

COSMETIC PRODUCT SAFETY REPORT

Hemp Massage Oil Raspberry

Safety report for Hemp Massage Oil Raspberry has been compiled in accordance with Regulation of the European Parliament and of the Council (WE) number 1223/2009 from 30 November 2009 regarding cosmetic products.

Data for safety assessment of the cosmetic product

Name:	<u>Hemp massage oil raspberry</u>	
Introducer of the product/Manufacturer:	Name:	Introducer of the product/Manufacturer:
	Address (street):	ul. Swiety Marcin 80/82 lok. 355
	Address (city, postcode):	61-809 Poznan
	Email:	
	Web:	
Duty holder:	Name:	Duty holder:
	Address (street):	ul. Swiety Marcin 80/82 lok. 355
	Address (city, postcode):	61-809 Poznan
	Email:	
	Web:	
Product type/ category:	skincare	
Direct package type:	bottle	
Direct package material:	glass	
Direct package closing:	cap	
Closing material:		
PP	PP	
Other		
Storage/ storage retention period:	24 months	
Product tests:	dermatologic test	
Period after opening (PAO):		
Preservative:	name, INCI composition	Preservative:
Intended use:	<u>Hemp massage oil raspberry</u> based on natural oils suitable for care of every type of skin. Composition of the product is made of hemp oil, apricot kernel oil, raspberry oil, sweet almond oil, sesame oil, avocado oil, watermelon seed oil, peppermint oil. Oils' active ingredients easily pamper the skin and result in moisturizing, firming and nourishing effect. It can be also used for relaxing massages.	

Product's ingredients with INCI names	Ingredients: Cannabis Sativa Seed Oil, Prunus Amygalus Dulcis Oil, Parfum, Prunus Armeniaca Kernel Oil, Rubus Idaeus Seed Oil, Sesamum Indicum Seed Oil, Citrullus Vulgaris Seed Oil, Mentha Piperita Oil
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PART A
INFORMATION REGARDING SAFETY OF THE COSMETIC PRODUCT

Cosmetic product Hemp Massage Oil Raspberry fits into the category of skincare (in accordance to *Decree of the Minister of Health from 16 June 2003 regarding defining cosmetic products category*)

1. **Quantitative and qualitative composition of the cosmetic product**

Trade name	CAS	INCI	Function of the raw material	Amount of use [%]
Hemp oil	89958-21-4	Cannabis Sativa Seed Oil	Emollient	84,2
Sweet Almond Oil	8007-69-0	Prunus Amygalus Dulcis Oil	Conditioning, nourishing	5,0
Raspberry Ketone EcoFlores	5471-51-2	Parfum	Aromatic compositon	5,0
Apricot Kernel Oil	68650-44-2/72869-3	Prunus Armeniaca Kernel Oil	Conditioning, nourishing	2,5
Black Raspberry Seed Oil	84929-76-0	Rubus Idaeus Seed Oil	Conditioning, nourishing	2,0
Sesame Oil	8008-74-0	Sesamum Indicum Seed Oil	Conditioning, nourishing	0,5
Watermelon Seed Oil	90244-99-8	Citrullus Vulgaris Seed Oil	Conditioning, nourishing	0,5
Peppermint Oil	84082-70-2	Mentha Piperita Oil	Conditioning, nourishing	0,3

2. **Chemical/ physical properties and stability of the cosmetic product**

Appearance	Oily liquid
Colour	Creamy/ pink
Smell	Pleasant, characteristic to this composition

2.1. Chemical/ physical properties of substances or mixtures and cosmetic product Microbiological quality and challenge test (waterless product)

Chemical and physical properties of the raw materials used in production of the cosmetic product Hemp Massage Oil Raspberry correspond to requirements Characteristics Cards of particular raw materials shared by the manufacturer of the finished good.

2.2 . Stability of the cosmetic product in rationally predicted storage conditions

Cosmetic product Hemp Massage Oil Raspberry was subjected to challenge tests in temperature from +5°C to 40°C. Duration of the tests: 1 month.

