Cosmetic Product Safety Report

SQT Anti-Aging Rejuvenation Set- SQT Biomicroneedling Firming Cream

This safety assessment relates to the formulation described below. If the information below is incorrect, please amend and resubmit for reassessment.

Hunan Sunshine Bio-Tech Co., Ltd
Building E7, Lugu Yuyuan, No.27, Wenxuan Road,
High-Tech Development Zone, Changsha, Hunan,
China, 410000

Formulation Ref: N/A

Buyer/Final Retailer: N/A

Manufacturer: N/A

PRODUCT FORMULATION

The chemical names shown below refer to the raw materials used to formulate this product. The identity of the raw materials is not necessarily based on the International Nomenclature of Cosmetic Ingredients (INCI) and does not represent the INCI listing that must be shown on the product label and is for assessment purposes only. An outline INCI label can be prepared on request.

Chemical Name	Conc	% Max Active	Max Active in Product	CAS No	Einecs No
AQUA (WATER)	56.27	100	56.27	7732-18-5	231-791-2
GLYCERIN	7	100	7	56-81-5 / 8013-25-0	200-289-5
PROPANEDIOL	5	100	5	504-63-2	207-997-3
HYDROLYZED SPONGE	4.9	100	4.9	-	-
C13-15 ALKANE	4.5	100	4.5	64742-46-7	265-148-2
ISONONYL ISONONANOATE	4.5	100	4.5	59219-71-5 / 42131-25-9	261-665-2
DIMETHICONE	2.2	100	2.2	9006-65-9 / 63148-62-9 / 9016-00-6	205-491-7 / 205-492-2
CETEARYL ALCOHOL	2.2	100	2.2	67762-27-0 / 8005-44-5	267-008-6
THEOBROMA GRANDIFLORUM SEED BUTTER	1.32	100	1.32	394236-97-6/906348-18-3 (GENERIC)	-
JOJOBA ESTERS	1.5	100	1.5	61789-91-1	307-350-6
SILICA	1.1	100	1.1	7631-86-9 / 112945-52-5 / 60676-86-0 /63231-67-4	231-545-4/ -/ 262-373-8
INOSITOL	1.1	100	1.1	6917-35-7 / 87-89-8	230-024-9 / 201-781-2
GLYCERYL STEARATE	0.8	100	.8	123-94-4 / 31566-31-1/11099-07-3	204-664-4 / 250-705-4
SODIUM ACRYLIC ACID/MA COPOLYMER	0.6	100	.6	52255-49-9	-
HELIANTHUS ANNUUS SEED WAX	0.6	100	.6	1286686-34-7	-
ACACIA DECURRENS FLOWER WAX	0.6	100	.6	98903-76-5	308-877-4
RICE FERMENT FILTRATE	0.5	100	.5	NOT KNOWN	
PEG-100 STEARATE	0.5	100	.5	9004-99-3	-
GLYCERYL STEARATE SE	0.5	100	.5	11099-07-3 / 85666-92-8 / 85251-77-0	234-325-6 / 286-490-9
BUTYLENE GLYCOL	0.45	100	.45	107-88-0	203-529-7
HYDROXYACETOPHENONE	0.35	100	.35	99-93-4	202-802-8 (I)
GLYCERYL CAPRYLATE	0.35	100	.35	26402-26-6	
CAPRYLHYDROXAMIC ACID	0.35	100	.35	7377-03-9	230-936-7
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER	0.3	100	.3	-	-
CARNOSINE	0.3	100	.3	305-84-0	206-169-9
BUTYROSPERMUM PARKII BUTTER	0.3	100	.3	91080-23-8/68920-03-6/194043-92-0	293-515-7
1,2-HEXANEDIOL	0.3	100	.3	6920-22-5	230-029-6
STEARETH-21	0.15	100	.15	9005-00-9	500-017-8 NLP
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER	0.15	100	.15	POLYMER	POLYMER
POLYGLYCERIN-3	0.1	100	.1	56090-54-1	259-986-8
TOCOPHERYL ACETATE	0.1	100	.1	7695-91-2 / 58-95-7	231-710-0 / 200-405-4
DISODIUM EDTA	0.1	100	.1	139-33-3 / 6381-92-6	205-358-3
ARGININE	0.08	100	.08	74-79-3 / 7200-25-1	200-811-1 / 230-571-3
ZINGIBER OFFICINALE ROOT OIL	0.05	100	.05	8007-08-7 / 84696-15-1	283-634-2
XANTHAN GUM	0.05	100	.05	11138-66-2	234-394-2
SOPHORA FLAVESCENS ROOT EXTRACT	0.05	100	.05	-	-
POLYSORBATE 20	0.05	100	.05	9005-64-5	500-018-3
PHENOXYETHANOL	0.05	100	.05	122-99-6	204-589-7
PALMITOYL TRIPEPTIDE-1	0.05	100	.05	147732-56-7	-
PALMITOYL TETRAPEPTIDE-7	0.05	100	.05	POLYMER	POLYMER
LYCIUM BARBARUM FRUIT EXTRACT	0.05	100	.05	85085-46-7	285-375-0
HEXANEDIOL	0.05	100	.05	629-11-8 / 26762-52-7	211-074-0
ETHYLHEXYLGLYCERIN	0.05	100	.05	70445-33-9	408-080-2
ECHINACEA PURPUREA EXTRACT	0.05	100	.05	90028-20-9	289-808-4
DENDROBIUM NOBILE STEM EXTRACT	0.05	100	.05	-	-
CARBOMER	0.05	100	.05	54182-57-9 / 9007-20-9 / 9003-01-4 / 76050-42-5 / 9062-04-8 / 9007-16-3 / 9007-17-4	POLYMER
CAPRYLYL GLYCOL	0.05	100	.05	1117-86-8	214-254-7
BISABOLOL	0.05	100	.05	515-69-5 / 23089-26-1	208-205-9 / 245-423-3
ALOE BARBADENSIS LEAF EXTRACT	0.05	100	.05	85507-69-3/ 8001-97-6	287-390-8
SODIUM SILICATE	0.05	100	.05	1344-09-8	215-687-4
CALCIUM SILICATE	0.05	100	.05	1344-95-2	215-710-8
SODIUM HYALURONATE	0.03	100	.03	9067-32-7	-

MSDS/SDS, CoA/TDS and toxicity profile (where applicable) were listed in the Appendix 1

LABELLED WARNINGS & INSTRUCTIONS OF USE

CONSUMER EXPOSURE

Product Class: Facial cream
IFRA Product type: Women's Facial Creams / Lotions / Butter / Make-up of all types
IFRA Category: Category 5
Targeted Population:Children 14 years of age 50.4kg (Mean)

Amount per application/g:
Skin Surface Area of Application/cm^2: 555
Total Amount applied per day/g: 1.54
Estimated Daily Exposure mg/kg/day: 24.14
Amount Per Unit Area of Skin per day mg/cm^2/day: 2.70
Retention factor: 1.00
Exposure Time Neat: 720-960 Minutes
Exposure Time Dilute: Not Applicable
Exposure time Solvent Inhalation: Not Applicable
Exposure time Aerosol Inhalation: Not Applicable

Number of applications per day: Twice a day
Physical form: Cream
Part of body exposed to undiluted product: Hands and face

MICROBIOLOGICAL QUALITY

To comply with "Guidelines on Microbiological Quality of the Finished Cosmetic Product" under SCCS's Notes of Guidance, the following limits apply to this product:

Category 2: Other cosmetic products. Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould) should not exceed 1000 cfu/g or ml in the product. Escherichia coli， Pseudomonas aeruginosa and Staphylococcus aureus must not be detectable in the cosmetic product
Microbiological specifications for the product have been supplied and meet the requirements specified therein for this type of product.

Microbiological specification test report or data was listed in the Appendix 2-1
This product is a single use cosmetic product which can be used only once and is then disposed of. Preservative challenge testing is therefore not applicable to the safety of this product and only microbiological quality testing of the finished cosmetic product is required.

STABILITY OF COSMETIC PRODUCT

It is assumed that the responsible person has selected all pertinent criteria required to evaluate the stability of this cosmetic product during reasonable foreseeable conditions of storage. The stability report provided by the supplier and based upon the conclusions made therein, this cosmetic product appears to be stable under reasonably foreseeable storage conditions.

Stability Test Report or Data of Cosmetic Product was listed in the Appendix 3

PACKAGING COMPATIBILITY

It is assumed that the responsible person has identified the most applicable testing required to determine the packaging stability and its interaction with the cosmetic product contained within it. Taking into consideration the information supplied to the assessor, there appears to be no immediate health concern due to the characteristics of packaging materials in direct contact with the final product.

Package Compatibility Test Report and/or data was listed in the Appendix 4

SERIOUS / UNDESIRABLE EFFECTS

The supplier has confirmed that no undesirable effects or serious undesirable effects of this cosmetic product have been reported or, where relevant, cosmetic products with a similar formulation.

Serious/ Undesirable Effects of Cosmetic Product Declaration was listed in Appendix 5

FRAGRANCE COMPOSITIONS

This formulation does not contain a synthetic fragrance and therefore a fragrance safety evalution as per IFRA code of practice is not applicable to this product.

According to Cosmetic Regulation (EC) No. 1223/2009, a complete cosmetic product safety report shall, at a minimum, contain cosmetic product safety information and cosmetic product safety assessment. The former includes raw materials and packaging material specifications, toxicological profile of substance (taking into account of purity of substance) contained in the cosmetic product and any known undesirable effects of the cosmetic product.

TOXICOLOGICAL & REGULATORY REVIEW

The product is mainly a mixture of solvent, moisturizer, skin conditioner, emollient and emulsifier. None of the ingredients is on the prohibition list of the Cosmetic Regulation (EC) No. 1223/2009.
Most of the ingredients are commonly used in cosmetic products and reviewed by CIR Panel, CIR confirmed that cetearyl alcohol, theobroma grandiflorum seed butter, glyceryl caprylate, ammonium acryloyldimethyltaurate/vp copolymer, butyrospermum parkii butter, 1,2-hexanediol, steareth-21, acrylates/c10-30 alkyl acrylate crosspolymer, arginine, hexanediol are safe for use at the current level.
According to above information, there is no safety concern for the ingredients used in this product. However, the possibility cannot be discounted that a small number of users may experience an allergic reaction or other idiosyncratic reaction to an ingredient in the formulation if they have been previously sensitized to the ingredient.

Limits of heavy metals were satisfied legal requirements and testing report was listed in the Appendix 7

No existing studies from human volunteers were provided.

Effects of the product as supplied on the skin

The formulation as supplied may cause only minimal skin irritation even if exposure is prolonged and/or repeated.

Repeated exposure to the formulation as supplied is unlikely to produce allergy by skin contact.

Exposure to this product is unlikely to result in phototoxic effects.

Unlikely to cause damage to internal organs following absorption through the skin.

Effects of the product as supplied on the eye

Accidental exposure of the eye to the formulation as supplied may result in minimal eye irritation.

Effects following ingestion of the product as supplied

The formulation as supplied if swallowed is unlikely to cause harm.

