# Cosmetic Product Safety Report

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|---|---|
| **Product type** | **Mouthwash** |
| **Product name** | **CBD Oil wlh p2o 20%** |
| **Category / usage** | **For mucous membrane / Leave on** |
| **Responsible person** | **Whitelabel-hub by GSH GmbH, Am Walde 14, 49453 Wetschen, Germany** |
| **Report date** | **27.10.2023** |
| **Report number** | **WL/10/23/01/GS** |

I certify that this safety report refers to a CBD Oil wlh p2o 20% cosmetic product for human use with no medicinal properties.

**Cosmetic product safety report is according with the Regulation on EC 1223/2009 and the SCCS's Notes of Guidance for the Testing of Cosmetic Substances and their Safety Evaluation 12th Revision – SCCS/1647/22**

## Table of contents

# Part A. Cosmetic Products Safety Information

## 1. Product composition

The responsible person certifies that neither the product undergoing the safety assessment nor any of the raw materials used to make it were tested on animals in accordance with the Article 18 of Reg. EC 1223/2009. The product does not contain any CMR substances of categories: 1A, 1B and 2 according to Reg. EC 1272/2008.

**TABLE 1: Qualitative and Quantitative Product Composition**

| Trade Name | INCI | CAS | Function | Concentration | NOAEL | SED | MOS |
|---|---|---|---|---|---|---|---|
| Hemp Leaf Extract | **Cannabis Sativa Leaf Extract** | - | Skin conditioning | 24,85000% | - | 8,08619 | - |
| Hempseed Oil | **Cannabis Sativa Seed Oil** | 89958-21-4 | Emollient | 75,15000% | - | 24,45381 | - |
| **Estimated daily exposure** | **32,54** | **Retention Factor** | **0,1** | | | | |

## 2. Physical and chemical characteristics

| | |
|---|---|
| **Appearance** | Liquid |
| **Color** | Green-ish |
| **Fragrance** | - |
| **pH** | - |

## 3. Stability of the cosmetic product

| | |
|---|---|
| **Suggested durability** | Suggested durability: PAO 24M |
| **Storage conditions** | Room temperature.<br><br>The stability of the cosmetic product and the compatibility of the cosmetic mass with the packaging were tested by GSH GmbH. The stability and compatibility studies were performed under the controlled conditions described in the test report. The test results confirm the stability of the cosmetic and the compatibility of the packaging with the cosmetic mass. There is no interaction between the cosmetic and its packaging. |

Durability date was estimate based on:

- product composition
- Stability and compatibility tests
- Challenge test
- Finished product usage time

## 4. Microbiological quality

This cosmetic belongs to the low microbiological risk product category according with ISO 29621:2017-04. It is not necessary to do the microbiological tests.

- *Raw material microbiological quality:*

For the raw materials which belong to low microbiological risk substances there is no necessity to attach results of microbiological test. As for the rest of the ingredients the customer provided correct documents confirming that ingredients are microbiologically clean.

## 5. Impurities and information about the packaging material

According with raw material mixtures specification and according with the information from suppliers, forbidden trace elements do not exist in the finished product. If any forbidden trace elements are expected in the finished product, correct analysis will be done. Information about packaging elements and packaging material is shown below. The responsible person has shown a declaration which complies with regulation EC 1935/204 (for the packaging applied in food industry) and declares that there are no heavy metals in finished products.

The packaging does not contain any hazardous ingredients which can impact product safety. The packaging is clean and can be used as a cosmetic packaging. Packaging: 10 ml Brown glass bottle with pipette and label, box

## 6. Normal and reasonably foreseeable use

Product intended for use as mouthwash. Used in accordance with the instructions provided is not expected to cause any harm. Product not specifically designed for children under 3 years of age.

## 7. Exposure estimates used in this safety report

| | |
|---|---|
| **Product class** | Mouthwash |
| **Product characterization** | Leave on |
| **Site of application** | Mouth |
| **Body surface affected** | No datas in SCCS 1602/18 |
| **Amount of substance applied per use (daily)** | 21,62 g |
| **Frequency of use** | 2/day |
| **Intended consumer** | Adults |
| **Calculated daily exposure** | 32,54 |
| **Retention factor** | 0,1 |

*Information in this table are according to Recommendation of* SCCS/1647/22

## 8. Systemic toxicity data and calculations of Margins of Safety

In accordance with the guidance SCCS/1647/22, substances with MoS>100 are considered to be safe as used. For substances with no known NOAEL we make the assessment with reference to professional and scientific publications accessible in journals, independent tests, professional bodies monitoring product safety, EU advisory boards, information from the manufacturer and experience with similar substances, SCCS and EFSA opinions. Ingredients used in this formulation were assessed against a possibility of interactions. There is no reason to believe that interactions leading to forming new chemicals or leading to significant changes in quality are possible.

| INCI | Comments |
|---|---|
| **Cannabis Sativa Leaf Extract** | Cannabis Sativa Leaf Extract is the extract of the leaves of Cannabis sativa L., Cannabaceae. According to Safety |

| | |
|---|---|
| | Assessment of a Hemp Extract using Genotoxicity and Oral Repeat-Dose Toxicity Studies in Sprague-Dawley Rats, February 2020 Toxicology Reports 7(9) Cannabis Sativa Leaf Extract during 90-day study, there were no adverse clinical observations that were consistent across treatment groups and these observations were not linked with pathological observations. This compound can be used in cosmetics product and it is not restricted according to Regulation EC 1223/2009. |
| **Cannabis Sativa Seed Oil** | According to the CIR Plant derived fatty acid oils as used in cosmetics, 04.04.2011, Plant-derived oils are considered safe at any level of use. |

Daily exposure dose is:

$$\mathbf{E_{product} = mg/kg/d}$$

According with the highest raw material concentration in the finished product. (worst case scenario).