Repeated assessment of the chemical and physical properties after the completion of the challenge test has confirmed the minimal established date of storage retention period of the finished good. Based on conducted challenge tests, date of the minimal durability has been determined for 24 months since the date of production.

Cosmetic product Hemp Massage Oil Raspberry in rationally predicted conditions of storage and usage is guaranteed by the adequately refined formula.

3. Microbiological quality

Product is of low microbiological risk. Waterless product.

4. Contamination, trace amounts, package material information

4.1. Substances and mixtures clarity

According to data included in documents for particular raw materials used in this cosmetic product that were shared by the manufacturer, it is attested that there is no presence of trace amounts of illicit substances which intensity may rise a concern whether the cosmetic product is safe or not. Moreover, the manufacturer of finished goods has not delivered any information regarding presence of contaminations or trace amounts of illicit substances developed during the production of the cosmetic product.

4.2. Package material information

Cosmetic product Hemp Massage Oil Raspberry is packed in a bottle made of glass. The package also includes:

-a cap made of PP

The materials used for the package are durable and resistant to most chemical substances.

In order to confirm the right choice of the material, compatibility test have been conducted with the finished good.

Repeated assessment of the chemical and physical properties has confirmed the established durability of the finished good.

5. Normal and predictable usage

Cosmetic product Hemp Massage Oil Raspberry fits into the category of skincare.

Exposition of the product as well as the unambiguous information on the label informing about the intended use, indicates the easily predictable usage. Instructions regarding how to use the product are visible on the package.

6. Exposure to the cosmetic product

Exposure to the cosmetic product was assessed based on calculation of the cosmetic product that has contact with particular parts of human body (dependent on advised usage). In order to assess, a.o. *SCCS's Notes for the Testing of Cosmetics and their Safety Evaluation* (9th Revision) was used.

Following facts have been included:

- Product type-Product that remains on the skin
- target/exposed population or potential exposure of determined population- people over 16 years old
- normal way of exposure: dermal- skin
- surface of application: 15670 cm²
- amount of the product in an advised or rationally predicted usage- 7,82 g
- incidence of usage- 2,28/day

7. Exposure to substances

In case of cosmetic products, *Margin of Safety (MoS)* is used to assess the exposure of particular substances. This rate is obtained by dividing the lowest value of NOAEL by the calculated SED value (Systematic Exposure Dosage) of the dose of substance to which the consumer is exposed. A substance is safe when the MoS value is at least 100. For some ingredients of the considered formula, which have no identified NOAEL value, in order to assess them other scientific data regarding safety of the product was used.

For all of the substances from particular substances SED value was calculated:

$$\text{SED} = A(\text{mg/kg month/day}) \times C(\%)/100 \times \text{DA}(\%)/100$$

A- daily exposure to cosmetic product, calculated on the basis of the amount of the applied product and frequency of use, including the weight of the person

Skladnik	A	C	DA	SED
Cannabis Sativa Seed Oil	123,20	84,2	100	103,7344
Prunus Amygdalus Dulcis Oil	123,20	5,0	100	6,16
Parfum	123,20	5,0	100	6,16
Prunus Armeniaca Kernel Oil	123,20	2,5	100	3,08
Rubus Idaeus Seed Oil	123,20	2,0	100	3,08
Sesamum Indicum Seed Oil	123,20	0,5	100	0,616
Citrullus Vulgaris Seed Oil	123,20	0,5	100	0,616
Mentha Piperita Oil	123,20	0,3	100	0,3696

C- maximum intensity of the particular ingredient in a finished good

DA- absorption by skin

8. Toxicological profile of substances

Based on:

- Contract from 30 March 2011 about cosmetics (Dz. U. z 2001 nr 42. Pos. 473 with later amendments)
- Regulation of the European Parliament and of the Council (WE) nr 1223/2009 from 30 November 2009 regarding cosmetic products
- Regulation of the Minister of Health from 30 March 2005 regarding lists of illicit or licit substances with restrictions of usage in cosmetics and graphic signs placed on the packages of cosmetics (Dz. U. From 2005, number 72 poz. 642 with later amendments)

It is attested that the product: Hemp Massage Oil Raspberry does not contain illicit substances in amounts that rise concerns about safety.

