

## COSMETIC PRODUCT SAFETY REPORT

**PRODUCT:** Cooling Gel

**DATE:** 16 April 2020

Responsible Person: Holitstic Hemp Scotland Ltd  
**Holitstic Hemp Scotland Ltd**  
Auchentinnny Cairn Road  
Northmuir  
Scotland DD8 4PW



## PART A – Cosmetic Product Safety Information

### 1. Quantitative and qualitative composition

	<b>Ingredient INCI name</b>	<b>CAS</b>	<b>Function</b>	<b>Limits</b>	<b>Amount</b>
1	Aqua	7732-18-5	Solvent		90.50
2	Glycerin	56-81-5	Denaturant, humectant,		4.06
3	Cannabis sativa seed oil	89958-21-4	Emollient, skin conditioning		2.00
4	Xanthan gum	11138-66-2	Binding, emulsifying,		1.00
5	Benzyl alcohol	100-51-6	Perfuming, preservative,	III/45, V/34	0.88
6	Cannabidiol	13956-29-1	Antioxidant,	not in list	0.50
7	Menthol	1490-04-6 / 2216	Denaturant, masking,		0.349
8	Cinnamomum camphora bark oil	92201-50-8 /	Masking, skin conditioning,		0.186
9	Eucalyptus radiata leaf/stem oil	92201-64-4	Masking, perfuming		0.186
10	Mentha arvensis herb oil	90063-97-1	Perfuming		0.186
11	Salicylic acid	69-72-7	Antidandruff, hair	III/98	0.15
12	Lavandula angustifolia oil	8000-28-0 /	Masking, tonic		0.093
13	Sorbic acid	110-44-1	Preservative	V/4	0.04

Allergens present in this product and estimated amounts\*:

Geraniol: 0.002%; d-Limonene: 0.1%; Linalol: 0.04%

\* 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 **Aqua**

Aqua (water) is a liquid at standard temperature and pressure with the chemical formula  $H_2O$ : one molecule of water has two hydrogen atoms covalently bonded to a single oxygen atom.

#### Ref. 1. 2 **Glycerin**

Glycerin, or glycerol, is a simple polyol compound, with three hydroxyl groups, which is a colourless, odourless, viscous liquid. Glycerin is naturally occurring in all animals and plant matter in combined form as glycerides in fats and oils, or, in intracellular spaces, as lipids. The glycerol backbone is central to all triglycerides, and its molecular formula is  $C_3H_8O_3$ . In December 2014 the Cosmetic Ingredient Review (CIR) Expert Panel also noted the high frequency of use that is reported for glycerin and the low instances of reports of toxicity, irritation, and sensitisation and that glycerin is GRAS for food packaging and as a multiple-purpose food substance. When considering the safety of glycerin, the Panel noted that it is naturally occurring in animal and human tissues, including the skin and blood. The data demonstrated low oral and dermal toxicity for multiple animal species and humans, in both acute and long-term studies. The CIR Expert Panel concluded that glycerin is safe in the present practices of use and concentration described in this safety assessment.

#### Ref. 1. 3 **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.

## 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. 1.4 **Xanthan gum**

Xanthan gum is a high molecular weight heteropolysaccharide gum secreted by the bacterium *Xanthomonas campestris*, commonly used as a food additive, rheology modifier, and a stabiliser with the molecular formula  $C_{35}H_{49}O_{29}$ . It is composed of pentasaccharide repeat units, comprising glucose, 6-acetyl mannose, 4,6-pyruvylated mannose and glucuronic acid in the molar ratio 2.0:2.0:1.0. Xanthan gum is produced by a pure culture fermentation of a carbohydrate (glucose, sucrose, or lactose) with *Xanthomonas campestris* and is composed of glucose, glucuronic acid, 6-acetyl mannose and 4,6-pyruvylated mannose residues. After a fermentation period, the polysaccharide is precipitated from a growth medium with isopropyl alcohol, dried, and ground into a fine powder. Xanthan gum has a long history of safe use worldwide. It was approved for use in foods in 1968 and is accepted as a safe food additive in the USA, Canada, and European countries, with the E number E415. In 2016 the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Xanthan gum is safe in the present practices of use and concentration, as described in this safety assessment.