Effects of inhaling the product

Inhalation is an unlikely route of exposure

Overall Assessment Conclusion

The ingredients are legally permitted as per Cosmetic Regulation (EC) No 1223/2009 and its amendments and the safety assessment has been carried out in accordance to this regulation. They must comply with the relevant purity standards for cosmetic ingredients. It is assumed that these ingredients do not contain any undisclosed impurities/contaminants that would affect the conclusions reached. The product must be manufactured in accordance with EU Guidance on Good Manufacturing Practice.

Under normal or reasonably foreseeable conditions of use, product made to this formulation is unlikely to produce an abnormally high number of adverse reactions.

Cosmetic Regulations Product Safety Assessor

Leshuai Zhang,Toxicologist,PhD, DABT, ERT, UKRT
Intertek GM Testing Services Zhuhai Co. Ltd.
6/F, R&D and Testing/B, Guangdong-Macau TCM Park commercial Service center, 2522 Huan Dao Bei Road, Henggin New Area, Zhuhai, China

Date: 22 Nov 2022

SUMMARY OF TOXICOLOGICAL INFORMATION OF SUBSTANCES

Remark: Substance toxicological summary was listed in this section and used only for MoS calculation, please refer to Toxicological Profiles of Substances for full information.

Chemical Substance: AQUA (WATER)

EU INCI NAME:aqua (Water)

CAS: 7732-18-5 Function: Solvent

EINECS 231-791-2 Melting Point: 0°C

Appearance: Liquid Boiling Point: 100°C

Water Solubility: highly soluble

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› Unclassified

EU CLP Harmonised Classification› Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 14.44263 No NOAEL Available NOAEL mg/kg bw day: -

SED Child mg/kg bw/day: 51.88970 No NOAEL Available NOAEL test method: -

SED Baby mg/kg bw/day: 146.8742 No NOAEL Available

Toxicological Summary:

Simply water unlikely to cause irritation, allergy or harm. Used in many cosmetic products as a solvent and necessary to sustain biological life. The source of water should be known, monitored to GMP and either a deionized or high purity grade free from toxins, pollutants and bacteriological contamination should be used in cosmetic products.

Chemical Substance: GLYCERIN

EU INCI NAME:GLYCERIN

CAS: 56-81-5 / 8013-25-0 Function: Denaturant / Humectant / Perfuming / Solvent / Fragrance Ingredient / Hair & Skin Conditioning Agent / Oral Care Agent / Skin Protectant / Viscosity Decreasing Agent

EINECS 200-289-5

Appearance: liquid Melting Point: ~18°C

Log Kow: -1.76 Boiling Point: 290°C

Water Solubility: miscible with water Vapour Pressure: <0.01 mm Hg @ 20°C

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› unclassified

EU CLP Harmonised Classification› unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 1.79666 MoS - Adult 60kg: 2549.1 NOAEL mg/kg bw day: 4580

SED Child mg/kg bw/day: 6.45508 MoS - Child 16.7kg: 709.5 NOAEL test method: 90-day oral

SED Baby mg/kg bw/day: 18.27118 MoS - Baby 5.9kg: 250.6

Toxicological Summary:

The ingredient is not acutely toxic, a skin irritant, an eye irritant, a skin sensitizer, mutagenic, carcinogenic, a reproductive toxicant, nor is it bioaccumulative. No information was available on its phototoxicity. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics.

Chemical Substance: PROPANEDIOL

EU INCI NAME:PROPANEDIOL

CAS: 504-63-2 Function: Solvent

EINECS 207-997-3

Appearance: liquid

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› Not known

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 1.28333 MoS - Adult 60kg: 649350.6 NOAEL mg/kg bw day: 1000

SED Child mg/kg bw/day: 4.61077 MoS - Child 16.7kg: 180735.9 NOAEL test method: 13-week rat study (developmental)

SED Baby mg/kg bw/day: 13.05084 MoS - Baby 5.9kg: 63852.8

Toxicological Summary:

Cosmetic Functions : Solvent / Viscosity Controlling / Viscosity Decreasing Agent. Widely used alcoholic solvent. In most cases a low irritation potential substance but can enhance the irritancy of soap mixtures especially in patch tests. Propandiol was tested for inhalation toxicity (Inhal Toxicol. 2005 Aug;17(9):487-93). The highest concentration tested, 1800 mg/m^3 was also considered the no-observed-effect level (NOEL) for this study. 1,3-Propanediol does not appear to pose a significant hazard via inhalation of either the vapor or a vapor/aerosol mixture. 1,3-propanediol is of low toxicity following oral administration. In a 13-week rat study the NOAEL was 1000 mg/kg bw/day. In the developmental study, the LOAEL was 250 mg/kg bw/day for marginal fetal effects (retarded ossification).

A more recent study published in cosmetic and toiletries magazine, provided a review of 1,3-propandiol vs propylene glycol. In studies on 100 human volunteers, PDO up to 50% was found to be non irritating, non sensitizing and non fatiguing.A few people in a 200 volunteer RIPT study, displayed signs of only mild redness following challenge application. It was concluded that PDO has low potential to irritate or sensitize human skin.

Reference: SCF/CS/CNTM/CARGO/16 Final4 April 2003.
Belcher, Dupont; Cosmetics and toiletires Magazine, 125, 5, 81-86.

Chemical Substance: HYDROLYZED SPONGE

CAS: -
EINECS -

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 1.25766 No NOAEL Available
SED Child mg/kg bw/day: 4.51856 No NOAEL Available
SED Baby mg/kg bw/day: 12.78983 No NOAEL Available

Toxicological Summary:

Description: Hydrolyzed Sponge is the hydrolysate of sponge obtained by acid, enzyme or other method of hydrolysis. Function: SKIN CONDITIONING. The ingredient is not listed on the prohibition list of the Cosmetic Regulation (EC) No. 1223/2009.

Chemical Substance: C13-15 ALKANE

CAS: 64742-46-7
EINECS 265-148-2

Cosmetic Regulatory Summary:

EU Cosmetics Status: Controlled

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 1.15500 No NOAEL Available
SED Child mg/kg bw/day: 4.14970 No NOAEL Available
SED Baby mg/kg bw/day: 11.74576 No NOAEL Available

Toxicological Summary:

C13-15 Alkane is a mixture of alkanes with 13 to 15 carbon atoms in the alkyl chain. Unlikely to cause senstisation.Not restricted by the Cosmetic Regulations.

Chemical Substance: ISONONYL ISONONANOATE

EU INCI NAME:ISONONYL ISONONANOATE

CAS: 59219-71-5 / 42131-25-9 Function: Skin conditioning agent
EINECS 261-665-2

Appearance: Liquid

Log Kow: 6.27

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› Unclassified

EU CLP Harmonised Classification› Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 1.15500 MoS - Adult 60kg: 96.1 NOAEL mg/kg bw day: 11.1
SED Child mg/kg bw/day: 4.14970 MoS - Child 16.7kg: 26.7 NOAEL test method: 4 weeks oral
SED Baby mg/kg bw/day: 11.74576 MoS - Baby 5.9kg: 9.4

Toxicological Summary:

The ingredient is not acutely toxic when administered orally, irritating to the eyes, skin sensitizing, reproductively toxic, carcinogenic nor is it mutagenic but it is slightly irritating to the skin. Surrogate data indicates that the ingredient is not acutely toxic when administered dermally, carcinogenic or bioaccumulative but it is acutely harmful through inhalation. Surrogate compounds do not absorb in the 250 to 400 nm range (CIR, 2010). The ingredient is also included in the Health Canada Natural Health Products Ingredients Database, which generally contains chemicals of minimal toxicological concern (Health Canada, 2013). Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics when formulated to be non-irritating.

Chemical Substance: DIMETHICONE

EU INCI NAME:DIMETHICONE

CAS: 9006-65-9 / 63148-62-9 / 9016-00-6 Function: Antifoaming/Emollient/Skin Conditioning/Skin Protecting
EINECS 205-491-7 / 205-492-2

Appearance: Liquid

Water Solubility: Insoluble

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› Unclassified

EU CLP Harmonised Classification› Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.56466 MoS - Adult 60kg: 88547.8 NOAEL mg/kg bw day: 5000
SED Child mg/kg bw/day: 2.02874 MoS - Child 16.7kg: 24645.8 NOAEL test method: 90 days in rats
SED Baby mg/kg bw/day: 5.74237 MoS - Baby 5.9kg: 8707.2

Toxicological Summary:

The ingredient is not acutely toxic through the dermal, oral and inhalation routs. It is non to severe ocular and skin irritant . It is not sensitizing, carcinogenic, reprotoxic or genotoxic. It has no dermal percutaneous absorption potential and does not bioaccumulate in the body. No information is readily available on the phototoxicity of the ingredient. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics.

Chemical Substance: CETEARYL ALCOHOL

EU INCI NAME:CETEARYL ALCOHOL

CAS: 67762-27-0 / 8005-44-5 Function: Emollient

EINECS 267-008-6

Appearance: solid

Log Kow: 6.7-7.2

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> unclassified

EU CLP Harmonised Classification> unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.56466	No NOAEL Available	NOAEL mg/kg bw day: -
SED Child mg/kg bw/day: 2.02874	No NOAEL Available	NOAEL test method: -
SED Baby mg/kg bw/day: 5.74237	No NOAEL Available	

Toxicological Summary:

The ingredient is not acutely toxic, a skin irritant, an eye irritant, a skin sensitizer, mutagenic and phototoxic. No data was available for carcinogenicity and reproductive toxicity. However, based on their close structural similarities to fatty acids and long-chain aliphatic esters, safety concerns are not expected with this ingredient for use in cosmetics.

Chemical Substance: THEOBROMA GRANDIFLORUM SEED BUTTER

EU INCI NAME:THEOBROMA GRANDIFLORUM SEED BUTTER

CAS: 394236-97-6/906348-18-3 (generic)

EINECS -

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

EU DSD/DPD Classification>

EU CLP Harmonised Classification>

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.33880	No NOAEL Available
SED Child mg/kg bw/day: 1.21724	No NOAEL Available
SED Baby mg/kg bw/day: 3.44542	No NOAEL Available

Toxicological Summary:

Description: Theobroma Grandiflorum Seed Butter is the fat obtained from the seeds of Theobroma grandiflorum, Sterculiaceae. Function: SKIN CONDITIONING. The ingredient is not listed on the prohibition list of the Cosmetic Regulation (EC) No. 1223/2009.

Chemical Substance: JOJOBA ESTERS

EU INCI NAME:JOJOBA ESTERS

CAS: 61789-91-1 Function: Exfoliating agent

Cosmetic Regulatory Summary:

Regulatory Summary:

EU DSD/DPD Classification> Eye Irrit.2

EU CLP Harmonised Classification>

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.38500	No NOAEL Available
SED Child mg/kg bw/day: 1.38323	No NOAEL Available
SED Baby mg/kg bw/day: 3.91525	No NOAEL Available

Toxicological Summary:

Cosmetic Functions : Emollient / Moisturising / Skin Conditioning / Soothing. Mixed fatty esters of vegetable origin. Low potential to irritate the skin and eye. Unlikely to be allergenic.

