Cosmetic Safety Solutions Ltd

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

Report reference	SC180724LBCPSR
Product name	Lip Balm
Product category	Cosmetic balm - leave on product
Responsible person	Stacey Charles Mill Farm, Trelleck Grange Chepstow, NP16 6QN United Kingdom

Report Contents

Report Validity Conditions

This Cosmetic Product Safety Report is valid only for the named responsible person/manufacturer 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 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.

Material Safety Data Sheets (MSDS) for all materials used must be included by the responsible person/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 and qualitative formulation, concentration ranges, toxicity classes and Margin of Safety summaries

Concentration ranges:

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%

INCI	Weight, %	Concentration Range	Toxicity Class †	MOS Summary
Orbignya Oleifera Seed Oil	44.40	C	A	>100
Carthamus Tinctorius Seed Oil	39.96	C	A	>100
Cera Alba	14.21	D	A	>100
Tocopherol	0.99	G	B	>100
Helianthus Annuus Seed Oil	0.43	G	A	>100

† See Section 10 for detailed toxicity class information

2. Final product characteristics

Physical and Chemical Properties:
Semi-solid balm, natural beige/off-white colour, unscented.

Raw Materials and Ingredient Purity:
Raw materials used are acquired from approved cosmetic, pharmaceutical or food grade ingredient suppliers. Please refer to relevant Material Safety Data Sheets and Certificates of Analysis which are held by the responsible person / manufacturer and should be used in conjunction with this document as per Report Validity Conditions.
Significant amounts of heavy metal impurities in raw materials are not expected. The use of heavy metals in cosmetic products is prohibited, however it is acknowledged that heavy metal impurities in certain raw materials are unavoidable due to the ubiquitous nature of these elements. Heavy metals in raw materials are removed wherever technically feasible.
According to Health Canada 2012, heavy metal impurity concentrations in cosmetic products

are seen to be technically avoidable when they exceed the following limits:
Antimony: 5 ppm, Arsenic: 3 ppm, Cadmium: 3 ppm, Lead: 10 ppm, Mercury: 1 ppm.
Where other specific purity criteria apply these remain the responsibility of the responsible person / manufacturer.

Stability and Reactivity:
Due to the single phase nature of the product, it is expected to be nominally stable at ambient storage conditions. To be confirmed by responsible person / manufacturer based on observation of previous products made.

Microbiological Purity:
The product is anhydrous and does not support microbial growth under normal storage conditions.

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

Cosmetic or food grade packaging materials must be used. Examples of suitable packaging materials include cardboard, glass, aluminium, inert plastics or similar. Migration of substance from packaging to product to any toxicologically significant degree is not expected.

4. Warnings

No specific labelled warnings are 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 moisturising / skin conditioning lip balm for topical application. Leave on 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 and ingestion under foreseeable conditions of use – a retention factor of 100 % has been used for all ingredients (leave on 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).

	Lip products (lipstick, lip salve, lip balm) 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
Concentration Ranges	0.01	4	0.04	100 %	0.04	4.8	0.667	8.3333
A – >75% - ≤100%	0.0100	4	0.0400	100 %	0.0400	4.8	0.6667	8.3333
B – >50% - ≤75%	0.0075	4	0.0300	100 %	0.0300	4.8	0.5000	6.2500
C – >25% - ≤50%	0.0050	4	0.0200	100 %	0.0200	4.8	0.3333	4.1667
D – >10% - ≤25%	0.0025	4	0.0100	100 %	0.0100	4.8	0.1667	2.0833
E – >5% - ≤10%	0.0010	4	0.0040	100 %	0.0040	4.8	0.0667	0.8333
F – >1% - ≤5%	0.0005	4	0.0020	100 %	0.0020	4.8	0.0333	0.4167
G – >0.1% - ≤1%	0.0001	4	0.0004	100 %	0.0004	4.8	0.0067	0.0833
H – ≤0.1%	0.0000	4	0.0000	100 %	0.0000	4.8	0.0007	0.0083

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

External reference for MOS summary and toxicological data (for Competent Authorities only. More information available upon request):
http://cosmetic-compliance.co.uk/web_documents/grainger_100713_toxicology_and_mos_data.xlsx

Ingredient Toxicity profile
Substance classification of toxicological significance

A Low or limited toxicological significance – edible and inert ingredients with NOAEL values of >1000 mg kg $bw^{-1}d^{-1}$ or non-determined due to no toxicological concerns. Cramer class I – no structural alerts – no determined CMR activity.
Examples – edible and/or plant-derived fixed oils and fats, water, bulking minerals, saponified oils and fats, BP grade mineral oils.
MOS >100

B Limited toxicological significance – functional components with determined NOAEL values 100-500 mg kg $bw^{-1}d^{-1}$. Cramer Class I / Cramer class II – no structural alerts - no determined CMR activity.
Examples – surfactants, emulsifiers, conditioning agents.
SED <1 – 5 mg kg $bw^{-1}d^{-1}$ = MOS >100

C Moderate toxicological significance – active components with determined NOAEL values 50-100 mg kg $bw^{-1}d^{-1}$. Cramer Class I / Cramer class II – potential structural alerts – no determined CMR activity at concentrations used in formulation.
Examples – essential oils* and fragrance ingredients, plant extracts‡.
SED <0.5 – 1.0 mg kg $bw^{-1}d^{-1}$ = MOS >100

* - Absence of Cramer class III components (e.g. Methyleugenol, safrole, estragole).
‡ - Absence of Cramer class III components (e.g. Pyrrolizidine alkaloids).

