Cosmetic Product Safety Report

Conforming to

REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on COSMETIC PRODUCTS and SCHEDULE 34 OF THE PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

By Cosmetic Safety Solutions Ltd on behalf of the named manufacturer below

CSS Reference	ED070323HHCPCPSR
Product reference	Honey and Hemp Shampoo Bar
Product category	Solid cold process soap - rinse off product
Responsible person	EU: Angelina de Jesus Rocha Soares Bairro Sra da Graca porta 16, Roussas-Melgaco 4960-581 Portugal UK: Sandra Estefania Dogan 5 Oxford Road, Southsea, PO51NP Portsmouth

Report content

Report Validity Conditions

Report Part A

1. Quantitative formulation, concentration ranges (CPNP) and Margin of Safety summaries
2. Final Product characteristics (including stability, microbiology etc.)
3. Packaging
4. Warnings
5. Normal and reasonably foreseeable use
6. Target Population
7. Undesirable effects and serious undesirable effects
8. Information on the cosmetic product / Proof of effects
9. Product and substance exposure characteristics
10. Ingredient toxicity profiles and MOS calculations

Report Part B

1. Assessment Conclusion
2. Labelled Warnings and Instructions for Use
3. Reasoning
4. Assessor's credentials and approval of part B

Report Validity Conditions

This Safety Assessment Report is valid only for the named responsible person and is not transferable to any other party without prior written agreement from Cosmetic Safety Solutions Ltd.

Cosmetic Safety Solutions ltd. and its directors will accept no liability for the misuse of this document or for any cosmetic product formulated outside the remit of this document; this includes, but is not limited to 'cupcake' type soaps or any product which may be mistaken for food and is subsequently in violation the European food imitation regulations.

All manufacture must comply with appropriate standards of Good Manufacturing Practice as detailed in REGULATION (EC) No 1223/2009

All raw material specifications and finished product specifications must comply with any restrictions (purity etc.) detailed in REGULATION (EC) No 1223/2009

Any deviation from the prescribed formulation and list of permitted ingredients is NOT covered by this safety report.

MSDS sheets for all materials used must be included by the manufacturer as part of Safety Report Part A – additional information on raw materials (Identification and function) - http://ec.europa.eu/consumers/cosmetics/cosing/

Safety Report Part A

1. Quantitative formulation, concentration ranges (CPNP) and Margin of Safety summaries

Concentration ranges (CPNP):

A	>75% - ≤100%
B	>50% - ≤75%
C	>25% - ≤50%
D	>10% - ≤25%
E	>5% - ≤10%
F	>1% - ≤5%
G	>0.1% - ≤1%
H	≤0.1%

Cosmetic Safety Solutions Ltd confirms that Sodium Hydroxide (lye) is completely neutralized in the provided formulation below (minimum 3% superfatting discount).

INCI names for saponified oils are used when these exist - where INCI names have not yet been registered, the names given follow the rules of nomenclature used in INCI name derivation.

For details of initial formulations please see attached Annex 1 - ED070323SOAP.

INCI	Weight, %	Concentration Range (CPNP)	MOS Summary†
Sodium Olivate	36.22	C	>100
Sodium Cocoate	17.70	D	>100
Sodium Hempseedate	10.70	D	>100
Sodium Castorate	4.53	F	>100
Sodium Jojobate	11.52	D	>100
Aqua	8.07	E	>100
Glycerin	8.13	E	>100
Mel	0.82	G	>100
Mentha Piperita Oil	2.30	F	>100

† See Section 10 for detailed information

2. Final product characteristics

Physical and Chemical Properties:
Solid soap with fragrance characteristic of essential oils used.
pH – expected range 9.5-10.5 for soaps.

Raw Materials:
Please refer to supplier MSDS and CoA information which should be used in conjunction with this report.

Stability and Reactivity:
The product is expected to be nominally stable at ambient storage conditions – to be confirmed by manufacturer based on observation of previous products made.

Ingredient Purity:
Approved cosmetic, pharmaceutical or food grade ingredients are used. Where specific purity criteria (e.g. secondary amine content, heavy metals content) apply (as detailed in Ingredient toxicity profiles and MOS calculations section) these remain the responsibility of the responsible person.