Chemical Substance: SILICA

EU INCI NAME:SILICA

CAS: 7631-86-9 / 112945-52-5 / 60676-86-0 /63231-67-4 Function: Abrasive/ Absorbent/ Anticaking/ Bulking, Opacifying/ Viscosity Controlling

EINECS 231-545-4/ -/ 262-373-8

Appearance: White fluffy powder (CIR, 2009)

Water Solubility: Insoluble (JECFA, 1973)

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> unclassified

EU CLP Harmonised Classification> unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.28233	MoS - Adult 60kg: 31806.3	NOAEL mg/kg bw day: 8980
SED Child mg/kg bw/day: 1.01437	MoS - Child 16.7kg: 8852.7	NOAEL test method: 6 months oral in rats
SED Baby mg/kg bw/day: 2.87118	MoS - Baby 5.9kg: 3127.6	

Toxicological Summary:

The ingredient is not acutely toxic by oral or dermal administration or inhalation. It is not a skin irritant, an eye irritant, a skin sensitizer. It is not mutagenic, carcinogenic nor a reproductive toxicant. It has low bioaccumulation potential. No data was available for phototoxicity. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics.

Chemical Substance: INOSITOL

EU INCI NAME:INOSITOL

CAS: 6917-35-7 / 87-89-8 Function: Humectant/Solvent

EINECS 230-024-9 / 201-781-2

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.28233 No NOAEL Available

SED Child mg/kg bw/day: 1.01437 No NOAEL Available

SED Baby mg/kg bw/day: 2.87118 No NOAEL Available

Toxicological Summary:

A cosmetic ingredient. Widely used as an antistatic, humectant and in hair conditioning products.

Chemical Substance: GLYCERYL STEARATE

EU INCI NAME:GLYCERYL STEARATE

CAS: 123-94-4 / 31566-31-1/11099-07-3 Function: Emollient

EINECS 204-664-4 / 250-705-4

Appearance: Solid

Log Kow: 6.1

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› unclassified

EU CLP Harmonised Classification› unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.20533 MoS - Adult 60kg: 36525.9 NOAEL mg/kg bw day: 7500

SED Child mg/kg bw/day: 0.73772 MoS - Child 16.7kg: 10166.3 NOAEL test method: three consecutive generations study

SED Baby mg/kg bw/day: 2.08813 MoS - Baby 5.9kg: 3591.7

Toxicological Summary:

The ingredient is not acutely toxic, a skin sensitizer, mutagenic, carcinogenic, a reproductive toxicant, phototoxic, but it might cause skin irritation and eye irritation. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics when formulated to be non-irritating.

Chemical Substance: SODIUM ACRYLIC ACID/MA COPOLYMER

CAS: 52255-49-9

EINECS -

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.15400 No NOAEL Available

SED Child mg/kg bw/day: 0.55329 No NOAEL Available

SED Baby mg/kg bw/day: 1.56610 No NOAEL Available

Toxicological Summary:

Description: 2-Propenoic Acid, Polymer with 2,5-Furandione, Sodium Salt. Function: VISCOSITY CONTROLLING. The ingredient is not listed on the prohibition list of the Cosmetic Regulation (EC) No. 1223/2009.

Chemical Substance: HELIANTHUS ANNUUS SEED WAX

CAS: 1286686-34-7

EINECS -

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.15400 No NOAEL Available

SED Child mg/kg bw/day: 0.55329 No NOAEL Available

SED Baby mg/kg bw/day: 1.56610 No NOAEL Available

Toxicological Summary:

Description: Helianthus Annuus (Sunflower) Seed Wax is the wax obtained from the seed of the sunflower, Helianthus annuus, Asteraceae. Function: SKIN CONDITIONING. The ingredient is not listed on the prohibition list of the Cosmetic Regulation (EC) No. 1223/2009.

Chemical Substance: ACACIA DECURRENS FLOWER WAX

EU INCI NAME:ACACIA DECURRENS FLOWER CERA

CAS: 98903-76-5

EINECS 308-877-4

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.15400 No NOAEL Available

SED Child mg/kg bw/day: 0.55329 No NOAEL Available

SED Baby mg/kg bw/day: 1.56610 No NOAEL Available

Toxicological Summary:

Cosmetic function: skin conditioning, protecting and emollient. Wax obtained from the flowers of Acacia decurrens, Leguminosae. Acacia decurrens can be substitute for Gum Arabic, for example in the production of fruit jelly.

Chemical Substance: RICE FERMENT FILTRATE

EU INCI NAME:RICE FERMENT FILTRATE

CAS: Not known Function: Botanical

Appearance: Liquid (clear to light yellow) Boiling Point: 100 °C

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> Unclassified

EU CLP Harmonised Classification> Not controlled

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.12833 No NOAEL Available

SED Child mg/kg bw/day: 0.46107 No NOAEL Available

SED Baby mg/kg bw/day: 1.30508 No NOAEL Available

Toxicological Summary:

Function: Skin conditioning agent. Rice Ferment Filtrate (sake) is a filtrate of the product obtained by the fermentation of Oryza sativa. Not classified as hazardous to health. Not reported to cause irritation or allergy. There are no known reported effects of carcinogenicity by IARC, OSHA, NTP or EPA nor as a reprotoxin. Use in cosmetic formulation is likely to be uneventful.

Chemical Substance: PEG-100 STEARATE

EU INCI NAME:PEG-100 Stearate

CAS: 9004-99-3 Function: surfactants

EINECS -

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> unclassified

EU CLP Harmonised Classification> unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.12833 MoS - Adult 60kg: 7792.2 NOAEL mg/kg bw day: 1000

SED Child mg/kg bw/day: 0.46107 MoS - Child 16.7kg: 2168.8 NOAEL test method: 2% in diets for 2 years

SED Baby mg/kg bw/day: 1.30508 MoS - Baby 5.9kg: 766.2

Toxicological Summary:

The ingredient is not acutely toxic via oral route. It is neither a skin irritant nor an eye irritant. It is not a skin sensitizer. It is not mutagenic, carcinogenic, phototoxic or a reproductive toxicant. It has no bioaccumulation potential. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics when formulated to be non-sensitizing.

Chemical Substance: GLYCERYL STEARATE SE

EU INCI NAME:glyceryl Stearate SE

CAS: 11099-07-3 / 85666-92-8 / 85251-77-0 Function: Emulsifier/Surfactant

EINECS 234-325-6 / 286-490-9

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> unclassified

EU CLP Harmonised Classification> unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.12833 No NOAEL Available

SED Child mg/kg bw/day: 0.46107 No NOAEL Available

SED Baby mg/kg bw/day: 1.30508 No NOAEL Available

Toxicological Summary:

Function: emollients, emulsifiers, and stabilizers A monofatty ester of glycerol and the esterification products of glycerine and stearic acid. In acute oral toxicity studies in rats, both ingredients were slightly toxic. Five percent Glyceryl Stearate did not promote the carcinogenicity of DMBA in mouse skin. Primary eye irritation studies, at concentrations up to 100%, were mildly irritating or nonirritating to rabbits. Single and Repeated Insult Patch Tests showed both ingredients to be nonsensitizing and nonirritating. Products containing 2% Glyceryl Stearate were nonphototoxic and nonphotoallergenic Such esters have a good history of being of low potential to irritate the skin and eye and is considered safe for cosmetic use at the present practices of use and concentration. Reference: International Journal of Toxicology, Vol. 1, No. 4, 169-192 (1982)

Chemical Substance: BUTYLENE GLYCOL

EU INCI NAME:Butylene Glycol

CAS: 107-88-0 Function: humectants / solvents

EINECS 203-529-7 Melting Point: -77°C

Appearance: Viscous liquid Boiling Point: 207.5 °C

Log Kow: -0.29

Water Solubility: miscible Vapour Pressure: 0.08 at 20°C

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> Unclassified

EU CLP Harmonised Classification> Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.11550 MoS - Adult 60kg: 61842.9 NOAEL mg/kg bw day: 6000

SED Child mg/kg bw/day: 0.41497 MoS - Child 16.7kg: 17212.9 NOAEL test method: 90-days toxicity study to dogs

SED Baby mg/kg bw/day: 1.17457 MoS - Baby 5.9kg: 6081.2

Toxicological Summary:

The ingredient is not acutely toxic via dermal and oral route; it is not a skin irritant, a skin sensitizer, mutagenic, carcinogenic, a reproductive toxicant, or photosensitizer. Low bioaccumulation potential based on study results. Undiluted butylenes glycol was not an eye irritant to rabbits, but was to humans. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics when formulated to be non-irritating.

Chemical Substance: HYDROXYACETOPHENONE

EU INCI NAME:HYDROXYACETOPHENONE

CAS: 99-93-4

EINECS 202-802-8 (I)

Melting Point: 109 °C (REACH Dossiers, 2017)

Boiling Point: the normal boiling temperature could not be determined

Appearance: solid (REACH Dossiers, 2017)

Water Solubility: 10 g/L at 22 °C

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› Unclassfied

EU CLP Harmonised Classification› Unclassfied

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.08983 MoS - Adult 60kg: 500.9 NOAEL mg/kg bw day: 45

SED Child mg/kg bw/day: 0.32275 MoS - Child 16.7kg: 139.4 NOAEL test method: 90 day to rats by oral

SED Baby mg/kg bw/day: 0.91355 MoS - Baby 5.9kg: 49.2

Toxicological Summary:

The ingredient is not acutely toxic, an eye irritant, a skin sensitizer, mutagenic, a reproductive toxicant, but it is an eye irritant. No safety concern at current levels of intake when used as a flavouring agent by JECFA (JECFA, 2017). Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics when formulated to be non-irritating.

Chemical Substance: GLYCERYL CAPRYLATE

EU INCI NAME:GLYCERYL CAPRYLATE

CAS: 26402-26-6 Function: Surfactant

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› Unclassified

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.08983 No NOAEL Available

SED Child mg/kg bw/day: 0.32275 No NOAEL Available

SED Baby mg/kg bw/day: 0.91355 No NOAEL Available

Toxicological Summary:

Function: Emollient and emulsifying agent. This is a glyceryl ester of a conditioning agent. May cause some skin and eye irritation if used neat though when incorporated into a cosmetic product, any adverse health effect is unlikely.

Chemical Substance: CAPRYLHYDROXAMIC ACID

EU INCI NAME:CAPRYLHYDROXAMIC ACID

CAS: 7377-03-9

EINECS 230-936-7

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.08983 No NOAEL Available NOAEL mg/kg bw day: -

SED Child mg/kg bw/day: 0.32275 No NOAEL Available

SED Baby mg/kg bw/day: 0.91355 No NOAEL Available

Toxicological Summary:

Function: CHELATING. At a low concentration used in cosmetic products, not expected to pose an adverse risk to health.

Chemical Substance: AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER

CAS: -

EINECS -

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.07700 No NOAEL Available

SED Child mg/kg bw/day: 0.27664 No NOAEL Available

SED Baby mg/kg bw/day: 0.78305 No NOAEL Available

Toxicological Summary:

Description：Ammonium Acryloyldimethyltaurate/VP Copolymer is a copolymer of ammonium acryloyldimethyltaurate and vinylpyrrolidone monomers. Function: VISCOSITY CONTROLLING. The ingredient is not listed on the prohibition list of the Cosmetic Regulation (EC) No. 1223/2009.

