe for use.

4.3.3. Normal and reasonably foreseeable use

The labelling as Face Oil in combination with the general description of the product on the label, support the safe use of the product during intended and reasonably foreseeable use. (Unintended) reasonably foreseeable use (not a misuse) is not recognizable.

4.3.4. Exposure to the cosmetic product and the substances

The calculation of the exposure to the product and to each of the ingredients in the cosmetic product was carried out according to the "SCCS's Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation, 10th revision 2018". For the exposure calculation, reasonably foreseeable use is calculated as an oil with a total application of six drops daily. Neurogan CBD Face Oil 4000 is a leave-on product and therefore a retention factor of 1 (100%) is used. E_{dermal} for this type of product is calculated to be 3.5 mg/kg bw/day.

4.3.5. Toxicological profile of the substances

The safety of the cosmetic product is based on the safety of its ingredients. All raw materials and ingredients in the finished product were assessed as safe for the use as cosmetic ingredients in the finished product.

The Margin of Safety (MoS) calculated for each of the substances contained in the cosmetic product is above 100, which supports the safety of the cosmetic product.

The responsible for the product formulation confirms that the raw material for Cannabis Sativa Stem Extract is derived from hemp stalks and does not contain any hemp flowers.

4.3.6. Undesirable effects and serious undesirable effects

No undesirable effects reported.

4.3.7. Information on the cosmetic product

No further information provided.

4.4. Assessor's credentials and approval of Part B

Assessor´s credentials and approval		
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