Microbiological Purity:
Product does not support microbial growth under normal storage conditions due to elevated pH and limited water availability (osmotic potential).

The product is not specifically marketed as a product for use by children under 3 years, in the eye area and on mucous membranes, therefore it is classified as a Category 2 product: "Other products".
For cosmetics classified as Category 2, the total viable count for aerobic mesophilic microorganisms (bacteria plus yeast and mould) should not exceed 10^3 CFU per g or ml of product (CFU - colony forming unit).
Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus and *Candida albicans* are considered the main potential pathogens in cosmetic products. These specific potential pathogens must not be detectable in 1 g or ml of a cosmetic product.

3. Packaging

No specific requirements (e.g. absence of nitrosating agents). Cosmetic / food grade packaging materials must be used.

4. Warnings

No specific warnings required other than standard product usage instructions – for external use only – avoid direct eye contact – not for application to the mucous membranes or on broken skin. If irritation occurs discontinue use.

5. Normal and reasonably foreseeable use

The product is intended for use as a solid hair shampoo for topical application. Rinse off product.

The product is intended for external use only and is not marketed for infant use, or for application to mucous membranes, broken skin or the eye area.

6. Target Population

Marketed as products for general population – not specifically marketed for infant use.

7. Undesirable effects and serious undesirable effects

None declared at the time of preparation of this document – a separate file must be made to record any declared incidences of undesirable effects – any serious undesirable effects must be notified to the competent authority and or local poison control agency.

8. Information on the cosmetic product / Proof of effects

No specific medicinal claims are made. All constituents have been used widely in cosmetic preparations – no newly introduced or novel ingredients are used.

9. Product and Substance exposure characteristics

Exposure is by dermal absorption only under foreseeable conditions of use – a retention factor of 1 % has been used for all ingredients (rinse off products) and calculations are based on typical exposure values (RIVM report 320104001/2006 Cosmetics Fact Sheet. H.J. Bremmer, L.C.H. Prud'homme de Lodder, J.G.M. van Engelen).

	Shampoo Maximum amount per application / g	Potential frequency of application	g / day applied	Retention factor	g / day exposure	Surface area cm^2	Systemic Exposure Dose (SED) mg/kgbw/day (based on 60 kg avg.)	Specific Exposure mg/cm^2
CPNP Concentration Ranges	20.0	1	20.0	1 %	0.20	1440	3.333	0.1389
A – >75% - ≤100%	20.000	1	20.000	1 %	0.20000	1440	3.333	0.1389
B – >50% - ≤75%	15.000	1	15.000	1 %	0.15000	1440	2.500	0.1042
C – >25% - ≤50%	10.000	1	10.000	1 %	0.10000	1440	1.667	0.0694
D – >10% - ≤25%	5.000	1	5.000	1 %	0.05000	1440	0.833	0.0347
E – >5% - ≤10%	2.000	1	2.000	1 %	0.02000	1440	0.333	0.0139
F – >1% - ≤5%	1.000	1	1.000	1 %	0.01000	1440	0.167	0.0069
G – >0.1% - ≤1%	0.200	1	0.200	1 %	0.00200	1440	0.033	0.0014
H – ≤0.1%	0.020	1	0.020	1 %	0.00020	1440	0.003	0.0001

10. Ingredient toxicity profiles and MOS calculations based on maximum percentages

See attached Annex 2 - ED070323SOAP

Safety Report Part B

CSS Reference	ED070323HHCPCPSR
Product reference	Honey and Hemp Shampoo Bar
Product category	Solid cold process soap - rinse off product
Responsible person	EU: Angelina de Jesus Rocha Soares Bairro Sra da Graca porta 16, Roussas-Melgaco 4960-581 Portugal UK: Sandra Estefania Dogan 5 Oxford Road, Southsea, PO51NP Portsmouth

1. Assessment Conclusion

This product meets the criteria for safety specified by the requirements of Article 3 of REGULATION (EC) No 1223/2009 and SCHEDULE 34 OF THE PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019.

2. Labelled Warnings and Instructions for Use

No specific warnings required other than standard product usage instructions – for external use only – avoid direct eye contact – not for application to the mucous membranes or on broken skin. If irritation occurs discontinue use.
No other specific instructions for use are prescribed.

