

Colin's Cosmetic Consultancy Ltd
1 Market Square
Petworth
West Sussex
GU28 0AH

Product Safety Assessment

Oatsoak Balm

Rook Stores Ltd

Reference RSL023

Issue 1

Issue Date 04-Apr-23

Oatsoak Balm

Sponsor

Rook Stores Ltd

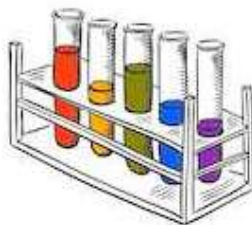
Part A

Section 1 - Quantitative and Qualitative Composition

Ingredient	CAS Number	%w/w
Avena Sativa (Oat) Kernel Oil	84012-26-0	43.011
Helianthus Annuus (Sunflower) Seed Oil	8001-2-6	39.140
Cera Alba (Beeswax)	8006-40-4, 8012-89-3	12.903
Calendula Officinalis Extract	84776-23-8	3.871
Colloidal Oatmeal	n/a	1.075

Quantities below third decimal place not reported on this table, but have been used in calculations later in the report.

Fragrance allergens are quoted as additional items so percentages may not add up to 100.



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Section 2 - Product Characteristics

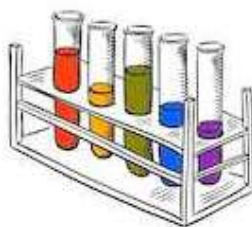
Ingredient List

Avena Sativa (Oat) Kernel Oil, Helianthus Annuus (Sunflower) Seed Oil, Cera Alba (Beeswax), Calendula Officinalis Extract, Colloidal Oatmeal

Frame Formulation Number Skin Care Cream Lotion, Gel 1.2

IFRA Category 3:Products applied to the face/body using fingertips

Adult or Child Adult



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Section 3 - Microbiological Quality

This product is non-aqueous and consequently raises no microbiological issues. The reasoning behind this statement is detailed in ISO 29621 Microbiology -- Guidelines for the risk assessment and identification of microbiologically low-risk products.

Section 4 - Impurities and packaging

This formulation does not contain any ingredients with toxicologically relevant impurities.

There are no known or likely interactions with the pack that have any safety implications.

Section 5 - Normal and Foreseeable Use

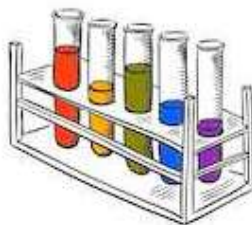
This product is intended for topical application to a limited body area in small quantities.

Section 6 - Exposure

Where Used	This product is applied to the skin		
Estimated Daily Amount Used	7.82 g	Calculated relative daily exposure mg/kg	130
Frequency Of Use	Daily		
Assumed Body Weight	60 Kg		
Rinse Status	Leave On		

Section 7 - Exposure to Ingredients

Ingredient	CAS Number	%w/w	Dose	SED	NOAEL	MoS
Avena Sativa (Oat) Kernel Oil	84012-26-0	43.011	7.820	56.06		



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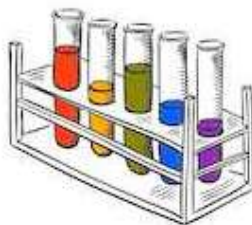
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Helianthus Annuus (Sunflower) Seed Oil	8001-2-6	39.140	7.820	51.01		
Cera Alba (Beeswax)	8006-40-4, 8012- 89-3	12.903	7.820	16.82		
Calendula Officinalis Extract	84776-23-8	3.871	7.820	0.50	1000	1982.1
Colloidal Oatmeal	n/a	1.075	7.820	1.40		

The Margin of Safety (MoS) is calculated by working out the maximum feasible exposure and comparing it to the level at which no adverse effect is observed (the NOAEL). If the MoS is 100 then the use level is one hundredth the level at which any effect is observed. Any level above 100 is considered to be acceptable.



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Section 8 - Toxicological Profile of Ingredients

Avena Sativa (Oat) Kernel Oil

84012-26-0

Avena Sativa Kernel Oil is the fixed oil expressed from the kernels of the Oat, Avena sativa L., Poaceae.