Chemical Substance: CARNOSINE

EU INCI NAME:CARNOSINE

CAS: 305-84-0 Function: Skin conditioning agent

EINECS 206-169-9 Melting Point: 253

Appearance: solid

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> Unclassified

EU CLP Harmonised Classification>

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.07700	No NOAEL Available
SED Child mg/kg bw/day: 0.27664	No NOAEL Available
SED Baby mg/kg bw/day: 0.78305	No NOAEL Available

Toxicological Summary:

Cosmetic function: skin conditioning. This is a natural occurring antioxidant comprising of two amino acids, alanine and histidine. It is generally used in anti-aging products. Material when tested on animals shown to retard cancer growth and protect against alcohol-induced oxidative stressas well as ethanol-induced chronic liver damage. Carnosine found to be neuroprotective against permanent cerebral ischemia in mice model. Listed on CosIng as an cosmetic ingredient.

Chemical Substance: BUTYROSPERMUM PARKII BUTTER

EU INCI NAME:BUTYROSPERMUM PARKII BUTTER

CAS: 91080-23-8/68920-03-6/194043-92-0 Function: Skin conditioning agent

EINECS 293-515-7

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> Unclassified

EU CLP Harmonised Classification> Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.07700	No NOAEL Available
SED Child mg/kg bw/day: 0.27664	No NOAEL Available
SED Baby mg/kg bw/day: 0.78305	No NOAEL Available

Toxicological Summary:

Cosmetic Functions: Skin Conditioning / Viscosity Controlling. Butyrospermum Parkii Butter is the fat obtained from the fruit of the Shea Tree, Butyrospernum parkii, Sapotaceae. It is a mixture of fatty acid/fatty alcohol esters with low potential to irritate the skin or eye. As well as from the fat of the fruit of Butyrospermum Parkii, it can also be obtained from the Shea or Shea nut tree. In Africa also used as a food source for dietary fat. Its main constituents are palmitic, stearic, oleic, linoleic, and arachidic with stearic and oleic acids accounting for about 85 -90% of the total. The consistency of the butter depends on the proportion of the fatty acids relative to each other. For example,a high stearic acid content results in a solid consistency whereas oleic acid content may affect whether it is soft or hard. Shea Butter may also be rich in phenolic compounds, namely catechins which are being studied for their antioxidant properties. Refined Shea Butter has a low irritation potential (Draize Test), non-irritating to human skin (but shown to be mildly irritating *in vitro*, not a skin sensitizer and is negative in mutagenicity assays. Studies have shown that an oil fraction derived from Shea nut, Shea oleine, when examined for its carcinogenic at 15% (w/w) in comparison with Shea nut oil, and palm oil, given as a dietary intake to rats over 104 weeks, produced tumorigenic incidence which was comparable to other commercially available sheanut and palm oils in the rat. The specific tumuors were namely hepatomas for females, pancreatic exocrine adenomas for males and skin keratoacanthomas for males fed shea oleine diets and were attributed to high fat content of the diets also seen with other edible oils and were not considered as adverse effects of the oil *per se* (Carthew, P, Baldrick. P and Hepburn PA. 2001. An assessment of the carcinogenic potential of shea oleine in the rat. . *Food Chem Toxicol, 39*(8):807-15. Abstract). Notable differences with other oils were "reduced body weight gain and food intake, reduced cholesterol and increased alkaline phosphatase levels, reduced heart weight and an increased incidence of pulmonary lipidosis with shea oleine diets" which may also be due to the high fat content. Following evaluation of the physicochemical properties of Shea butter and its uses in medicinal creams and ointments, another study concluded that it can be a suitable replacement for conventional fatty acids (Mital HC.1977. Shea butter: cosmetic/drug applications. *Drug Cosmet. Ind., 120*, 30-32. Abstract).

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Chemical Substance: 1,2-HEXANEDIOL

EU INCI NAME:1,2-HEXANEDIOL

CAS: 6920-22-5 Function: Solvent

EINECS 230-029-6

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> Unclassified

EU CLP Harmonised Classification>

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.07700	No NOAEL Available
SED Child mg/kg bw/day: 0.27664	No NOAEL Available
SED Baby mg/kg bw/day: 0.78305	No NOAEL Available

Toxicological Summary:

A diol alcohol, Hexane diol has the formula $CH_3(CH_2)_3CH_2CH(OH)CH_2OH$. This alcohol is widely used in cosmetic products and incorporation into skin formulations will be uneventful.

Chemical Substance: STEARETH-21

EU INCI NAME:STEARETH-21

CAS: 9005-00-9 Function: Cleansing / Emulsifying / Surfactants

EINECS 500-017-8 NLP

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› Unclassified

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.03850 No NOAEL Available

SED Child mg/kg bw/day: 0.13832 No NOAEL Available

SED Baby mg/kg bw/day: 0.39152 No NOAEL Available

Toxicological Summary:

Cosmetic Functions : Cleansing / Emulsifying / Surfactant / Solubilizing Agent. The polyethylene glycol ether of stearyl alcohol. As supplied, has potential to irritate the skin and eye. Any irritation potential is low at typical concentration levels.

Chemical Substance: ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER

EU INCI NAME:ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER

CAS: polymer Function: Emollient/Hair & Skin Conditioning

EINECS polymer

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› unclassified

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.03850 No NOAEL Available

SED Child mg/kg bw/day: 0.13832 No NOAEL Available

SED Baby mg/kg bw/day: 0.39152 No NOAEL Available

Toxicological Summary:

Cosmetic Functions : Emulsion Stabilising / Film Forming / Viscosity Controlling. May contain residual acrylic acid. Toxicological Data: Eye Irritation: Moderate to strong eye irritant. Particulates may cause mechanical irritation. Skin Irritation: Not expected to be a primary skin irritant. Prolonged or repeated contact may cause dermatitis. Contact dermatitis may occur in sensitive individuals under extreme and unusual conditions of prolonged and repeated contact, such as high exposure accompanied by elevated temperature and occlusion by clothing. This effect may be the result of the product's hygroscopic properties, abrasion, or pH. Respiratory Irritation: May cause nose, throat, and lung irritation. Dermal Toxicity: The LD50 in rabbits is > 2000 mg/Kg. Oral Toxicity The LD50 in rats is > 2000 mg/Kg. Based on data from components or similar materials. Swallowing material may cause irritation of the gastrointestinal lining, nausea, vomiting, diarrhoea, and abdominal pain. Dermal Sensitization: A human repeated insult patch test with 98 panellists gave a negative allergy response. Not expected to cause skin sensitization. Inhalation Sensitization: No data available to indicate product or components may be respiratory sensitizers. Carcinogenicity: Not listed as a carcinogen or suspect carcinogen by NTP, IARC or OSHA. Mutagenicity: No data available to indicate either product or components present at greater than 0.1% that may cause reproductive toxicity, mutagenicity, teratogenicity or genotoxicity. Inhalation not an likely exposure route in cosmetic products.

Chemical Substance: POLYGLYCERIN-3

CAS: 56090-54-1

EINECS 259-986-8

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.02566 No NOAEL Available

SED Child mg/kg bw/day: 0.09221 No NOAEL Available

SED Baby mg/kg bw/day: 0.26101 No NOAEL Available

Toxicological Summary:

Function: HUMECTANT. The ingredient is not listed on the prohibition list of the Cosmetic Regulation (EC) No. 1223/2009.

Chemical Substance: TOCOPHERYL ACETATE

EU INCI NAME:TOCOPHERYL ACETATE

CAS: 7695-91-2 / 58-95-7 Function: Antioxidant

EINECS 231-710-0 / 200-405-4 Boiling Point: 200-220

Appearance: Pale yellow viscous oil (HSDB, 2006)

Log Kow: 12 (estimated) (HSDB 2006)

Water Solubility: immiscible

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› Unclassified

EU CLP Harmonised Classification› Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.02566 MoS - Adult 60kg: 4870.1 NOAEL mg/kg bw day: 125

SED Child mg/kg bw/day: 0.09221 MoS - Child 16.7kg: 1355.5 NOAEL test method: oral study in rat

SED Baby mg/kg bw/day: 0.26101 MoS - Baby 5.9kg: 478.8

Toxicological Summary:

The ingredient is not acutely toxic, mutagenic, carcinogenic and reproductive toxicant. It is neither a skin irritant, eye irritant nor a skin sensitizer. It is not a photo sensitizer and not a bioaccumulative. (CIR Compendium 2012; HSDB, 2006; WHO, 1986; SCF, 2003). Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics when formulated to be non-irritating.

Chemical Substance: DISODIUM EDTA

EU INCI NAME:disodium EDTA

CAS: 139-33-3 / 6381-92-6 Function: Chelating/ Viscosity Controlling

EINECS 205-358-3

Appearance: powder

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› Xi R36-52/53

EU CLP Harmonised Classification› Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.02566	MoS - Adult 60kg: 26961.0	NOAEL mg/kg bw day: 692	
SED Child mg/kg bw/day: 0.09221	MoS - Child 16.7kg: 7504.1	NOAEL test method:	orally in diet
SED Baby mg/kg bw/day: 0.26101	MoS - Baby 5.9kg: 2651.1		

Toxicological Summary:

The ingredient is not acutely toxic by the oral route based on 5 acute oral toxicity studies in rats. However, it was acutely harmful in one acute oral toxicity study using mice. No information is readily available on its acute toxicity by dermal or inhalation routes. It is non skin or eye irritating and non skin sensitizing. EDTA and its salts including Disodium EDTA are classified as weak mutagens. In a variety of studies using bacteria, mammalian cells lines, and mammals, Disodium EDTA gave both positive and negative results. It has the potential to cause reproductive and developmental toxicity via zinc depletion. It is not carcinogenic and has no bioaccumulation potential. No information is readily available on the ingredient's phototoxicity. Any of the hazard effects of Disodium EDTA are related to metal deficiency and therefore would only be considered relevant human hazards where there is significant exposure (SIAP, 2012). Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics.

Chemical Substance: ARGININE

EU INCI NAME:ARGININE

CAS: 74-79-3 / 7200-25-1 Function: Antistatic/Hair & Skin Conditioning

EINECS 200-811-1 / 230-571-3

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.02053	No NOAEL Available
SED Child mg/kg bw/day: 0.07377	No NOAEL Available
SED Baby mg/kg bw/day: 0.20881	No NOAEL Available

Toxicological Summary:

Cosmetic Functions : Antistatic / Hair Conditioning / Masking / Skin Conditioning. An essential amino acid with low potential to cause irritancy or toxicity. It is unlikely to give rise to adverse effects when incorporated into a product.

Chemical Substance: ZINGIBER OFFICINALE ROOT OIL

EU INCI NAME:ZINGIBER OFFICINALE ROOT OIL

CAS: 8007-08-7 / 84696-15-1 Function: Masking/Tonic

EINECS 283-634-2

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› Xn R43-52/53-65

EU CLP Harmonised Classification› Skin Sens.1, Aqautic Chronic 2, Asp. Tox.1 .

