BTI Marketing Ltd.

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Cosmetic Product Safety Report

Product(s): Face/Body Paints

Formation Reference: T3152, T3153, T3154, T3155, T3156, T3157, T3158

Date: 27th March 2014

CPSR Reference: BTI CPSR0072

Customer/ Sponsor: UV Glow Ltd

Part A

Section 1 Quantitative & Qualitative Composition of the Product

		%
INGREDIENTS	CAS Number	Weight
AQUA (WATER)	7732-18-5	73.7468
BENZOGUANAMINE/ FORMALDEHYDE/ MELAMINE CROSSPOLYMER		9.5
TALC	14807-96-6	5
DIMETHICONE	9006-65-9/63148-62-9	2
TRIETHANOLAMINE	102-71-6	1.251
ACRYLATES/STEARETH-20 METHACRYLATE COPOLYMER		0.9
PROPYLENE GLYCOL	57-55-6	0.86
AMMONIUM ACRYLATES COPOLYMER		0.24
DMDM HYDANTOIN	6440-58-0	0.22
METHYLPARABEN	99-76-3	0.2004
CAMELIA SINENSIS (GREEN TEA) LEAF EXTRACT	84650-60-2	0.2
TOCOPHERYL ACETATE	7695-91-2	0.2
PROPYLPARABEN	94-13-3	0.10002
CENTAUREA CYANUS (CORNFLOWER) FLOWER EXTRACT	84012-18-0	0.04
CUCUMIS SATIVUS (CUCUMBER) FRUIT EXTRACT	89998-01-6	0.04
SODIUM BENZOATE	532-32-1	0.0008
PHENOXYETHANOL	122-99-6	0.00072
SORBIC ACID	110-44-1	0.00016
ETHYLPARABEN	120-47-8	0.00004
BUTYLPARABEN	94-26-8	0.00004
ISOBUTYLPARABEN	4247-02-3	0.00002
MAY CONTAIN +/-		
CI 45161	3068-39-1	0.25
CI 45174	73398-89-7	0.25
CI 74160	147-14-8	0.25

CI 77891	13463-67-7	5
DIETHYLAMINOMETHYLCOUMARIN SOLVENT YELLOW 172	91-44-1 68427-35-0	0.5 0.4
	TOTAL	100%

<u>Section 2</u> Physical/Chemical Characteristics & Stability of the Cosmetic Product

The individual ingredients used in the preparation of this Cosmetic Product are manufactured and purchased to agreed quality specifications which meet the Cosmetic Regulations EU1223/2009

The finished Cosmetic Product is produced to an agreed specification and quality that meets the Cosmetic Regulations EU1223/2009

The Stability of the Cosmetic Product has been demonstrated with Stability Tests conducted at 5°C, Room Temperature & Elevated Temperature over a minimum period of three months and compared to the parameters of the specifications. This was sufficient to determine a shelf life of 30months unopened and a Period After Opening of 12months.

Section 3 Microbial Quality

The individual ingredients used in the preparation of this Cosmetic Product are manufactured and purchased to agreed Microbial Quality which meet the Cosmetic Regulations EU1223/2009

The Microbial Quality of the finished Cosmetic Product has been tested following the Ph Eur Preservative Efficacy test and meets the requirements of the Cosmetic Regulations EU1223/2009

<u>Section 4</u> Impurities, Traces, Information about the Packaging Material

The individual ingredients used in the preparation of this Cosmetic Product are manufactured and purchased to agreed Quality which does not contain any relevant toxicologically impurities or traces and meet the Cosmetic Regulations EU1223/2009

The finished Cosmetic Product does not contain any relevant toxicological impurities or traces and meets the requirements of the Cosmetic Regulations EU1223/2009

The Primary Packaging used for the finished Cosmetic Product has been tested using against the specifications with a Compatibility Test and determined to be suitable.

Section 5 Normal & Reasonable Foreseeable Use

The Cosmetic Product is intended to be applied to the Face in sufficient quantity to perform the function of its intended use.

Section 6 Exposure to the Cosmetic Product

SCCS Notes of Guidance 7th Revision (Face Cream closest to Product)

Application Area: Face

Assumed Amount Used: 1.54grams

Frequency of Use: 2.14per day

Default Body weight: 60kg

Rinse Off/ Leave On Leave On

The Exposure to the Face Paint is 25.6667mg/kg bw/day.

<u>Section 7</u> Exposure to the Substances

Calculation of MoS (Margin of Safety) all values must be greater than 100

The Cosmetic Product is not expected to be used on a daily basis but infrequently.

Restricted Ingredients:

CI 77891	Annex IV/143	Purity Criteria as E171
Methylparaben	Annex V/12	Maximum 0.4% Complies
Ethylparaben	Annex V/12	Maximum 0.4% Complies
Isobutylparaben	Annex V/12	Maximum 0.4% Complies
Propylparaben	Annex V/12	Maximum 0.19% Complies
Butylparaben	Annex V/12	Maximum 0.19% Complies
Phenoxyethanol	Annex V/29	Maximum 1% Complie
Sorbic Acid	Annex V/4	Maximum 0.6% Complies
Sodium Benzoate	Annex V/1(c)	Maximum 0.5% Complies
Butylparaben Phenoxyethanol Sorbic Acid	Annex V/12 Annex V/29 Annex V/4	Maximum 0.19% Complies Maximum 1% Complie Maximum 0.6% Complies

DMDM Hydantoin Annex V/33 Maximum 0.6% below Free

Formaldehyde Declaration Level

Trithenolamine Annex III/62 Purity Criteria & Not used with

Nitrosating System

See Section 10 below for remaining colour ingredients.