Systemic Exposure Dose (SED) for the ingredients:

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

- C – The highest ingredients concentration in the product (%)
- DAp – Transepidermal absorption (if DAp does not exist - DAp=100%)

Margin of Safety (MoS):

$$\mathbf{MoS = PoD_{sys}/SED\ (mg/kg/d)}$$

Values of NOAEL and SED (if exist) are in the Table 1

According with the Regulation (EC) No 1223/2009, its necessary to show the allergens concentration in the finished product if their concentration is higher than **0.01%** for the rinse off products and **0.001%** for the leave on products.

**Allergen declaration:**

| Allergen | CAS | Concentration [%] | Source |
|---|---|---|---|

## 9. Raw materials toxicological profile

Local toxicity and critical effects are not expected for substances with MoS >100.

Toxicological profile

| | | |
|---|---|---|
| **INCI** | Cannabis Sativa Leaf Extract | **Molecular structure** |
| **CAS** | - | |
| **Function** | Skin conditioning | |
| **Source** | Natural | |
| Molecular mass: no available data<br>log Pow: no available data<br>Solubility: insoluble in water<br>Toxicological end points:<br>-oral: no available data<br>-dermal: no available data<br>-inhalatory: no available data | | |

<table>
<tr><td colspan="2">-carcinogenic: no available data<br>-teratogenic: no available data</td><td></td></tr>
<tr><td>INCI</td><td>Cannabis Sativa Seed Oil</td><td rowspan="6">Molecular structure</td></tr>
<tr><td>CAS</td><td>89958-21-4</td></tr>
<tr><td>Function</td><td>Emollient</td></tr>
<tr><td>Source</td><td>Plant</td></tr>
<tr><td colspan="2">Molecular mass: no available data<br>log Pow: no available data<br>Solubility: insoluble in water<br>Toxicological end points:<br>-oral: no available data<br>-dermal: no available data<br>-inhalatory: no available data<br>-carcinogenic: no available data<br>-teratogenic: no available data</td></tr>
</table>

## 10.Undesirable effects and serious undesirable effects

Product entering the market for the first time. No data about adverse events. Based on the presented data and our assessment, we do not expect serious adverse effects to be possible when product is used in the intended manner.

According to Regulation EC 1223/2009, the responsible person is required to document, determine the root-cause and report any known adverse effects cause by this product.

## 11.Information on the cosmetic product

1. This safety assessment refers to in its entirety to a product manufactured, distributed or sold by the responsible person stated.

2. This safety assessment is valid only for a cosmetic product corresponding to the formula presented in the Table 1. in Section 1 of this report. Any changes made to the formula will require this assessment to be updated.
3. This assessment is only valid if the product is manufactured according to Good Manufacturing Practice PN-EN ISO 22716:2009.
4. Any labelling and marketing claims were not checked for legal compliance other than when it may be of importance for consumer safety.
5. This product was not specifically assessed for use by children below 3 years old.

**Labeling information about ingredients according with INCI:**

| **INGREDIENTS:** |
|---|
| Cannabis Sativa Seed Oil, Cannabis Sativa Leaf Extract |

# Part B. Cosmetic Product Safety Assessment

| **Product Name** | | **Responsible Person** |
|---|---|---|
| CBD Oil wlh p2o 20% | | Whitelabel-hub by GSH GmbH, Am Walde 14, 49453 Wetschen, Germany |
| Report date: | 27.10.2023 | |

## 1. Assessment conclusion

I confirm that the product is safe in the stated application when used under normal and reasonably foreseeable use. The raw materials used meet the quality and exposure requirements of the regulation EC 1223/2009 and all its annexes.

## 2. Labelled warnings and instruction of use

Information on the label must be agreed with Regulation EC 1223/2009 if the finished product contains the ingredients which are shown on III – VI attachments of this regulation. We cannot write a necessary warning on the label but they can be if they are reasonable.

According with the 18 Article of Regulation EC 1223/2009 all marketing declaration on the label are correct and all of them are agreed with Regulation EC 655/2013.

## 3. Reasoning

The type of product undergoing the assessment has been in common use in cosmetics over many years without any particular concerns. In due course of product assessment, a range of tests were performed:

- physicochemical stability, its compatibility with packaging material, microbial count at the time of manufacturing and preservative challenge test. All tests returned satisfactory results. Furthermore, dermal patch tests were performed producing no dermal irritation from exposure to the final product.

The safety assessment is based on:

- analyzing toxicological profiles of all raw materials used;
- calculated exposure to the raw materials taking into account the material quantity, body area and type of consumer population;
- Margins of Safety, based on NOAEL values where available;
- where necessary, the assessment refers to opinions from trustworthy professional experts groups (SCCS, CIR, IFRA, EMeA);
- read-across approach, taking into account similar products with comparable ingredients which are already present on the market.

## 4. Assessor`s credentials and approval of Part B

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DYPLOM

Pan(i) Grzegorz Sychowski
(imię/imiona i nazwisko)

urodzony(a) dnia 16 października 1982 r.
w Kielcach
odbył(a) studia na kierunku Technologia chemiczna
w zakresie specjalności: Technologia nieorganiczna
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i uzyskał(a) w dniu 29 czerwca 2006 r.
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Dziekan lub kierownik jednostki organizacyjnej
prof. dr hab. inż. Zbigniew Żurek
(pieczęć imienna i podpis)

Rektor
prof. dr hab. inż. Józef Gawlik
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mp.

Kraków (miejscowość) dnia 18 lipca 2006 r.