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283	No NOAEL Available
SED Child mg/kg bw/day: 0.04610	No NOAEL Available
SED Baby mg/kg bw/day: 0.13050	No NOAEL Available

Toxicological Summary:

As supplied classified R43-52/53-65. Zingiber Officinale Oil is the volatile oil obtained from the dried rhizomes of the Ginger, Zingiber officinale L., Zingiberaceae 1(Commission Decision 2006/257/EC on amending Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products). Has GRAS status. When tested in humans at 5% showed no signs of allergy or irritancy. Has definite allergenic potential and the oils has provoked dermatitis in sensitised people. At levels of up to 0.17% in leave on products unlikely to contribute to the irritancy of a formulation. At levels below 0.17% the concentration of each sensitiser will be at least ten times lower that a concentration that has failed to produce skin sensitisation in humans. Components toxicity information indicated low acute oral and dermal toxicity (LD50: (rat) > 5000 mg/kg and LD50: (rabbit) > 5000 mg/kg) respectively.

Approved by the EU and USA for food flavouring (FEMA 2522) and as total food additives (21 CFR 182.20) and as food additives generally recognised as safe (GRAS) (21 CFR 182.20 classification 2 and 15). It contains about 90% hydrocarbons and is thus harmful: may cause lung damage if swallowed (classified R65) (MSDS from Earthoil Plantations Ltd., January 2010).

Chemical Substance: XANTHAN GUM

EU INCI NAME:XANTHAN GUM

CAS: 11138-66-2 Function: Binders / Emulsion stabilisers / Viscosity controlling agents

EINECS 234-394-2

Appearance: Cream coloured powder (JECFA,1999; CIR, 2012)

Water Solubility: Soluble (JECFA, 1999)

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› unclassified

EU CLP Harmonised Classification› unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283	MoS - Adult 60kg: 77922.0	NOAEL mg/kg bw day: 1000	
SED Child mg/kg bw/day: 0.04610	MoS - Child 16.7kg: 21688.3	NOAEL test method:	CD rats 104 weeks oral
SED Baby mg/kg bw/day: 0.13050	MoS - Baby 5.9kg: 7662.3		

Toxicological Summary:

The ingredient is not acutely toxic through the oral and inhalation routs. It is not an ocular or skin irritant and is not sensitizing. It is not carcinogenic, reprotoxic and does not bioaccumulate in the body. No information is readily available on the mutagenicity, dermal absorption/ percutaneous potential as well as the acute dermal toxicity of the ingredient. It should be noted that this ingredient has been approved by the EU and FDA as a food additive. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics

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Chemical Substance: SOPHORA FLAVESCENS ROOT EXTRACT

EU INCI NAME:SOPHORA FLAVESCENS ROOT EXTRACT

CAS: - Function: Antioxidant/Skin Conditioning/Anti- itch

EINECS -

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› Not applicable

EU CLP Harmonised Classification› Not applicable

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283	No NOAEL Available	NOAEL mg/kg bw day: -
SED Child mg/kg bw/day: 0.04610	No NOAEL Available	NOAEL test method: -
SED Baby mg/kg bw/day: 0.13050	No NOAEL Available	

Toxicological Summary:

The substance is not acutely toxic via oral route. It is not mutagenic toxic in Ames test. No available information for other toxicological end points for this substance. Sophora flavescens is a Traditional Chinese Medicine which has been widely used over many years without adverse effects reported. Chinese Pharmacopoeia suggest to extract 4.5-9 g dried material with water and apply on skin. It was also classified as Class 1 -Herbs that can be safely consumed when used appropriately in American Herbal Products Association's Botanical Safety Handbook (2nd Ed).

Chemical Substance: POLYSORBATE 20

EU INCI NAME:POLYSORBATE 20

CAS: 9005-64-5 Function: Emulsifier/Surfactant

EINECS 500-018-3

Log Kow: 4.23

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› unclassified

EU CLP Harmonised Classification› Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283	MoS - Adult 60kg: 38961.0	NOAEL mg/kg bw day: 500
SED Child mg/kg bw/day: 0.04610	MoS - Child 16.7kg: 10844.1	NOAEL test method: developmental toxicology test to SD rats
SED Baby mg/kg bw/day: 0.13050	MoS - Baby 5.9kg: 3831.1	

Toxicological Summary:

The ingredient is not acutely toxic via oral and dermal route, mutagenic, carcinogenic, a reproductive toxicant, bioaccumulative. The substances may not be classified as skin irritating and eye irritating based on available studies via weight of evidence according to CLP criteria. The current data are insufficient to make a conclusion for skin sensitization. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics when formulated to be non-irritating and non-sensitizing.

Chemical Substance: PHENOXYETHANOL

EU INCI NAME:PHENOXYETHANOL

CAS: 122-99-6 Function: preservatives

EINECS 204-589-7

Appearance: Liquid

Log Kow: 1.16

Cosmetic Regulatory Summary:

EU Cosmetics Status: Approved preservative

Regulatory Summary:

EU DSD/DPD Classification› R22-36

EU CLP Harmonised Classification› Acute Tox. 4; Eye Irrit. 2

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283	MoS - Adult 60kg: 64935.0	NOAEL mg/kg bw day: 500
SED Child mg/kg bw/day: 0.04610	MoS - Child 16.7kg: 18073.5	NOAEL test method: GLP 90-day repeated-dose sub-chronic dermal toxicity study
SED Baby mg/kg bw/day: 0.13050	MoS - Baby 5.9kg: 6385.2	

Toxicological Summary:

The ingredient is acutely harmful if swallowed. It is not acutely toxic by dermal routes. It is not carcinogenic, mutagenic, reproductive and is not phototoxic. The substance also has low bioaccumulation. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics.

Chemical Substance: PALMITOYL TRIPEPTIDE-1

CAS: 147732-56-7

EINECS -

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283	No NOAEL Available	
SED Child mg/kg bw/day: 0.04610	No NOAEL Available	
SED Baby mg/kg bw/day: 0.13050	No NOAEL Available	

Toxicological Summary:

Description: Palmitoyl Tripeptide-1 is the reaction product of palmitic acid and Tripeptide-1. Function: SKIN CONDITIONING. The ingredient is not listed on the prohibition list of the Cosmetic Regulation (EC) No. 1223/2009.

Chemical Substance: PALMITOYL TETRAPEPTIDE-7

EU INCI NAME:PALMITOYL TETRAPEPTIDE-7

CAS: polymer Function: Emollient/Hair & Skin Conditioning

EINECS polymer

Regulatory Summary:

EU DSD/DPD Classification› Not classified

EU CLP Harmonised Classification› Not classified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283 No NOAEL Available

SED Child mg/kg bw/day: 0.04610 No NOAEL Available

SED Baby mg/kg bw/day: 0.13050 No NOAEL Available

Toxicological Summary:

Manufacturers information indicates that the product is minimally irritating to skin or eyes, not a skin sensitiser, negative the the Ames test. Use in a cosmetic product should not present any problems.

Chemical Substance: LYCIUM BARBARUM FRUIT EXTRACT

CAS: 85085-46-7

EINECS 285-375-0

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283 No NOAEL Available

SED Child mg/kg bw/day: 0.04610 No NOAEL Available

SED Baby mg/kg bw/day: 0.13050 No NOAEL Available

Toxicological Summary:

Description: Lycium Barbarum Fruit Extract is an extract of the fruit of the Boxthorn, Lycium barbarum L., Solanaceae. Function: ASTRINGENT/HAIR CONDITIONING/SKIN CONDITIONING. The ingredient is not listed on the prohibition list of the Cosmetic Regulation (EC) No. 1223/2009.

Chemical Substance: HEXANEDIOL

EU INCI NAME:HEXANEDIOL

CAS: 629-11-8 / 26762-52-7 Function: Solvent

EINECS 211-074-0

Regulatory Summary:

EU DSD/DPD Classification› Unclassified

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283 No NOAEL Available

SED Child mg/kg bw/day: 0.04610 No NOAEL Available

SED Baby mg/kg bw/day: 0.13050 No NOAEL Available

Toxicological Summary:

May cause eye, skin, respiratory and digestive tracts irritation. Prolonged or repeated contact may cause in eczema. In a formulation at a low concentration, will not be expected to cause adverse effect.

Chemical Substance: ETHYLHEXYLGLYCERIN

EU INCI NAME:OCTOXYGLYCERIN

CAS: 70445-33-9 Function: Skin conditioning agent/ preservative

EINECS 408-080-2

Appearance: Solid

Log Kow: 2.4 +/- 0.55

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› R41-52/53

EU CLP Harmonised Classification› Eye Dam. 1

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283 MoS - Adult 60kg: 3896.1 NOAEL mg/kg bw day: 50

SED Child mg/kg bw/day: 0.04610 MoS - Child 16.7kg: 1084.4 NOAEL test method: subchronic oral toxicity study

SED Baby mg/kg bw/day: 0.13050 MoS - Baby 5.9kg: 383.1

Toxicological Summary:

This ingredient is not acutely toxic . May cause mild skin irritation. Undiluted ethylhexylglycerin causes serious eye damage; 5% aqueous solution of ethylhexylglycerin was mildly irritating to eyes. It is not sensitizing, mutagenic or reproductive toxic.

Chemical Substance: ECHINACEA PURPUREA EXTRACT

EU INCI NAME:ECHINACEA PURPUREA

CAS: 90028-20-9 Function: botanicals

EINECS 289-808-4

Regulatory Summary:

EU DSD/DPD Classification› Unclassified

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283 No NOAEL Available

SED Child mg/kg bw/day: 0.04610 No NOAEL Available

SED Baby mg/kg bw/day: 0.13050 No NOAEL Available

Toxicological Summary:

RTECS quotes that the extract has an LD50 (oral rat) >15g/kg with large im and iv LD50 values. Contains essential oils and echinacoside. Widely used as a herbal medicine with no obvious reports of adverse reaction. At the intended levels of use in a cosmetic product unlikely to cause irritancy or allergy.

Chemical Substance: DENDROBIUM NOBILE STEM EXTRACT

CAS: -
EINECS -

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283 No NOAEL Available
SED Child mg/kg bw/day: 0.04610 No NOAEL Available
SED Baby mg/kg bw/day: 0.13050 No NOAEL Available

Toxicological Summary:

Description: Dendrobium Nobile Stem Extract is the extract of the stems of Dendrobium nobile, Orchidaceae. Function: SKIN CONDITIONING. The ingredient is not listed on the prohibition list of the Cosmetic Regulation (EC) No. 1223/2009.

Chemical Substance: CARBOMER

EU INCI NAME:CARBOMER

CAS: 54182-57-9 / 9007-20-9 / 9003-01-4 / 76050-42-5 / 9062-04-8 / 9007-16-3 / 9007-17-4
EINECS polymer

Function: Thickener

Appearance: gel/powder

Cosmetic Regulatory Summary:

EU Cosmetics Status: May contain benzene whose use is prohibited by Saudi legislation. Should be analyzed to ensure that no benzene is present.