#### Ref. 1.5 **Benzyl alcohol**

Benzyl alcohol is an aromatic alcohol with the formula  $C_7H_8O$ . Benzyl Alcohol is used as a food additive, in OTC drug preparations, and in clinical settings. It is a membrane fluidiser and a local anesthetic. Benzyl alcohol is metabolised to Benzoic acid, which is then conjugated with glycine and excreted as hippuric acid. EPA reviews of mouse and rat oral-dosing studies conducted by the NTP determined subchronic and chronic oral reference doses for humans of 1 and 0.3 mg/kg/day, respectively. The WHO established an ADI of up to 5 mg/kg.

Investigators considered Benzyl alcohol to be a moderate respiratory hazard and toxic when administered by the parenteral route. It produced severe irritation when applied to the skin of nude mice. In clinical settings, Benzyl alcohol can produce nonimmunologic contact urticaria or nonimmunologic immediate contact reactions. It was not a sensitiser when tested in a maximisation test at 10% in petrolatum, and demonstrated a low incidence of sensitisation in provocation studies. Based on the available data, the Cosmetic Ingredient Review (CIR) Expert Panel concluded in 2001, and reconfirmed their conclusion in 2011, that Benzyl alcohol is safe for use in cosmetic formulations at concentrations up to 5% although Cosmetics Europe limits its maximum usage to 1%.

## 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 **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."

#### Ref. 1. 7 **Menthol**

Menthol is an organic compound obtained from corn mint, peppermint or other mint oils. A waxy, crystalline substance, clear or white in color, it is solid at room temperature. The main form of menthol occurring in nature is (-)-menthol. Menthol has local anesthetic and counter-irritant qualities. Molecular formula: C<sub>10</sub>H<sub>20</sub>O

#### Ref. 1. 8 **Cinnamomum camphora bark oil**

Cinnamomum camphora bark oil is the volatile oil expressed from the bark of the Camphor, Cinnamomum camphora (L.), Lauraceae

Cinnamomum camphora (commonly known as Camphor tree, Camphorwood or camphor laurel) is a large evergreen tree native to China south of the Yangtze River, Taiwan, Japan, Korea, and Vietnam. Camphor oil's main constituents are 1,8-cineole, α-pinene, camphene, β-pinene, sabinene, phellandrene, limonene, γ-terpinene, and p-cymene.

#### Ref. 1. 9 **Eucalyptus radiata leaf/stem oil**

Eucalyptus radiata leaf/stem oil is the volatile oil obtained from the leaves and stems of the Eucalyptus, Eucalyptus radiata, Myrtaceae.

#### Ref. 1. 10 **Mentha arvensis herb oil**

Mentha arvensis herb oil is an essential oil obtained from the herbs of the the Horse Mint, Mentha arvensis L., 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. 11 **Salicylic acid**

Salicylic acid is an aromatic monohydroxybenzoic acid (2-hydroxybenzoic acid), a crystalline organic acid that can be derived from salicin (a  $\beta$ -glucoside in willow bark) with the formula  $C_6H_4(OH)COOH$ , where the OH group is ortho to the carboxyl group. Salicylic acid is prohibited in products for children under three years old, unless used in a shampoo.

In 2003 the safety of Salicylic acid was assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated scientific data and concluded that Salicylic acid was safe as used when formulated to avoid skin irritation and when formulated to avoid increasing the skin's sun sensitivity, or, when increased sun sensitivity would be expected, directions for use include the daily use of sun protection.

A Scientific Committee on Consumer Safety (SCCS) 2018 Final Opinion on Salicylic acid supports the Cosmetic Europe's concentration limits in ready-for-use cosmetic preparations of 3% in rinse-off hair products and 2% in other products.

In June 2019 the CIR Expert Panel re-reviewed Salicylic acid and concluded it is safe in cosmetics in the present practices of use and concentration described in the safety assessment, when formulated to be non-irritating and non-sensitising, which may be based on a quantitative risk assessment (QRA).

