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	HL030523GBCPSR
Product line	Glitter Balm
Product variants	Variant 1 Variant 2 Variant 3 Variant 4 Variant 5 Variant 6 Variant 7
Product category	Cosmetic balm to be used as a facial make-up / decoration - leave on product
Responsible person	Himpe Lois Burgemeester G Dussartlaan 52 8860 Lendelede Belgium

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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 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 formulations, 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%

Product Formulations:

Variant 1

INCI	Weight, %	Concentration Range (CPNP)	MOS Summary†
Cera Alba	11.61	D	>100
Cocos Nucifera Oil	21.28	D	>100
Simmondsia Chinensis Seed Oil	13.54	D	>100
Prunus Armeniaca Kernel Oil	13.54	D	>100
Glycerin	7.74	E	>100
Lavandula Hybrida Oil	1.35	F	>100
Cosmetic Glitter COSM-3 PU (Sigmund Lindner GmbH) 56K-3 purple (Polyethylene Terephthalate, Polyurethane-11, CI 77000, 15850, 77510)	30.95	C	>100

Variant 2

INCI	Weight, %	Concentration Range (CPNP)	MOS Summary†
Cera Alba	11.61	D	>100
Cocos Nucifera Oil	21.28	D	>100
Simmondsia Chinensis Seed Oil	13.54	D	>100
Prunus Armeniaca Kernel Oil	13.54	D	>100
Glycerin	7.74	E	>100
Lavandula Hybrida Oil	1.35	F	>100
Cosmetic Glitter COSM-3 PU (Sigmund Lindner GmbH) 62K-3 light blue (Polyethylene Terephthalate, Polyurethane-11, CI 77000, 19140, 77510)	30.95	C	>100

Variant 3

INCI	Weight, %	Concentration Range (CPNP)	MOS Summary†
Cera Alba	11.61	D	>100
Cocos Nucifera Oil	21.28	D	>100
Simmondsia Chinensis Seed Oil	13.54	D	>100
Prunus Armeniaca Kernel Oil	13.54	D	>100
Glycerin	7.74	E	>100
Lavandula Hybrida Oil	1.35	F	>100
Cosmetic Glitter COSM-3 PU (Sigmund Lindner GmbH) 57K-3 fuchsia (Polyethylene Terephthalate, Polyurethane-11, CI 77000, 15850, 19140, 77510)	30.95	C	>100

Variant 4

INCI	Weight, %	Concentration Range (CPNP)	MOS Summary†
Cera Alba	11.61	D	>100
Cocos Nucifera Oil	21.28	D	>100
Simmondsia Chinensis Seed Oil	13.54	D	>100
Prunus Armeniaca Kernel Oil	13.54	D	>100
Glycerin	7.74	E	>100
Lavandula Hybrida Oil	1.35	F	>100
Cosmetic Glitter COSM-3 PU (Sigmund Lindner GmbH) 51K-3 gold (Polyethylene Terephthalate, Polyurethane-11, CI 77000, 19140)	30.95	C	>100

Variant 5

INCI	Weight, %	Concentration Range (CPNP)	MOS Summary†
Cera Alba	11.61	D	>100
Cocos Nucifera Oil	21.28	D	>100
Simmondsia Chinensis Seed Oil	13.54	D	>100
Prunus Armeniaca Kernel Oil	13.54	D	>100
Glycerin	7.74	E	>100
Lavandula Hybrida Oil	1.35	F	>100
Cosmetic Glitter COSM-3 PU (Sigmund Lindner GmbH) 08K-3 turquoise (Polyethylene Terephthalate, Polyurethane-11, CI 77000, 19140, 77510)	30.95	C	>100

Variant 6

INCI	Weight, %	Concentration Range (CPNP)	MOS Summary†
Cera Alba	11.61	D	>100
Cocos Nucifera Oil	21.28	D	>100
Simmondsia Chinensis Seed Oil	13.54	D	>100
Prunus Armeniaca Kernel Oil	13.54	D	>100
Glycerin	7.74	E	>100
Lavandula Hybrida Oil	1.35	F	>100
Cosmetic Glitter COSM-3 PU (Sigmund Lindner GmbH) 54K-3 blue (Polyethylene Terephthalate, Polyurethane-11, CI 77000, 77510)	30.95	C	>100

Variant 7

INCI	Weight, %	Concentration Range (CPNP)	MOS Summary†
Cera Alba	11.61	D	>100
Cocos Nucifera Oil	21.28	D	>100
Simmondsia Chinensis Seed Oil	13.54	D	>100
Prunus Armeniaca Kernel Oil	13.54	D	>100
Glycerin	7.74	E	>100
Lavandula Hybrida Oil	1.35	F	>100
Cosmetic Glitter Cosmetic Iris Mix (Sigmund Lindner GmbH) 50A-IMIX silver hologram iridescent (Polyethylene Terephthalate, Polybutylene Terephthalate, Acrylates Copolymer, Ethylene / VA Copolymer, Polyurethane-11, CI 77000)	30.95	C	>100

† **See Section 10 for detailed information**

2. Final product characteristics

Physical and Chemical Properties:
Semi-solid balm, lavandin scent, colour characteristic of the glitter used.

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:
The product is anhydrous and does not support microbial growth under normal storage conditions. **Appropriate microbiological purity testing must be carried out for each batch of the product to ensure that the following conditions are met:**

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 / food grade packaging materials must be used. Suitable packaging includes glass, PET, aluminium, cardboard. The potential for migration of substance from packaging to product for this type of formulation is negligible.

4. Warnings

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.
Use under adult supervision.

5. Normal and reasonably foreseeable use

The product is intended for use as a glitter containing balm to decorate face with. 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 only 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).

	Facial make-up 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	0.8	1	0.8	100 %	0.8	565	13.333	1.4159
A – >75% - ≤100%	0.800	1	0.800	100 %	0.800	565	13.333	1.4159
B – >50% - ≤75%	0.600	1	0.600	100 %	0.600	565	10.000	1.0619
C – >25% - ≤50%	0.400	1	0.400	100 %	0.400	565	6.667	0.7080
D – >10% - ≤25%	0.200	1	0.200	100 %	0.200	565	3.333	0.3540
E – >5% - ≤10%	0.080	1	0.080	100 %	0.080	565	1.333	0.1416
F – >1% - ≤5%	0.040	1	0.040	100 %	0.040	565	0.667	0.0708
G – >0.1% - ≤1%	0.008	1	0.008	100 %	0.008	565	0.133	0.0142
H – ≤0.1%	0.001	1	0.001	100 %	0.001	565	0.013	0.0014

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

See attached Annex 1 - HL030523GBCPSR

Safety Report Part B

CSS Reference	HL030523GBCPSR
Product line	Glitter Balm
Product variants	Variant 1 Variant 2 Variant 3 Variant 4 Variant 5 Variant 6 Variant 7
Product category	Cosmetic balm to be used as a facial make-up / decoration - leave on product
Responsible person	Himpe Lois Burgemeester G Dussartlaan 52 8860 Lendelede Belgium

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

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.
Use under adult supervision.

Allergen declaration
In a leave on 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 0.001% 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.

03/05/2023

 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.

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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

8+ 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