Regulatory Summary:

EU DSD/DPD Classification› unclassified

EU CLP Harmonised Classification› unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283 MoS - Adult 60kg: 7792.2 NOAEL mg/kg bw day: 100
SED Child mg/kg bw/day: 0.04610 MoS - Child 16.7kg: 2168.8 NOAEL test method: Chronic oral study
SED Baby mg/kg bw/day: 0.13050 MoS - Baby 5.9kg: 766.2

Toxicological Summary:

The ingredient is not acutely toxic by oral or dermal routes. It is considered to be acutely harmful by inhalation route. It is non to minimally skin irritating, non to moderately eye irritating, non phototoxic/non photo-allergic and has no to low potential for skin sensitization. It has a low bioaccumulation potential. No information is readily available on the ingredient's mutagenicity, carcinogenicity, reproductive/developmental toxicity or dermal/ percutaneous absorption. However, it has not been identified on any positive lists as having CMR potential (substitution of carcinogens, mutagens and reproductive toxins). In addition, being a large polymer, dermal absorption should not occur. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics.

Chemical Substance: CAPRYLYL GLYCOL

EU INCI NAME:CAPRYLYL GLYCOL

CAS: 1117-86-8
EINECS 214-254-7

Function: emollients / humectants

Appearance: liquid

Log Kow: 1.316 ± 0.215

Water Solubility: 4.4 g/l

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› Unclassified

EU CLP Harmonised Classification› Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283 MoS - Adult 60kg: 7792.2 NOAEL mg/kg bw day: 100
SED Child mg/kg bw/day: 0.04610 MoS - Child 16.7kg: 2168.8 NOAEL test method: 28 day oral study
SED Baby mg/kg bw/day: 0.13050 MoS - Baby 5.9kg: 766.2

Toxicological Summary:

The ingredient is not acutely toxic by oral, dermal or inhalation routes. It is non to severely dermal irritating, non to severely eye irritating and non skin sensitising. Caprylyl Glycol is non mutagenic/non genotoxic, non carcinogenic, non reproductive/non developmental toxic and non phototoxic or photosensitizing. It has no bioaccumulation potential. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics.

Chemical Substance: BISABOLOL

EU INCI NAME:BISABOLOL

CAS: 515-69-5 / 23089-26-1
EINECS 208-205-9 / 245-423-3

Function: Soothing
Skin Conditioning/Masking

Appearance: liquid

Log Kow: 5.070

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› unclassified

EU CLP Harmonised Classification› unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283 MoS - Adult 60kg: 15584.4 NOAEL mg/kg bw day: 200
SED Child mg/kg bw/day: 0.04610 MoS - Child 16.7kg: 4337.6 NOAEL test method: 200
SED Baby mg/kg bw/day: 0.13050 MoS - Baby 5.9kg: 1532.4

Toxicological Summary:

The ingredient is not acutely toxic by oral or inhalation routes. It was irritating to the skin in rats at concentration of 100%. However it was non skin irritating in a human clinical study at concentration of 5%. It is irritating to the eye and not a skin sensitizer. Bisabolol is non mutagenic/non genotoxic, non reproductive toxic/non developmental toxic, and non phototoxic/non photosensitizer. It has a high dermal/percutaneous absorption potential. No information is readily available on the ingredient's acute dermal toxicity, carcinogenicity or bioaccumulation potential. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics.

Chemical Substance: ALOE BARBADENSIS LEAF EXTRACT

EU INCI NAME:ALOE BARBADENSIS EXTRACT

CAS: 85507-69-3/ 8001-97-6

EINECS 287-390-8

Regulatory Summary:

EU DSD/DPD Classification› unclassified

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283	MoS - Adult 60kg: 155844.1	NOAEL mg/kg bw day: 2000
SED Child mg/kg bw/day: 0.04610	MoS - Child 16.7kg: 43376.6	
SED Baby mg/kg bw/day: 0.13050	MoS - Baby 5.9kg: 15324.6	

Toxicological Summary:

Cosmetic functions : Emollient / Humectant / Oral Care / Skin Conditioning / External Analgesic. Extract of aloe vera leaves. The plant is widely used in cosmetic products without adverse effects. Use of this extract is unlikely to cause problems. Aloe-derived material has fungicidal, antimicrobial, and antiviral activity, and has been effective in wound healing and infection treatment in animals. Aloe barbadensis (aka Aloe vera) derived ingredients were not toxic in acute oral studies using mice and rats. LD50 (mice) >200 mg/kg, LD50 (rat) >50 mg/kg, LD50 (dog) >50 mg/kg. In intravenous studies the LD50 using mice was >80 mg/kg, rats was >15 mg/kg, and dogs was >10 mg/kg. CIR concluded Aloe derived ingredients are safe if the anthraquinone levels in the ingredients do not exceed 50 ppm. Case reports include acute eczema, contact urticaria, and dermatitis in individuals who applied Aloe-derived ingredients topically. Aloe inner extract (gel) is not genotoxic in vitro or in vivo and; has an oral NOAEL greater than 2000 mg/kg bw/day following 90 days of oral exposure. (Regul Toxicol Pharmacol. 2010 Jun;57(1):90-8. Epub 2010 Jan 22)

Chemical Substance: SODIUM SILICATE

EU INCI NAME:SODIUM SILICATE

CAS: 1344-09-8

EINECS 215-687-4

Cosmetic Regulatory Summary:

Regulatory Summary:

EU DSD/DPD Classification› R36-37/38

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283	No NOAEL Available
SED Child mg/kg bw/day: 0.04610	No NOAEL Available
SED Baby mg/kg bw/day: 0.13050	No NOAEL Available

Toxicological Summary:

A strongly alkaline material used to adjust the pH of products. As supplied irritating to skin and eyes.
A final assessment have been conducted on Potassium Silicate, Sodium Metasilicate, and Sodium Silicate.
These are used as corrosion inhibitors in cosmetics and also as chelators and buffer. It is reported that sodium metasilicate is currently used at concentrations ranging from 13-18% and sodium silicate 0.3 -55%.
The silicate are also used in industrial cleaners such as detergents including laundry detergents. The corrosive properties of sodium silicate is determined by the molar ratio of SiO2:Na2O with the higher molar ratios being less alkaline. The toxicity is also related to the molar ratio.

Toxicological endpoints: LD50 (rat, oral) 847mg/kg-1349.3mg/kg (Sodium metasilicate).
Lesions reported in the oral cavity, pharynx, esophagus, stomach, larynx, lungs, and kidneys of dogs receiving 0.25 g/kg or more of a detergent containing sodium metasilicate.
Rats administered 464mg/kg of a 20% solution of varying ratios showed no signs of toxicity. 1000mg/kg and 2150mg/kg showed signs of gasping, dypsnea, and acute depression. Gross lesions observed in dogs (2.4 g/kg/day).

Dermal irritation ranged from negligible to severe depending on molar ratio and test species. Non sensitizing to the skin (LLNA) but delayed hyper sensitivity in mice.
Eye irritation (Potassium silicate) -: non irritating (rabbit). Sodium Metasilicate (42.4% H2O) - corrosive (rabbit). Overall the silicate ranged from severely irritating to the eye to non irritating in some studies.
Mutagenicity: (Sodium Metasilicate): non mutagenic in bacterial cells. Some effects observed with a reduced number of offspring in rats when silica was administered in drinking water.

Three adult rats injected intratesticularly and subcutaneously with 0.8 mM/kg of Sodium Silicate showed no morphological changes in the testes and no effect on the residual spermatozoa in the ductus deferens.
Human studies: (Sodium Metasilicate 37%)Effects of skin irritation observed on intact and abraded skin. Sodium silicate (6-13%) - non irritating to human skin. Also negative in HRIPT (10% of a 40% solution in water) but showed irritation in a cumulative study under normal use conditions.
The CIR panel supported their use in cosmetic products when formulated to reduce the effects of irritation whilst considering they already have GRAS status and the limited dermal absorption.
References:
Int J Toxicol. 2005;24 Suppl 1:103-17.
CIR Compendium 2010

Chemical Substance: CALCIUM SILICATE

EU INCI NAME:CALCIUM SILICATE

CAS: 1344-95-2 Function: absorbents / opacifiers / viscosity controlling agents

EINECS 215-710-8

Cosmetic Regulatory Summary:

EU Cosmetics Status:

Regulatory Summary:

EU DSD/DPD Classification› unclassified

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01283	No NOAEL Available
SED Child mg/kg bw/day: 0.04610	No NOAEL Available
SED Baby mg/kg bw/day: 0.13050	No NOAEL Available

Toxicological Summary:

This material may cause physical irritation to the eyes, nose and upper respiratory tract, as well dryness to the skin following prolonged contact. However the material is of a size unlikely to be inhaled.

Chemical Substance: SODIUM HYALURONATE

EU INCI NAME:SODIUM HYALURONATE

CAS: 9067-32-7 Function: Humectant / Skin Conditioning

EINECS -

Appearance: powder

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> unclassified

EU CLP Harmonised Classification> unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.00770	MoS - Adult 60kg: 7792.2	NOAEL mg/kg bw day: 60	
SED Child mg/kg bw/day: 0.02766	MoS - Child 16.7kg: 2168.8	NOAEL test method:	Reproductive / Developmental Toxicity study
SED Baby mg/kg bw/day: 0.07830	MoS - Baby 5.9kg: 766.2		

Toxicological Summary:

The ingredient is not acutely toxic via oral, a skin irritant, an eye irritant, a skin sensitizer, mutagenic, a reproductive toxicant, No enough information about the carcinogenic, bioaccumulative and phototoxic. Hyaluronic acid does not penetrate the skin.Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics.

Note: In the absence of NOAEL data, the Margin of Safety (MoS) has not been calculated.
Unless otherwise determined and in the absence of literature or other experimental data, a Dermal Absorption (DAp) of 100% is taken as the worst case scenario.
NOAEL: No Observed Adverse Effect Level; MoS: Margin of Safety; SED Systemic Exposure Dosage
Calculation of Margin of Safety: MoS = NOAEL / SED

Reference for skin surface area, exposures and application quantities are derived from:

1. RIVM Report 320104001/2006
2. References sited in Dermal Sensitization Quantitative Risk Assessment (QRA) For Fragrance Ingredients, 2006 revision
3. Exposure factors handbook 2009 Update
4. The SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 10th Revision SCCS/1501/12
5. Colipa Data SCCNFP/0321/02
6. McNamara et al, Food Chem. Tox; 2007, 45, 2086
7. Loretz et al, Food Chem. Tox; 2008, 46, 1516
N.B. Exposure times have been taken from RIVM Report 320104001/2006
8. Body weights taken from Exposure factors handbook 2009 Update and mean values have been used unless specified otherwise
9. ConsExpo database
10. New default values for the spray model, RIVM, March 2010

This formulation has been safety assessed by Intertek with reference to Articles 3 and 10 of Cosmetic Regulation (EC) No. 1223/2009. The safety assessment is based on the chemical specification and toxicological profile of the ingredients as supplied at the time of assessment.
The supplier to this safety assessment is advised to ask for a new safety evaluation if any change in formulation occurs, change in raw materials used, abnormally high number of adverse events are recorded, changes in recommended uses or other circumstances that may affect the safety of this product.

