

## COSMETIC PRODUCT SAFETY REPORT

**PRODUCT:** Sleepy Salts

**DATE:** 19 August 2020

Responsible Person: Tannine Montgomery  
**Sweet Pink CBD**  
Briercare House  
Harp Lane  
Cavandish Road Clare  
CO10 8PH



## PART A – Cosmetic Product Safety Informa

### 1. Quantitative and qualitative composition

	<b>Ingredient INCI name</b>	<b>CAS</b>	<b>Function</b>	<b>Limits</b>	<b>Amount</b>
1	Magnesium sulfate	7487-88-9	Bulking, hair conditioning,		35.00
2	Maris sal		Skin conditioning		30.00
3	Sodium chloride	7647-14-5	Bulking, masking, oral care,		20.00
4	Cannabis sativa seed oil	89958-21-4	Emollient, skin conditioning		7.30
5	Lavandula angustifolia flower	90063-37-9	Skin conditioning		5.00
6	Lavandula angustifolia oil	8000-28-0 /	Perfuming		1.50
7	Chamomilla recutita flower oil	8002-66-2	Masking, skin conditioning		1.00
8	Cannabidiol	13956-29-1	Antioxidant,	not in list	0.20

Allergens present in this product and estimated amounts\*:

Linalol: 0.75%

\* The presence of these allergens must be indicated in the list of ingredients when their concentration exceeds: 0.001% in leave-on products or 0.01% in rinse-off products

## 2. Physical & chemical properties and stability

### 2.1.1 Physical/chemical properties of ingredients (substances or mixtures)

See section 1. Quantitative and qualitative composition – additional specification of ingredients.

#### Ref. 1. 1 **Magnesium sulfate**

Magnesium sulfate (or magnesium sulphate), also called epsom salt, is a white crystalline compound, an inorganic salt containing magnesium, sulphur and oxygen, with the molecular formula  $MgSO_4$ .

Magnesium sulfate is on the World Health Organisation's List of Essential Medicines, a list of the most important medication needed in a basic health system.

The Food and Drug Administration (FDA) has reviewed the safety of magnesium sulfate and has placed magnesium sulfate on the list of direct food substances affirmed as Generally Recognised as Safe (GRAS).

#### Ref. 1. 2 **Maris sal**

Maris sal, a naturally occurring substance, is the inorganic salts derived from sea water. Salt in most oceans is approximately 85% sodium chloride while maris sal (Dead sea salt) is only 12-18% sodium chloride. It contains high concentrations of potassium, magnesium and bromide.

#### Ref. 1. 3 **Sodium chloride**

Sodium chloride, also known as salt, common salt, or halite, is a compound with equal proportions of sodium and chlorine with the molecular formula  $NaCl$  representing a 1:1 ratio of sodium and chloride ions. In addition to being an important component of food, the US FDA includes Sodium chloride on its list of substances considered Generally Recognised as Safe (GRAS) as a substance migrating to food from packaging. The Cosmetic Ingredient Review (CIR) has deferred evaluation of this ingredient because the safety has already been assessed by FDA. Sodium chloride is commonly consumed and presents no safety issues whatsoever in this cosmetic product.

#### Ref. 1. 4 **Cannabis sativa seed oil**

Cannabis sativa seed oil is the fixed oil expressed from the seeds of Cannabis sativa L., Cannabaceae.

The oil has a 3:1 ratio of omega-6 to omega-3 essential fatty acids. Cannabis sativa seed oil is comprised of mostly unsaturated fatty acids and is listed as a substance Generally Recognised as Safe (GRAS) by the US FDA. The Cosmetic Ingredient Review (CIR) Expert Panel evaluated the scientific data and concluded that Cannabis sativa seed oil is safe for use as a cosmetic ingredient. There are no drug effects from the seed. The topical application of the seed oil has no reported adverse effects and none are to be expected.

#### Ref. 1. 5 **Lavandula angustifolia flower**

Lavandula angustifolia flower are the dried flowers obtained from the Lavender, Lavandula angustifolia, Labiatae.

## 2. Physical & chemical properties and stability

### 2.1.1 Physical/chemical properties of ingredients (substances or mixtures)

See section 1. Quantitative and qualitative composition – additional specification of ingredients.

#### Ref. 1.6 **Lavandula angustifolia oil**

Lavandula angustifolia oil is the volatile oil obtained by the steam distillation of the flowers of the Lavender, *Lavandula angustifolia*, Labiatae. The majority of constituents are monoterpenols and esters.