It is listed on the EU's CosIng database without any restrictions on its use.

The cosmetic ingredient review included this oil in its review of fatty acid based triglyceride oils. This report found that these products, all of which have the same basic chemistry, were safe as used in cosmetics.

Given the nature of the oil in question, its lack of permeability coupled with being easily digested no NOAEL is appropriate and a margin of safety calculation is not necessary.

Cosmetic Ingredient Review Final Report Plant-Derived Fatty Acid Oils as Used in Cosmetics March 4, 2011

Calendula Officinalis Extract

84776-23-8

Calendula Officinalis Extract is the extract of the whole plant of the Calendula, Calendula officinalis L., Compositae

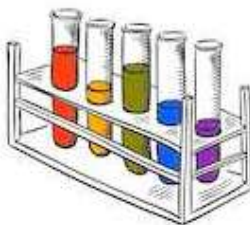
The cosmetic ingredient review has reviewed the scientific data on calendula based ingredients and concluded that they are safe as used in cosmetic ingredients.

In addition to safety data Calendula and its components have been extensively studied for their medical applications without any safety concerns emerging. As an example a study has been carried out indicating a counter irritant effect of calendula in combination with rosemary.

Calendula is permitted as a cosmetic ingredient in the European Union. There is no suitable NOAEL available, but a study has been carried out that titrated up to 1000mg/Kg/day without finding any adverse effects at any dose. This figure has been used to carry out the margin of safety calculation. Since this is acceptable, the true margin must be even more so.

Int J Toxicol. 2010 Nov-Dec;29(6 Suppl):221S-43 Final report of the Cosmetic Ingredient Review Expert Panel amended safety assessment of Calendula officinalis-derived cosmetic ingredients Andersen FA, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW.

Skin Pharmacol Physiol. 2005 Jul-Aug;18(4):195-200. Protective effects of different marigold (Calendula officinalis L.) and rosemary cream preparations against sodium-lauryl-sulfate-induced irritant contact dermatitis. Fuchs SM, Schliemann-Willers S, Fischer TW, Elsner P.



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Cera Alba (Beeswax)

8006-40-4, 8012-89-3

Beeswax has a very long history of use in cosmetics, pharmaceuticals and in many other traditional applications. There are no toxicity issues associated with it. The FDA recognise it as Generally Recognised as Safe (GRAS).

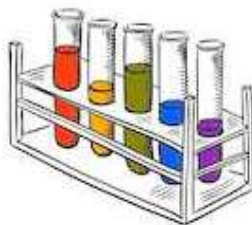
The nature of beeswax is such that it is extremely unlikely to penetrate the skin nor to cause a significant number of allergic reactions.

The CIR Expert Panel reviewed the safety data on Beeswax finding it produced no toxicity in acute or subchronic studies. It was not mutagenic when tested. In skin irritation tests, products containing it caused no irritation. When tested alone Beeswax was not irritating to the eyes. In clinical studies, products containing Beeswax were practically nonirritating in 21-day cumulative patch tests, and repeat insult patch tests. No phototoxicity of a product containing 10% Beeswax was seen. Additionally, a product containing 4% Beeswax was not sensitizing to the skin.

There are no restrictions on its use in topical products in either cosmetic or pharmaceutical regulations. There are no direct toxicity issues related to it and there is no reason to suppose that this ingredient poses any risk of any kind.

A pharmaceutical grade is used to ensure impurities are controlled at an acceptable level.

JACT 3(3):1-41, 1984 Final Report on Safety of Beeswax confirmed 06/03 IJT 24(S1):48-52, 200



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Colloidal Oatmeal

n/a

Naturally occurring substances oatmeal obtained from the Oat, *Avena sativa* L., Poaceae,

It is listed on the EU's CosIng database without any restrictions on its use.

In irritation tests using 2 to 200 % colloidal extracts of oats, no ocular or cutaneous toxicity were observed, nor any sensitization or photosensitization (Fabre 2004). Its anti-itch effects have been investigated with positive results.