The REACH dossier, IUCLID Datasheet, OECD SIDS and EU RAR often include unpublished data, not otherwise available; however, it must be noted that the authorities have issued legal disclaimers for the databases. The declaimer, among other cautions, stressed that the data in the dossier, datasheet, data set or report are not necessarily comprehensive, complete, accurate or up-to-date. Use of the data may also be subject to copyright laws. Therefore, data from the such resource are used as supporting information.

Appendixes of Cosmetic Product Safety Report

For

[SQT Anti-Aging Rejuvenation Set-

SQT Biomicroneedling Firming Cream]

The testing report, declaration letter, SDS/MSDS, TDS, CoA, IFRA Certificate and other supportive document listed in this appendix were provided from client and delivered to risk assessor to conduct the CPSR, it is supplier' s responsibility to make sure the accuracy of the documents.

Appendix 1- Toxicological Profiles of Substances

1. *Toxicity summary*
2. *MSDS/SDS*
3. *TDS/CoA*

Appendix 2- Microbiological Quality Test Report of Cosmetic Product

1. *Microbiological specification test report or data*
2. *Preservative challenge test report or data*

Appendix 3- Stability Test Report or Data of Cosmetic Product

Appendix 4- Packaging Compatibility Test Report and/or data

1. *Container data*
2. *Outer Packaging material*

Appendix 5- Serious/ Undesirable Effects of Cosmetic Product Declaration or Report

Appendix 6- Fragrance

1. *IFRA Certificate*
2. *MSDS/SDS*
3. *Allergen declaration*

Appendix 7- Heavy Metal Test Report of Cosmetic Product

Appendix 8- Human Volunteers Studies

1. *Human volunteers study for the cosmetic product*
2. *Human volunteers study for raw material*

Appendix 9- Assessor's credentials

Appendix 1- Toxicological Profiles of Substances

1. Toxicity summary

Substance toxicological summary was listed in this report and detailed data are stored in Intertek owned in house database, could provide on specific request.

2. MSDS/SDS

See below report(s) if available

3. TDS/CoA

See below report(s) if available

MATERIAL SAFETY DATA SHEET

(SQT Anti-Aging Rejuvenation Set)

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Identification of the substance or preparation:

Product Name: SQT Anti-Aging Rejuvenation Set
Use of the substance/preparation: Cosmetic additives

Company identification:

Manufactured By: Hunan Sunshine Bio-Tech Co., Ltd
Unit 1, E7 building, No. 27
Wenxuan Road, High-Tech Development Zone
Changsha 410000, P.R.of China
Phone Number: 86-731-83991999
Email: info@sunshineextract.com

2. HARZARDOUS IDENTIFICATION

Potential Acute Health Effects:

Hazardous in case of eye contact (irritant), of ingestion, of inhalation. Slightly hazardous in case of skin contact (irritant, permeator).

Potential Chronic Health Effects:

CARCINOGENIC EFFECTS: Not available.

MUTAGENIC EFFECTS: Not available.

TERATOGENIC EFFECTS: Not available.

DEVELOPMENTAL TOXICITY: Not available.

3. COMPOSITION/INFORMATION ON INGREDIENT

Chemical Identity: karnosin
Purity: 99%
ELINCS #: N/A
CAS#: 14808-60-7

4. FIRST AID MEASURES

Inhalation: Move person to fresh air immediately.

Eye Contact: Irrigate surfaces thoroughly with water

Skin Contact: Rinse areas thoroughly with water

Ingestion: Rinse mouth thoroughly with water

5. FIRE FIGHTING MEASURES

Special Fire Fighting Procedures: Ordinary extinguishing process can be taken in case of fire.

Extinguishing Media: No prohibited media.

Protection for the person-related fire fighting: Wear or use normal protective equipment. No special clothing or equipment is required.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions

Avoid dust formation.

Environmental precautions

Do not let product enter drains.

Methods for cleaning up

Sweep up and shovel. Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

Handling: Once the container is opened it should be used promptly, as coloration and decomposition may occur by moisture absorption.

Storage: Storage below room temperature preferred. Store tightly closed in cool, dry, dark and ventilated conditions to maintain the quality for long period.

8. EXPOSURE CONTROL PERSONAL PROTECTION

Desirable Concentration: Not established

Acceptable Concentration: Not established

Facility Care: No special care required

Protective Care: Not necessary during usual handling

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: white powder

Odor: Characteristic

Taste: Characteristic

Color: white powder

Critical Temperature: Not available.

Specific Gravity: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: Not available.

Solubility: Very slightly soluble in cold water.

10. STABILITY AND REACTIVITY

Stability: The product is stable.
Instability Temperature: Not available.
Conditions of Instability: Excess heat, incompatible materials
Incompatibility with various substances: Reactive with oxidizing agents.
Corrosivity: Non-corrosive in presence of glass.
Special Remarks on Reactivity: Not available.
Special Remarks on Corrosivity: Not available.
Polymerization: Will not occur.

11. TOXICOLOGICAL INFORMATION

Routes of Entry: Eye contact. Inhalation. Ingestion.
Toxicity to Animals:
LD50: Not available. LC50: Not available.
Chronic Effects on Humans: The substance is toxic to lungs, mucous membranes.
Other Toxic Effects on Humans:
Hazardous in case of ingestion, of inhalation. Slightly hazardous in case of skin contact (irritant, permeator).
Special Remarks on Toxicity to Animals: Not available.
Special Remarks on Chronic Effects on Humans: Not available.
Special Remarks on other Toxic Effects on Humans: Not available.

12. ECOLOGICAL INFORMATION

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The products of degradation are less toxic than the product itself.

Special Remarks on the Products of Biodegradation: Not available.

13. DISPOSAL CONSIDERATION

Disposal Method:

Disposal should be made in accordance with federal, state and local regulation.

Contaminated packaging

Dispose of as unused product.

14. TRANSPROT INFORMATION

DOT (US)

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

15. REGULATORY INFORMATION

The Law Concerning the Examination and Regulation of Manufacture etc. of Chemical Substances

- The Pharmaceutical Affairs Law

16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. HUNAN SUNSHINE BIO-TECH CO., LTD shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.

Updated Jan.1, 2022

End of MSDS

Appendix 2- Microbiological Quality Test Report of Cosmetic Product

1. Microbiological specification test report or data

See below report(s) if available

2. Preservative challenge test report or data

See below report(s) if available

Test Report Number: GZHH00472057

Applicant: Hunan Sunshine Bio-Tech Co., Ltd
Building E7, Lugu Yuyuan, No.27, Wenxuan Road, High-Tech Development Zone, Changsha, Hunan, China, 410000

Date: Nov 01, 2022

Sample Description:

One (1) style of submitted sample said to be :

Item Name	:	**SQT Anti-Aging Rejuvenation Set.**
Country of Origin	:	China.
Date Sample Received	:	Oct 20, 2022
Testing Period	:	Oct 20, 2022 to Nov 01, 2022

****

Tests conducted:

As requested by the applicant, refer to attached page(s) for details.

****

Conclusion:

Tested Sample	Standard	Result
Tested component(s) of submitted sample(s)	The European Cosmetic Regulation (EC) No.1223/2009 Annex I Part A 3, Microbiological control criteria of the cosmetic products.	Pass
	With reference to the Notification of the German Federal Health Office Centre (BGA) up to 1996 on toxic elements analysis for cosmetics	Meet

****

Intertek GM Testing Service Zhuhai Co. Ltd.

Maggie Liu
Technical Supervisor
Healthcare and Beauty Products

Intertek GM Testing Service Zhuhai Co. Ltd.
珠海天祥粤澳质量技术服务有限公司

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中国珠海市横琴新区环岛北路 2682 号粤澳合作中医药科技产业园研发检测大楼 601，519031

Tel:+86756 2167557
www.intertek.com.cn
www.intertek.com

Test Report Number: GZHH00472057

Tests Conducted

1 Microbiological examination of non-sterile products : Microbial Enumeration Tests and tests for specified microorganisms of submitted sample

With reference to British Pharmacopoeia (2020), Appendix XVI B2 & B1 and European Pharmacopoeia 10.0 Edition, Chapter 2.6.12 & 2.6.13.

Test Item		Result		Limit
		(1)	(2)	
(I)	Total Aerobic Microbial Count (per g)	＜10 CFU#	＜10 CFU#	Category (B): (I) + (II) should be ≤1,000 CFU
(II)	Moulds and Yeasts Count (per g)	＜10 CFU#	＜10 CFU#	
(III)	*Escherichia coli* (per g)	Absence	Absence	Absence
(IV)	*Pseudomonas aeruginosa* (per g)	Absence	Absence	Absence
(V)	*Staphylococcus aureus* (per g)	Absence	Absence	Absence
(VI)	*Candida albicans* (per g)	Absence	Absence	Absence
(VII)	Bile-Tolerant Gram-Negative Bacteria (per g)	Absence	Absence	-
(VIII)	*Salmonella sp.* (per 10g)	Absence	Absence	-
(IX)	*Clostridia sp.* (per g)	Absence	Absence	-

Test Item		Result		Limit
		(3)	(4)	
(I)	Total Aerobic Microbial Count (per g)	＜10 CFU#	＜10 CFU#	Category (B): (I) + (II) should be ≤1,000 CFU
(II)	Moulds and Yeasts Count (per g)	＜10 CFU#	＜10 CFU#	
(III)	*Escherichia coli* (per g)	Absence	Absence	Absence
(IV)	*Pseudomonas aeruginosa* (per g)	Absence	Absence	Absence
(V)	*Staphylococcus aureus* (per g)	Absence	Absence	Absence
(VI)	*Candida albicans* (per g)	Absence	Absence	Absence
(VII)	Bile-Tolerant Gram-Negative Bacteria (per g)	Absence	Absence	-
(VIII)	*Salmonella sp.* (per 10g)	Absence	Absence	-
(IX)	*Clostridia sp.* (per g)	Absence	Absence	-

****

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Test Report Number: GZHH00472057

Tests Conducted

Test component(s):
(1) White cream (4-1)
(2) Yellow liquid (4-2)
(3) Transparent liquid attached to white non-woven cloth (4-3)
(4) White cream (4-4)

Remark :

#	=	No colony was detected at the one-tenth dilution of the sample
CFU	=	Colony Forming Unit
<	=	Less than
≤	=	Less than or equal to

The limit for test item (I) and (II) is with reference to the notes of guidelines on microbiological quality of the finished cosmetic products adopted by Scientific Committee on Consumer Safety (SCCS, 11th Rev., 2021) of the European Commission, Microbiological Quantitative Limits for Category B Cosmetic Products.

Category A: Cosmetic products specifically intended for children under 3 years, eye area and mucous membranes.
Category B: Other cosmetic products.

Sample received condition: sample (1)、(2)、(4) in closed bottle, sample (3) in unopened container.

****

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Test Report Number: GZHH00472057

Tests Conducted

2 Toxic Element Analysis (Cosmetics)

Acid digestion for Antimony (Sb), Arsenic (As), Cadmium (Cd), Lead (Pb) and Mercury (Hg) and perspiration simulant extraction for Soluble Nickel (Ni), follow by Inductively Coupled Plasma Mass Spectrometry analysis.