#### Ref. 1. 12 **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. 13 **Sorbic acid**

Sorbic acid is straight-chain monocarboxylic acid with the molecular formula  $C_6H_8O_2$ . Specifically, Sorbic acid is a hexadienoic acid with double bonds at C-2 and C-4; it has four geometrical isomers, of which the trans,trans-form is naturally occurring. It is a polyunsaturated fatty acid, a medium-chain fatty acid and an alpha,beta-unsaturated monocarboxylic acid, a conjugate acid of a sorbate. Sorbic acid occurs naturally as the lactone, parasorbic acid, in berries of the mountain ash, *Sorbus aucuparia* L., Rosaceae. It can be synthesised by various processes, which include condensation of crotonaldehyde and acetic or malonic acid in pyridine solution, condensation of crotonaldehyde and ketene in the presence of boron trifluoride, preparation from 1,1,3,5-tetraalkoxyhexane, and dealkanolation and hydrolysis of a 3,5-dialkoxyhexanal dialkyl acetal under oxidative conditions. The trans,trans-isomer is usually obtained and is the commercial product. Sorbic acid is also used as a food preservative and has the e number E200. The FDA has conferred Generally Recognised as Safe (GRAS) status to Sorbic acid. In 1988, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Sorbic acid is safe in the present practices of use and concentration described in this safety assessment. In 2008 The CIR Expert Panel reconfirmed the 1988 decision.

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

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

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

<b>Appearance</b>	Cream/Paste/Gel
<b>Colour</b>	Green
<b>Aroma</b>	Floral/sweet
<b>pH</b>	6.0

\*RP: Responsible Person: Holitstic Hemp Scotland Ltd

#### 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 Holitstic Hemp Scotland Ltd confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 Holitstic Hemp Scotland Ltd uses a BBE based on the results of Holitstic Hemp Scotland Ltd's stability testing, including shelf life stability testing.

2.2.3 This product was subjected to Preservative Efficacy Testing and proved that it did not support microbial growth. PET reference: OxBio PET 1642

### 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).

This product was subjected to Preservative Efficacy Testing and proved that it did not support microbial growth. PET reference: OxBio PET 1642

## 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>	Bottle
<b>Container Material</b>	Glass
<b>Airless Container</b>	No

Glass is resilient and resistant to most solvents and represents a low hazard in terms of chemical leaching. Glass can be attacked by weak acids or bases and thus can leach sodium and calcium ions into the cosmetic product.

Holitstic Hemp Scotland Ltd 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:

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

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. Not to be used on children under 3yrs.*

6. Exposure to the cosmetic product

Area of application	Body
Product type: Leave-on or Rinse-off	Leave On
Duration and frequency	2.28
Possible additional routes of exposure	Face
Estimated skin surface area (cm <sup>2</sup> )	15670
Estimated amount of the product applied according to the SCCS (g/day)	7.82 g
Estimated retention factor according to the SCCS	1
Target group	Adult
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	123.2

## 7. Exposure to the ingredients

	Ingredient INCI name	Concentration	SED
1	Aqua	0.90500	111.49600
2	Glycerin	0.04060	5.00192
3	Cannabis sativa seed oil	0.02000	2.46400
4	Xanthan gum	0.01000	1.23200
5	Benzyl alcohol	0.00880	1.08416
6	Cannabidiol	0.00500	0.61600
7	Menthol	0.00349	0.42997
8	Cinnamomum camphora bark oil	0.00186	0.22915
9	Eucalyptus radiata leaf/stem oil	0.00186	0.22915
10	Salicylic acid	0.00150	0.18480
11	Lavandula angustifolia oil	0.00093	0.11458
12	Sorbic acid	0.00040	0.04928
13	Mentha arvensis herb oil	0.00186	0.22915

**SED:** Systemic Exposure Dose

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

	Ingredient INCI name	MOS
1	Aqua	896.89320
2	Glycerin	2519.03270
3	Cannabis sativa seed oil	4058.44160
4	Xanthan gum	36525.97400
5	Benzyl alcohol	1134.51890
6	Cannabidiol	12987.01300
7	Menthol	7395.89920
8	Cinnamomum camphora bark oil	14270.00420
9	Eucalyptus radiata leaf/stem oil	10822.51080
10	Salicylic acid	14069.26410
11	Lavandula angustifolia oil	37093.28310
12	Sorbic acid	149350.64940
13	Mentha arvensis herb oil	5411.25540

*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 800 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 Holitstic Hemp Scotland Ltd 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 Assessment

### 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. Not to be used on children under 3yrs.*

Allergens present in this product and estimated amounts\*:

*Geraniol: 0.002%; d-Limonene: 0.1%; Linalol: 0.04%*

\* 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.

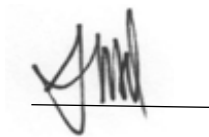
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The 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*

16 April 2020

*Date*