D High toxicological significance – active components with determined NOAEL Values <50 mg kg $bw^{-1}d^{-1}$. Cramer class II / Cramer class III – structural alerts – potential CMR activity.
Examples – active ingredients with presence of restricted components (Rose essential oil, Basil essential oil, Comfrey extract, Peptides, skin lightening, some anti-wrinkle actives).
MOS to be detailed specifically on report.

Threshold of Toxicological Concern (TTC):
Human exposure thresholds of 1800, 540, and 90 μg/person/d (corresponding to 30, 9, and 1.5 μg/kg bw/d) were proposed for Cramer Class I, II and III, respectively, using the 5th percentile value of distribution of NOELs for each class of chemicals, a body weight of 60 kg, and a safety factor of 100 (Munro *et al*., 1996). When organophosphates were excluded from Class III, the human exposure threshold increased to 180 μg/person/d (3.0 μg/kg bw/d; Munro *et al*., 2008). Due to high potential toxicity, a specific TTC of 18 μg/person/d may be applicable for organophosphates.
SCCP/1171/08 Scientific Committee on Consumer Safety (SCCS) Scientific Committee on Health and Environmental Risks (SCHER) Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) OPINION ON Use of the Threshold of Toxicological Concern (TTC) Approach for Human Safety Assessment of Chemical Substances with focus on Cosmetics and Consumer Products

Safety Report Part B

Report reference	SC180724LBCPSR
Product name	Lip Balm
Product category	Cosmetic balm - leave on product
Responsible person	Stacey Charles Mill Farm, Trelleck Grange Chepstow, NP16 6QN United Kingdom

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 leave on product, allergens that are present in the final product at a concentration greater than or equal to 0.001% 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.

18/07/2024

 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.

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Joanne Priestley CBiol MRSB BSc (Hons)

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- Qualifications

BSc (Hons) 1st Class (Biological Science)
Chartered Biologist (CBiol)
Full member of the Royal Society of Biology (MRSB)
Member of the British Toxicological Society
Irish National Framework of Qualifications (NFQ) Award Type/Level Batchelor's Honours Degree Level 8 - NARIC Ireland

- Relevant Experience

2022 to date Managing Director and Cosmetic Safety Assessor at Cosmetic Safety Solutions Ltd.
Ongoing participation in industry, CTPA, RSB and the BTS events to ensure continued professional development. Continued research into the toxicological profile of cosmetic ingredients and using this knowledge in various exposure scenarios to confirm cosmetic safety.

2012–2022 Safety Assessor and Partner in Cosmetic Safety Consultants Ltd.
Responsible for the preparation of CPSRs in line with the above. I was also responsible for mentoring a recently recruited trainee safety assessor. This included the requirements of safety assessments including the principles of quantitative risk assessment (QRA), the use of new approach methodologies (NAMs) as well as guidance in appropriate literature sources and their interpretation. As part of this mentoring, we touched upon the toxicity of many agents such as plant actives, pesticides, metals and potential contaminants present in specific cosmetic ingredients.

2010–2012 Trainee Cosmetic Product Safety Assessor with Cosmetic Safety Consultants Ltd.
Undergoing training to become a Cosmetic Product Safety Assessor. During this period, I trained under Scott Grainger (CChem) to develop my skills in the preparation of CPSRs. This included research into the toxicological profile of cosmetic ingredients and using this knowledge in various exposure scenarios to confirm cosmetic safety. This also involved interpretation of stability testing, microbiological testing and any additional detail required to support specific cosmetic claims which may pertain to the product in question.

Pre 2010 Cardiovascular Research Scientist
Cardiovascular Research Lab. University of Sunderland. Working on a number of areas including the putative effects of endocannabinoids in the mediation of hypertension and the effect of terfenadine and astemizole in the cardiac arrhythmias. During this time, I was involved in the publication of several scientific papers and defended them at conference. I was also responsible for the delivery of pharmacology and molecular biology seminars to pharmacy and pharmacology undergraduate students as well as the day-to-day supervision of students in the lab environment.

Simas Kazlauskas CBiol MRSB

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- Qualifications

2014-2016	Vilnius University, Faculty of Chemistry, Acquired Master's degree in Biochemistry.
2010-2014	Vilnius University, Faculty of Chemistry. Acquired Bachelor's degree in Biochemistry.

- Relevant Experience

2022 to date	Cosmetic product safety assessor at Cosmetic Safety Solutions Ltd.
2020-2022	Cosmetic product safety assessor at Cosmetic Safety Consultants Ltd.
2015-2020	Safety Assessment Consultant at Cosmetic Safety Consultants Ltd. Duties included compiling cosmetic product safety reports according to the requirements of EU Regulation (EC) No. 1223/2009, researching toxicity of cosmetic ingredients, calculating exposure scenarios, and conducting toxicological risk assessments for cosmetic products. During this period underwent training as a safety assessor under the guidance of Scott Grainger MSc BSc (Hons) CSci CChem MRSC.
2014-2015	Biochemist-analyst at UAB Uoga Uoga. Duties included close liaison with all departments of the company and ensuring the cosmetic products manufactured by the company meet all regulatory, stability and safety requirements.
2013	Participation in project "Promotion of Students' Scientific Activities" at Vilnius University, Department of Biochemistry and Molecular Biology.

- Achievements

2018 to date	Chartered Biologist (CBiol).
2018 to date	Participation in the Royal Society of Biology's Continuing Professional Development (CPD) scheme.
2017 to date	Member of the Royal Society of Biology (MRSB)