This is an aqueous extract of an edible plant that is generally recognised as safe. It is present at a vanishingly low level in the formulation. It has therefore no toxicological significance and does not need to be considered in assessment of the overall safety of the formulation.

Ema.Europa.Eu, 2020, https://www.ema.europa.eu/en/documents/herbal-references/list-references-supporting-assessment-report-avenae-herba-avenae-fructus-avena-sativa-l-oat-herb-oat_en.pdf. Accessed 30 Aug 2020.

KA, Reynertson et al. "Anti-Inflammatory Activities Of Colloidal Oatmeal (*Avena Sativa*) Contribute To The Effectiveness Of Oats In Treatment Of Itch Associated With Dry, Irritated Skin". *Journal Of Drugs In Dermatology : JDD*, vol 14, no. 1, 2015, p. ., <https://pubmed.ncbi.nlm.nih.gov/25607907/>. Accessed 30 Aug 2020.

Helianthus Annuus (Sunflower) Seed Oil

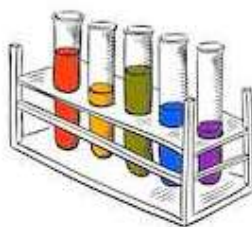
8001-2-6

Helianthus Annuus Seed Oil is the oil expressed from the seeds of the Sunflower, *Helianthus annuus* L., Compositae

The cosmetic ingredient review included this oil in its review of fatty acid based triglyceride oils. This report found that these products, all of which have the same basic chemistry, were safe as used in cosmetics.

Given the nature of the oil in question, its lack of permeability coupled with being easily digested no NOAEL is appropriate and a margin of safety calculation is not necessary.

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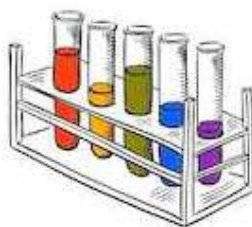
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Section 9 - Undesirable Effects

No undesirable effects are foreseen with this product when used under conditions of normal and foreseeable use.



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Part B

Section 1- Assessment Conclusion

This product has been assessed and found to comply with the requirements of current EU,UK and US cosmetic regulations. The ingredients selected have been reviewed and are used at levels suitable to ensure that the end user will experience the level of safety they can reasonably expect for this kind of product when used in accordance with the manufacturers instructions, and when manufactured following a suitable cosmetic GMP procedure.

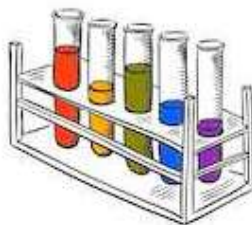
Section 2- Labels and Warnings

This product does not require any specific warnings over and above those customary in this category.

Period After Opening 12 Months

Section 3- Reasoning

This is a standard product using conventional ingredients at normal levels. This category of products has a good track record of safe use and so can be presumed to be safe under normal and foreseeable conditions of use. Interactions between ingredients are unlikely to be problematic in this kind of product.



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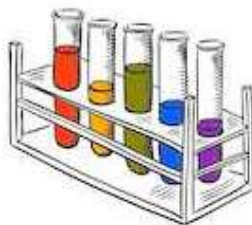
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Signed

Colin Sanders

A handwritten signature in cursive script that reads "Colin Sanders".

12/04/2023



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Appendix - Credentials of Assessor

Colin Sanders Bsc(Hons) FRSB Dip SCS
Date of Birth 19.5.1960

Academic Qualifications

Bachelor of Science in Environmental Science from Leicester Polytechnic, lower second with honours awarded in 1983.

Diploma in Cosmetic Science awarded by the Society of Cosmetic Science awarded in 1985

Membership of Professional Bodies

Society of Cosmetic Scientists

Fellow of the Royal Society of Biology

Experience

Development Chemist at Intergen Cosmetics 1983-1987

Quality Assurance W.M.Stills 1987-1990

Formulation Scientist/Formulation Laboratory Manager Stiefel Laboratories 1990-2004

Head of Product Formulation Medex/Montagne Jeunesse 2004-2013

Managing Director Colin's Cosmetic Consultancy 2013-