The characteristics of the substances used to produce cosmetic product Hemp Massage Oil Raspberry in terms of toxicology, were compiled on the basis of the data obtained in progress of toxico-

logical overview of databases. (a.o. TOXNET, PubMed, CIR, European Chemical Agency, ECHA and others) and information included in point 11 of Characteristics Cards of particular ingredients, shared by the manufacturer of the finished good.

9. Side effects and severe side effects

There is no data regarding reported side effects or severe side effects after using this cosmetic product. Therefore, it indicates that the product is safe.

10. Information about cosmetic product

Cosmetic product Hemp Massage Oil Raspberry.

The product was not tested on animals.

PART B

COSMETIC PRODUCT SAFETY ASSESSMENT

1. Conclusion from the assessment

In agreement with *Regulation of the European Parliament and of the Council (WE) number 1223/2009 from 30 November 2009 regarding cosmetic products* on the basis of the safety assessment of the product Hemp Massage Oil Raspberry which fits into the category of skincare I declare that this product can be considered as safe for human's health in normal or rationally predicted usage.

The assessment was made on the basis of the composition provided by the manufacturer and data regarding the ingredients and the finished good.

2. Warnings and instructions placed on the label

Proposed package provides suitable presentation of this product and therefore guarantees predictable conditions of use and its intended use. Moreover, the text on the package includes information about composition, manufacturer information and defines the retention period.

There are no remarks regarding the text on the package.

3. Reasoning

Conclusion described in point 1. Is the result of the data analysis, which was conducted in Part A

- of quantitative and qualitative composition of the cosmetic product along with restriction regarding particular substances, required by the WE Regulation nr 1223/2009
- Physical and chemical properties of substances and stability of the finished good (along with microbiological data), connected to those substances
- Toxicological data of the individual ingredients, including data regarding topical and systematic toxicity and exposure to those substances
- Results of the finished good test, including dermatological test
- Information about observed or potential side effects

Ingredients which fall within restrictions according to WE Regulation were used in acceptable intensity and usage.

Toxicological profile of individual substances which were used in this product does not rise any concerns.

When it comes to ingredients to which NOAEL value was available, the safety margins were defined (MoS). In all cases they were over 100. For the remaining ingredients to which no data regarding chronic toxicity or severe, topical toxicity was available, proven history of safe use allows to use the substance in the advised intensity and terms of use.

Moreover, in this assessment following data has been included:

- clarity of the substance and possible contaminations- no objections
- cleanliness and stability of the package material- no objections
- product substances interactions, substance and package interactions- they are not expected
- way of marking the product- no objections

4. Expert's qualifications and confirmation of Part B

4.1. Confirmation of Part B/ claiming the cosmetic product as safe

In result of completing the overview of the data regarding the cosmetic product Hemp Massage Oil Raspberry and the raw materials used to produce it, this product has been accepted to use according to its intended use.

Assessment of the influence of this product to human's health safety was obtained on the basis of dermatological and applicational tests of the finished good, as well as microbiological tests, toxicological profile of the ingredients and the toxicological specification and profile of the finished good. In result of this assessment, it can be

claimed that this product is safe to human's health when used correctly and in rationally predicted conditions.

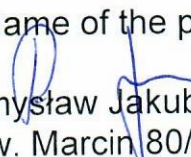
Taking into consideration the foregoing data and the correct usage of the product, no significant risk potential has been proved.

This assessment of the impact of the product on human's health safety has been made according to the current knowledge. Update of this assessment will be made as soon as new information will be obtained.

This report fulfills the formal requirements regarding assessment of the cosmetic's impact on human's health safety included in article 11 from 30 March 2001 about cosmetics (Dz. Ustaw 2001 number 42 pos. 473) and Regulation of the European Parliament and of the Council (WE) number 1223/2009 from 30 November 2009 regarding cosmetic products..

The production of this product may be commenced, including GMP guidelines.

4.2. Name of the person conducting the assessment


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5.10.2019

SIGNATURE