Section 8 Toxicological Profile of the Substances

The Toxicological Profiles of all Substances have been considered and are attached in the Appendix 1.

Consideration is given to the main route of absorption for this Cosmetic Product with respect to its normal use. The calculation of the Margin of Safety in Section 7 gives confidence to a reasonable margin of safety that there are no toxicological concerns for this Cosmetic Product.

Safety Data has been sourced from Cosing, CIR Safety Reports, SCCS Opinions, EFSA, TOXNET and INCHEM

Section 9 Undesirable Effects & Serious Undesirable Effect

The Cosmetic Product will be reviewed for serious undesirable effects and any adverse reactions will be reported back to the Safety Assessor for evaluation.

Section 10 Information on the Cosmetic Product:

The colour ingredients in these formulations are entrapped in the solid Benzoguanamine/ Formaldehyde/ Melamine Crosspolymer matrix, similar to that of glitters. The crosspolymer is only in contact with the skin. The polymer matrix is designed to be leach resistant and to encapsulate completely the colours.

PART B

Section 1 CPSR Conclusion

The Cosmetic Product Safety Assessment concludes that this product is safe for its intended use according to the data provided and meets the Regulation EU1223/2009. The Assessment has been conducted based on the information currently available and is subject to reviewed in light of regulatory changes or significant adverse reactions. It is recommended that the CPSR should be reviewed after two years.

Section 2 Labelling Warnings & Instruction of Use

The Label has been reviewed and is acceptable for this Cosmetic Product. No statutory warnings are required to be added.

Section 3 Reasoning

All ingredients are well known for Cosmetics Products and regularly used for this purpose. The Toxicological profile and Safety Evaluation concludes that the Cosmetic Product is suitable for the purpose intended if used in the manner intended.

Section 4 Assessor's Credentials & Approval of Part B

The above Cosmetic Product is approved for use and conforms to the Regulation EU1223/2009 and may be placed on the market in Europe.

Signed:

Adrian P Mellor MRSC

(Qualifications & Experience of the Safety Assessor is given in Appendix 2)

Dated 27th March 2014

Appendix 1 References

BENZOGUANAMINE/ FORMALDEHYDE/ MELAMINE CROSSPOLYMER Listed on Cosing

CI 45161 3068-39-1

Listed on Cosing

CI 45174 73398-89-7

Listed on Cosing

SOLVENT YELLOW 172 68427-35-0

Listed on Cosing

CI 74160 147-14-8

Permitted under Annex IV/105 EU1223/2009

CI 74260 1328-53-6

Listed on Cosing

DIETHYLAMINOMETHYLCOUMARIN 91-44-1

Listed on Cosing

CI 77891 Titanium Dioxide 13463-67-7

Titanium Dioxide is an Opacifying/ Colour Ingredient. It is permitted under Annex IV/1

EU1223/2009 Maximum 25%. SCCNFP/0005/98 24/10/2000

Water (Agua) 7732-18-5

Water has no Toxicological significance in this formulation

Dimethicone 63148-62-9/9006-65-9

CIR Final Report, International Journal Of Toxicology 2003, 22 (Suppl 2)211-315 Safe as used in

Cosmetics

Triethanolamine 102-71-6

CIR Final Report Spet 26-27, 2011 Safe when used without Nitrosamine forming products

Acrylates/ Steareth-20 Methacrylates Copolymer CIR Final Report Safe for Cosmetics, 25 June 2002

Cucumis Sativus (Cucumber) Fruit Extract 89998-01-6

Listed on Cosing

Centaurea Cyanus (Cornflower) Flower Extract 84012-18-0

Listed on Cosing

Sodium Benzoate 532-32-1 SCCP Opinion, Safe in Cosmetics at Specified levels 21st June 2005 Phenoxyethanol 122-99-6 Preservative pernitted

under Annex VI EU1223/2009

Sorbic Acid 110-44-1 Declared under Annex

V/4 EU1223/2009

Propylene Glycol 57-55-6

EFSA Journal 2011:9(12) Doc 2482 Safe for Food

Ammonium Acrylates Copolymer

CIR Final Report Safe for Cosmetics, 25 June 2002

DMDM Hydantoin 6440-58-0

Preservative permitted under EU1223/2009 Annex V/33. SCCNFP/587/02 Final Opinion

Camellia Sinensis (Green Tea) Leaf Extract 84650-60-2

Listed on Cosing used as antioxidant

Parabens (All)

Listed under Annex VI/12 EU1223/2009, International Journal of Toxicology Suppl4:1-82, Safe in Cosmetics, SCCS Opinion on Parabens 2013

Tocopheryl Acetate 7695-91-2

CIR Expert Panel Final Report Safe For Cosmetics, International Journal of Toxicology Nov 2002 Vol21 no3 51-116

Talc 14807-96-6

CIR Tenative Report, Safe for Cosmetics December 18, 2012