#### Ref. 1.7 **Chamomilla recutita flower oil**

Chamomilla recutita flower oil is the volatile oil distilled from the dried flower heads of the *Matricaria recutita*, syn. *Chamomilla recutita* (L.), Compositae

#### Ref. 1.8 **Cannabidiol**

Cannabidiol (CBD) is a naturally occurring cannabinoid constituent of cannabis. CBD is a 21 carbon terpenophenolic compound which is formed following decarboxylation from a cannabidiolic acid precursor. Unlike Tetrahydrocannabinol (THC), CBD does not have any psychoactive effects due to its very low affinity for the cannabinoid CB<sub>1</sub> and CB<sub>2</sub> receptors. In November 2017 The World Health Organisation (WHO) published their report entitled "Cannabidiol" in which the WHO concluded that "CBD is generally well tolerated with a good safety profile. To date, there is no evidence of recreational use of CBD or any public health related problems associated with the use of pure CBD."

## **PART A – Cosmetic Product Safety Inform** *continued*

### 2. Physical & chemical properties and stability *continued*

#### 2.1.2 Physical/chemical properties of the cosmetic product

<b>Appearance</b>	Other
<b>Colour</b>	Various
<b>Aroma</b>	Floral
<b>pH</b>	n/a

\*RP: Responsible Person: Sweet Pink CBD

#### 2.2 Stability of the cosmetic product

The ingredients used in the production of the cosmetic product comply with the relevant legal regulations.

Both the product and constituent ingredients are stable under normal use and warehousing conditions during the entire time of the BBE period.

2.2.1 Sweet Pink CBD confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 Sweet Pink CBD uses a BBE based on the results of Sweet Pink CBD's stability testing, including shelf life stability testing.

2.2.3 A Preservative Efficacy Test was not necessary since this is not a water-based product.

### 3. Microbiological quality

#### 3.1.1 Microbiological specification of ingredients (substances and mixtures).

Based on available information from the ingredient specification (see section 1. Quantitative and qualitative composition– specification of ingredients), the ingredients used can be assessed as microbiologically safe.

### 3.1.2 Microbiological specification of the finished product

The given cosmetic product can be regarded as microbiologically safe for consumers' health under the ISO 29621:2010 standard "Cosmetics -- Microbiology -- Guidelines for the risk assessment and identification of microbiologically low-risk products".

The microbiological harmlessness of the ingredients and the cosmetic product is assessed according to COLIPA: Guideline for Microbiological Quality Management (MQM).

A Preservative Efficacy Test was not necessary since this is not a water-based product.

## 4. Impurities, trace amounts of forbidden substances, & information about packaging material

### 4.1 Impurities and trace amounts of forbidden substances

According to specifications (see section 1. Quantitative and qualitative composition – specification of ingredients) submitted by ingredient suppliers, the ingredients do not contain impurities or trace amounts of forbidden substances.

### 4.2 Information about packaging material

The packaging material applied is suitable for the given type of cosmetic product and meets the predictable use requirements.

<b>Container</b>	Bag
<b>Container Material</b>	Acid-free paper
<b>Airless Container</b>	No

Acid-free paper is paper that yields a neutral or basic pH if it comes in to contact with water. It can be made from any cellulose fibre and is lignin- and sulfur-free. Since wood or cellulose pulp is naturally acidic, calcium carbonate, CaCO<sub>3</sub>, is added as the main filler material resulting in a chemically neutral or alkaline pulp. Archival paper is an especially permanent, durable acid-free paper.

Since archival paper is chemically stable and since calcium carbonate is widely used medicinally as a dietary calcium supplement or gastric antacid there is no concern over chemical leaching from this packaging choice into a solid soap bar.

Sweet Pink CBD confirms that the results of reference sample monitoring show no reaction between the packaging material and the product during the product's stated minimum useable life. During that life no changes to physical and chemical properties of the product were noticed that would affect its usability and safety.

5. Normal and reasonably foreseeable use

The current label advice:

*Sprinkle into a warm bath.*

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19(1)(d) of *Cosmetic Regulation (EC) No. 1223/2009*:

*For external use only. Keep out of reach of children.*

6. Exposure to the cosmetic product

Area of application	Body
Product type: Leave-on or Rinse-off	Rinse Off
Duration and frequency	1.43
Possible additional routes of exposure	Face
Estimated skin surface area (cm <sup>2</sup> )	17500
Estimated amount of the product applied according to the SCCS (g/day)	18.67 g
Estimated retention factor according to the SCCS	.01
Target group	Adult
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	2.79

## 7. Exposure to the ingredients

	Ingredient INCI name	Concentration	SED
1	Magnesium sulfate	0.35000	0.00977
2	Maris sal	0.30000	0.00837
3	Sodium chloride	0.20000	0.00558
4	Lavandula angustifolia oil	0.01500	0.00042
5	Lavandula angustifolia flower	0.05000	0.00140
6	Chamomilla recutita flower oil	0.01000	0.00028
7	Cannabis sativa seed oil	0.07300	0.00204
8	Cannabidiol	0.00200	0.00006