Allergen declaration
In a rinse off product, any of the 26 allergens detailed in the European Commission Directive **2003/15/EC,** that are present in the final product at a concentration greater than or equal to 0.01% must be declared on the product labelling.

3. Reasoning

Appropriate data were available for all components and a full review of this information has been made. The following information was reviewed as a minimum requirement.

Relating to the final product:
Physical and chemical properties;
Stability and reactivity;
Microbiological purity;
Packaging;
Normal and reasonably foreseeable use;
Target population.

And specifically:
The general toxicological profile of each ingredient used;
The chemical structure of each ingredient;
The level of exposure of each ingredient;
The specific exposure characteristics of the areas on which the cosmetic product will be applied;
The specific exposure characteristics of the class of individuals for whom the cosmetic product is intended.

Margins of safety have been calculated for all components, with additional safety factors applied where appropriate due to the use of data from structurally related compounds.
CALCULATION OF THE MARGIN OF SAFETY
Maximum amount of ingredient applied (mg) **I**
Typical body weight (bw) of human (kg) **60**
Maximum absorption through the skin (%) **A**
Systemic Exposure Dose (mg/kgbw) SED = **I x A / 60**
Margin of Safety **NOAEL / SED**
Where NOAEL equals no observed adverse effect level in mg/kgbw from appropriate repeated dose studies.
MOS values for all toxicologically significant components (other than those whose presence is governed / prescribed specifically by the Annexes of Regulation (EC) No 1223/2009) have been calculated and are satisfactory (MOS >100).

Local toxicity – phototoxic materials are not included in this formulation at levels of concern.
CMRs – not included in this formulation.
Nano materials – not included in this formulation.

Dermal irritants / sensitizers – no significant exposure. Compatibility testing is generally advised if the product formulation uses ingredients at concentrations significantly greater than in previously well tolerated formulations. This formulation is very similar to other formulations that have been marketed previously, over a number of years without report of adverse reaction.

Interaction of substances

No significant interactions expected, based on a review of the chemical properties of the species included in this formulation. There are no components present that are likely to undergo spontaneous reaction – no species are present that have structural alerts with regard to carcinogenic activity.

4. Assessor's credentials and approval of part B

Approved - This product meets the criteria for safety specified by the requirements of Article 3 of REGULATION (EC) No 1223/2009 and SCHEDULE 34 OF THE PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019.

07/03/2023

 Joanne Priestley CBiol MRSB Managing Director, Safety Assessor ☒	 Simas Kazlauskas CBiol MRSB Safety Assessor ☒

On behalf of Cosmetic Safety Solutions Ltd, Reg. 13922324 DL14 6HE, England

Cosmetic Safety Solutions Ltd.

Westlea Avenue Bishop Auckland, DL14 6HE, England

Safety Assessor Information

Joanne Priestley CBiol MRSB Bsc (Hons)

Email info@cosmeticsafetyassessment.com

- Qualifications

BSc (Hons) 1st Class (Biological Science)
Chartered Biologist (CBiol)
Full member of the Royal Society of Biology (MRSB)

- Experience

11 years in cosmetic product safety, of which cosmetic toxicology forms at least 8 years.
3 years in cardiovascular research and delivery of physiology seminars to undergraduates.

Simas Kazlauskas CBiol MRSB

Email lietuva@cosmeticsafetyassessment.com

- Qualifications

Bachelor's degree in Biochemistry (Vilnius University)
Master's degree in Biochemistry (Vilnius University)
Chartered Biologist (CBiol)
Full member of the Royal Society of Biology (MRSB)

- Experience

5+ years in cosmetic product safety and cosmetic toxicology.
3 years in applied enzymology (lipase) research.

Royal Society of Biology

This is to certify that

Joanne Priestley

has been admitted as a

Chartered Biologist

by resolution of the Council

Membership Number P0115871
Election Date 2 July 2015

Dr Mark Downs CSci FRSB
Chief Executive

Incorporated by Royal Charter
Registered Charity No: 277981

Royal Society of Biology

This is to certify that

Simas Kazlauskas

has been admitted as a

Chartered Biologist

by resolution of the Council

Membership Number P0130074
Election Date 6 April 2018

Dr Mark Downs CSci FRSB
Chief Executive

Incorporated by Royal Charter
Registered Charity No: 277981