

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

Cosmetic Product Safety Report (CPSR)

OatSoak Body Butter

Sponsor Rook Stores

Reference RSL059
Issue 1
Issue Date 03-Oct-25

OatSoak Body Butter

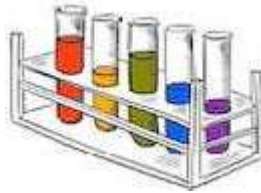
Part A

Section 1 - Quantitative and Qualitative Composition

Ingredient	CAS Number	%w/w
Butyrospermum Parkii (Shea) Butter	91080-23-8	71.000
Avena Sativa Kernel Oil	84012-26-0	29.000

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

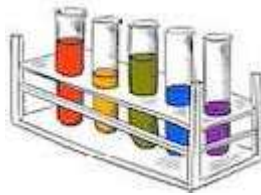
Ingredient List

Butyrospermum Parkii (Shea) Butter, Avena Sativa Kernel Oil

Frame Formulation Number Skin Care Cream Lotion, Gel 1.2

IFRA Category 5A:Body lotion products applied to the body using the hands (palms), primarily leave on

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 7.82g **Calculated relative daily exposure mg/kg** 130

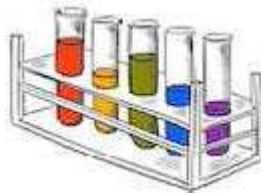
Frequency Of Use Daily

Assumed Body Weight 60 Kg

Rinse Status Leave On

Section 7 - Exposure to Ingredients

Ingredient	CAS Number	%w/w	Dose	SED	NOAEL	MoS
Butyrospermum Parkii (Shea) Butter	91080-23-8	71.000	7.820	0.93	2000	2161.31



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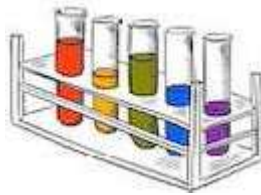
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Avena Sativa	84012-26-0	29.000	7.820	37.80
Kernel Oil				

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 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.

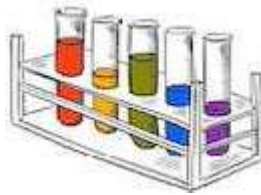
It has been registered with ECHA under the REACH regulations.

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

Becker LC, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW, Gill LJ, Heldreth B. Safety Assessment of *Avena sativa* (Oat)-Derived Ingredients As Used in Cosmetics. Int J Toxicol. 2019 Nov/Dec;38(3_suppl):23S-47S. doi: 10.1177/1091581819889904. PMID: 31840550.



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Butyrospermum Parkii (Shea) Butter

91080-23-8

Butyrospermum Parkii (Shea) Butter, usually called simply Shea Butter is derived from the shea tree, *Butyrospermum parkii*, also called *Vitellaria paradoxa*. Shea Butter and the other ingredients made from the shea tree are used in many types of cosmetics and personal care products including bath products, cleansing products, eye makeup, lotions and creams, suntan products, lipstick and hair care products. In the parts of Africa where the shea tree is native, shea butter is used in cooking.

The Food and Drug Administration (FDA) includes sheanut oil on its list of direct food substances affirmed as Generally Recognized As Safe (GRAS).

The safety of *Butyrospermum Parkii (Shea) Butter* has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated scientific data and concluded that these ingredients were safe for use as ingredients in cosmetics and personal care products

As with all natural products, some people are allergic to shea butter. Tree nuts including the nuts from the shea tree from which shea butter is derived do illicit an above average level of allergies compared to natural products in general. Shea butter containing products should warn about this if they are also claiming to be particularly suitable for people with sensitive skin.

EU regulations do not limit the use of shea butter in any way.

As a foodstuff and a product that is generally regarded as safe, shea butter has never been studied in such a way that an NOAEL level can be meaningfully calculated, but its very extensive culinary use as well as its wide use in cosmetics indicate that were such a value to be determined it would be a high one and the substance's toxicity raises no concerns.

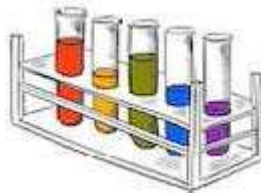
The cosmetic ingredient review included this oil in its review of fatty acid based triglyceride oils. This report found that these products, all of which have the same basic chemistry, were safe as used in cosmetics.

A proxy for a margin of safety calculation is a study carried out on chemically analogous triglycerides.

Studies on oral repeated dose toxicity were available for the following Category members (CAS No.): 73398-61-5, 8001-79-4, 91845 -19-1 and for medium- and long-chain triglyceride mixtures.

All available studies resulted in oral NOAELs of 1000 mg/kg bw/d or greater than 1000 mg/kg bw/d.

Studies on dermal repeated dose toxicity were available for the following Category member (CAS No.): 73398-61-5.



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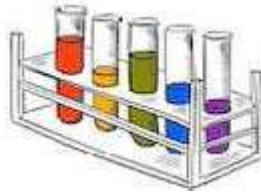
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A subacute (28 days) dermal NOAEL of 2000 mg/kg bw/d for rabbits was reported.
Using this last figure gives a very adequate margin of safety.
Cosmetic Ingredient Review Final Report Plant-Derived Fatty Acid Oils as Used in Cosmetics March 4, 2011
"Registration Dossier - ECHA". Echa.Europa.Eu, 2023, <https://echa.europa.eu/mt/registration-dossier/-/registered-dossier/6068/7/6/1>. Accessed 3 Aug 2023.



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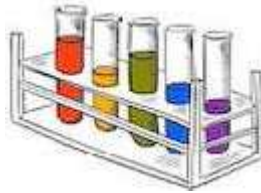
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Section 9 - Undesirable Effects

No undesirable effects have been reported nor are any foreseen with this product when used under conditions of normal and foreseeable use. Any reports received will be reviewed and kept on file for future reference.



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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.

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.

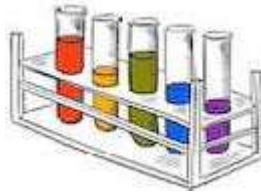
Section 2- Labels and Warnings

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. There is no indication that the product's stability has any impact on its safety.



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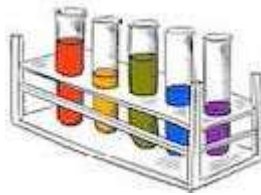
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Signed

Colin Sanders

25/10/2025



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Appendix - Credentials of Assessor

Colin Sanders Bsc(Hons) FRSB Cbiol 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

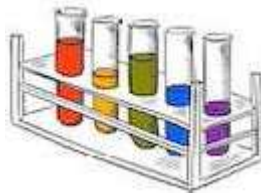
Membership of Professional Bodies

Society of Cosmetic Scientists

Chartered Biologist and 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-



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