*SED: Systemic Exposure Dose*

8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Magnesium sulfate	11776753.71220
2	Maris sal	358422.93910
3	Sodium chloride	537634.40860
4	Lavandula angustifolia oil	10155316.60690
5	Lavandula angustifolia flower	3584229.39070
6	Chamomilla recutita flower oil	35842293.90680
7	Cannabis sativa seed oil	4909903.27490
8	Cannabidiol	143369175.62720

*MOS: Margin of Safety*

#### 8. Toxicological profile of the ingredients in the formulation - continued

Based on the calculation of MoS (Margin of Safety) for ingredients that can be classified as hazardous to human health, the product does not contain ingredients with toxicologically significant profiles in terms of consumer health.

An ingredient with an MoS above 1000 is considered safe. An ingredient with an MoS above 100 but lower than 1000 must be further considered by the assessor.

Since all of the ingredients have a margin of safety above 1,000 this product is considered safe for consumers to use.

#### 9. Undesirable effects and serious undesirable effects

The cosmetic product with a similar composition has been supplied to the market in the long term and until nowadays, no undesired effects to human health have been noticed in relation to the use of this product. Therefore, no undesired effects are anticipated at the common and reasonably predictable application of the given cosmetic product.

After its launch, the cosmetic product will be further monitored by Sweet Pink CBD in accordance to procedures detailed in *Cosmetic Regulation* (EC) No 1223/2009. The safety of the product should be reviewed on a regular basis. To that end, undesirable and serious undesirable effects on human health during in market use of the product should be filed (complaints during normal and improper use, and the follow-up done) and details forwarded to the safety assessor.

The safety assessor will then update the Cosmetic Product Safety Report (CPSR) based on the new findings and the adopted corrective measures.

#### 10. Additional information on the product

No additional information is available and no additional studies were carried out.

## 11. References

- THE SCCS'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC SUBSTANCES AND THEIR SAFETY EVALUATION 8TH REVISION  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>
- MSDS of ingredients
- Commission Implementing Decision of 25<sup>th</sup> November 2013 Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products
- SCCS - Opinions  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/opinions/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm)
- CosIng: the European Commission database on cosmetic substances  
<http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple>
- REGULATION 1223/2009 ANNEXES  
[http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=ref\\_data.annexes\\_v2](http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=ref_data.annexes_v2)

## **PART B – Cosmetic Product Safety Asses:**

### 1. Assessment conclusion

**Based on the information supplied, the cosmetic product detailed in this report is safe for human health when used in common or reasonably predictable conditions in compliance with the instructions provided for the consumer.**

This conclusion is only applicable to this cosmetic product with the composition, properties, purpose, and method of use of which are detailed in this documentation, and laboratory tests attached to this assessment, including the detailed production and labelling which has been assessed as meeting the requirements of *Cosmetic Regulation* (EC) No. 1223/2009 effective on the date this report was issued.

### 2. Labelled warnings and instructions of use

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19(1)(d) of *Cosmetic Regulation* (EC) No. 1223/2009:

*For external use only. Keep out of reach of children.*

Allergens present in this product and estimated amounts\*:

*Linalol: 0.75%*

\* The presence of these allergens must be indicated in the list of ingredients when their concentration exceeds: 0.001% in leave-on products or 0.01% in rinse-off products. Only the allergen, not the estimated amount, is required on the label.

### 3. Reasoning

Based on the formulation of this cosmetic product, its qualitative and quantitative composition according to its INCI ingredients, basic physical and chemical characteristics and microbiology, Preservation Challenge Test performed, classification of the cosmetic product type, including its purpose and method of application, and available toxicological information and safety sheets of the ingredients used, the cosmetic product safety has been assessed for the consumer by assessing the toxicological profile of all ingredients, their chemical structure, exposure level and Margin of Safety (MoS) depending on the purpose of use in this cosmetic product.

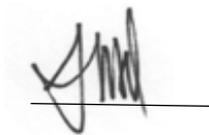
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The evaluation of the entire composition and applied ingredient concentrations indicate that as a whole the composition of this cosmetic product complies with the requirements of *Cosmetic Regulation* (EC) No. 1223/2009 of the European Parliament and of the Council.

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

Safety Assessor: Allison Wild  
Oxford Biosciences Ltd.  
The Oxford Science Park  
Magdalen Centre  
Oxfordshire  
OX4 4GA

#### Experience and qualifications:

- MSc in Clinical Pharmacology, University of Oxford
- 10+ years experience formulating cosmetic products
- Full member of the Society of Cosmetic Scientists (SCS)
- Member of the British Pharmacological Society



*Signature*

19 August 2020

*Date*