Element	Result (ppm) Test component(s)				Reporting Limit (ppm)	Limit# (ppm)
	(1)	(2)	(3)	(4)		
Total Antimony (Sb)	ND	ND	ND	ND	0.1	10
Total Arsenic (As)	ND	ND	ND	ND	0.1	5
Total Cadmium (Cd)	ND	ND	ND	ND	0.1	5
Total Lead (Pb)	ND	ND	ND	ND	0.1	20
Total Mercury (Hg)	ND	ND	ND	ND	0.1	1
Soluble Nickel (Ni)	ND	ND	ND	ND	0.1	10

Test component(s):
(1) White cream (4-1)
(2) Yellow liquid (4-2)
(3) Transparent liquid attached to white non-woven cloth (4-3)
(4) White cream (4-4)

Remark :
ppm = parts per million = mg/kg
# = The limit is with reference to the Notification of the German Federal Health Office (BGA), Pg 28, No. 7, July 1985 and No. 7/1992 and No. 4/1996 for cosmetics
ND = Not detected (less than reporting limit)

****

End of report

Intertek GM Testing Service Zhuhai Co. Ltd.
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Appendix 3- Stability Test Report or Data of Cosmetic Product

See below report(s) if available

SQT Anti-Aging Rejuvenation Set Stability Test Report

Inspection number：CP2022070310

Product Name	SQT Biomicroneedling Firming Cream	Batch Number	2526C16161
Specification	5g/vial	Source	Production Department
Representative Amount	10419 vials	Sampling Date	July 03, 2022
Sampling Amount	10 vials	Report Date	October 25, 2022
Inspection Purpose	Finished product inspection	Testing Basis	QB/T 1857

Test items	Standard Regulation	0 week	2 week	4 weeks	6 weeks	8 weeks	12 weeks	16 weeks
Appearance	Cream	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Odor	Odorless	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Colour	White	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Packaging materials	brown glass bottle	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Heat resistance	At (40+1)°C ,no oil-water separation after return to room temperature.	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Cold resistance	At (5+1)°C, no significant differences in traits after return to room temperature.	Comply	Comply	Comply	Comply	Comply	Comply	Comply
PH	4.0-8.5	6.7	6.5	6.6	6.8	6.7	6.8	6.7
Net content	Should comply with the regulations	Comply	Comply	Comply	Comply	Comply	Comply	Comply

Total number of colonies	≤ 1000CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g
Total Mold and Yeast	≤ 100CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g
Conclusion	This product was tested according to QB/T 1857 and the results were in accordance with the regulations.							

Head of Quality ： Phil　　Reviewer：Peter　　Inspector：Adam

Inspection number：CP2022070311

Product Name	SQT Firming Rejuvenation Essence	Batch Number	2526B16151
Specification	5ml/vial	Source	Production Department
Representative Amount	10367 vials	Sampling Date	July 03, 2022
Sampling Amount	4 vials	Report Date	October 25, 2022
Inspection Purpose	Finished product inspection	Testing Basis	QB/T 2660

Test items	Standard Regulation	0 week	2 week	4 weeks	6 weeks	8 weeks	12 weeks	16 weeks
Appearance	Liquid	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Odor	Odorless	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Colour	Pale yellow	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Packaging materials	Brown glass vial	Comply	Comply	Comply	Comply	Comply	Comply	Comply

Heat resistance	At (40+1)°C , no significant differences in traits after return to room temperature.	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Cold resistance	At (5+1)°C, no significant differences in traits after return to room temperature.	Comply	Comply	Comply	Comply	Comply	Comply	Comply
PH	4.0-8.5	6.7	6.8	6.9	6.7	6.9	6.6	6.7
Net content	Should comply with the regulations	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Total number of colonies	≤ 1000CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g
Total Mold and Yeast	≤ 100CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g
Conclusion	This product was tested according to QB/T 2660 and the results were in accordance with the regulations.							

Head of Quality ： Phil　　Reviewer：Peter　　Inspector：Adam

Inspection number：CP2022070312

Product Name	SQT Firming Repairing Mask	Batch Number	2527A15301
Specification	28ml/Piece	Source	Production Department
Representative Amount	10568 pieces	Sampling Date	July 03, 2022
Sampling Amount	4 pieces	Report Date	October 25, 2022
Inspection Purpose	Finished product inspection	Testing Basis	QB/T 2872

Test items	Standard Regulation	0 week	2 week	4 weeks	6 weeks	8 weeks	12 weeks	16 weeks
Appearance	Moist fiber film, free from impurities	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Odor	Odorless	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Colour	Colorless	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Packaging materials	Clear facial mask bag	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Heat resistance	At (40+1)°C , no significant differences in traits after return to room temperature.	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Cold resistance	At (5+1)°C, no significant differences in traits after return to room temperature.	Comply	Comply	Comply	Comply	Comply	Comply	Comply
PH	4.0-8.5	5.9	6.1	6.0	6.0	5.9	6.1	5.9
Net content	Should comply with the regulations	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Total number of colonies	≤ 1000CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g
Total Mold and Yeast	≤ 100CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g
Conclusion	This product was tested according to QB/T 2872 and the results were in accordance with the regulations.							

Head of Quality ： Phil　　Reviewer：Peter　　Inspector：Adam

Inspection number：CP2022070313

Product Name	SQT Firming Rejuvenation Cream	Batch Number	2526B26151
Specification	5g/vial	Source	Production Department
Representative Amount	10435 vials	Sampling Date	July 03, 2022
Sampling Amount	10 vials	Report Date	October 25, 2022
Inspection Purpose	Finished product inspection	Testing Basis	QB/T 1857

Test items	Standard Regulation	0 week	2 week	4 weeks	6 weeks	8 weeks	12 weeks	16 weeks
Appearance	Cream	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Odor	Odorless	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Colour	White	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Packaging materials	Brown glass vial	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Heat resistance	At (40+1)°C , no oil-water separation after return to room temperature.	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Cold resistance	At (5+1)°C, no significant differences in traits after return to room temperature.	Comply	Comply	Comply	Comply	Comply	Comply	Comply
PH	4.0-8.5	6.9	7.0	6.8	6.7	6.9	6.9	6.9
Net content	Should comply with the regulations	Comply	Comply	Comply	Comply	Comply	Comply	Comply
Total number of colonies	≤ 1000CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g

Total Mold and Yeast	≤ 100CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g	<10CFU/g
Conclusion	This product was tested according to QB/T1857 and the results were in accordance with the regulations.							

Head of Quality ： Phil　　Reviewer：Peter　　Inspector：Adam

Appendix 4- Packaging Compatibility Test Report and/or data

1. Container data

1.1 Basic information

No detail information was provided

2. Outer Packaging material

See below report(s) if available

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Test Report Number: GZHH00472085

Applicant: Hunan Sunshine Bio-Tech Co., Ltd
Building E7, Lugu Yuyuan, No.27, Wenxuan Road, High-Tech Development Zone, Changsha, Hunan, China, 410000

Date: Oct 28, 2022

Sample Description:

One (1) style of submitted sample said to be :

Item Name	:	(**1) 5g brown soda lime glass bottle** **(2) PP clear inner plug.**
Country of Origin	:	China.
Date Sample Received	:	Oct 20, 2022
Testing Period	:	Oct 20, 2022 to Oct 28, 2022

****

Tests conducted:

As requested by the applicant, refer to attached page(s) for details.

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Conclusion:

Tested Sample	Standard	Result
Tested component(s) of submitted sample(s)	Heavy Metals Content Requirement in Directive 94/62/EC and amendments on packaging and packaging waste	Pass

****

Intertek GM Testing Service Zhuhai Co. Ltd.

Maggie Liu
Technical Supervisor
Healthcare and Beauty Products

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Test Report Number: GZHH00472085

Tests Conducted

1 Toxic Elements Analysis

Alkaline digestion method was used and Hexavalent Chromium was determined by UV-Visible Spectrophotometry; Acid digestion method was used and Lead, Cadmium and Mercury were determined by Inductively Coupled Plasma Mass Spectrometry.

Element	Result (ppm) Tested Component		Detection Limit (ppm)	Limit (ppm)
	(1)	(2)		
Lead (Pb)	ND	ND	5	--
Cadmium (Cd)	ND	ND	5	--
Mercury (Hg)	ND	ND	5	--
Chromium VI (Cr (VI))	ND	ND	1	--
Sum of Pb, Cd, Hg and Cr (VI)	ND	ND	--	100

Tested Component(s):
(1) Brown glass bottle
(2) Translucent plastic inner plug

ppm = part per million = mg/kg
ND = Not detected (less than detection limit)

Remark: Only detected element(s) is / are included in calculation of the sum.

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End of report

Intertek GM Testing Service Zhuhai Co. Ltd.
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Appendix 5- Serious/ Undesirable Effects of Cosmetic Product Declaration or Report

See below report(s) if available

LETTER OF DECLARATION

To Whom It May Concern:

Product Name: SQT Anti-Aging Rejuvenation Set

Product: SQT Biomicroneedling Firming Cream

Chemical Name	Trade Name	Concentration (%)
AQUA	AQUA	53.66-58.74
GLYCERIN	GLYCERIN	6-6.6
PROPANEDIOL	PROPANEDIOL	5-5.5
HYDROLYZED SPONGE	HYDROLYZED SPONGE	5
CALCIUM SILICATE	CALCIUM SILICATE	
SODIUM SILICATE	SODIUM SILICATE	
C13-15 ALKANE	C13-15 ALKANE	4.5-5.0
ISONONYL ISONONANOATE	ISONONYL ISONONANOATE	4-4.5
AQUA	AQUA	3-3.3
GLYCERIN	GLYCERIN	
SODIUM ACRYLIC ACID/MA COPOLYMER	SODIUM ACRYLIC ACID/MA COPOLYMER	
BUTYLENE GLYCOL	BUTYLENE GLYCOL	
CAPRYLYL GLYCOL	CAPRYLYL GLYCOL	
HEXANEDIOL	HEXANEDIOL	
CETEARYL ALCOHOL	CETEARYL ALCOHOL	2-2.2
DIMETHICONE	DIMETHICONE	1.5-1.65
GLYCERYL STEARATE	GLYCERYL STEARATE	1.35-1.5
PEG-100 STEARATE	PEG-100 STEARATE	
RICE FERMENT FILTRATE (SAKE)	RICE FERMENT FILTRATE (SAKE)	1.4-1.54
HYDROXYACETOPHENONE	HYDROXYACETOPHENONE	
1,2-HEXANEDIOL	1,2-HEXANEDIOL	
BUTYLENE GLYCOL	BUTYLENE GLYCOL	
THEOBROMA GRANDIFLORUM SEED BUTTER	THEOBROMA GRANDIFLORUM SEED BUTTER	1.2-1.32
SILICA	SILICA	1-1.1
INOSITOL	INOSITOL	1-1.1
JOJOBA ESTERS	JOJOBA ESTERS	0.8-0.88

HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX	HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX	
ACACIA DECURRENS FLOWER WAX	ACACIA DECURRENS FLOWER WAX	
POLYGLYCERIN-3	POLYGLYCERIN-3	
GLYCERYL CAPRYLATE	GLYCERYL CAPRYLATE	
CAPRYLHYDROXAMIC ACID	CAPRYLHYDROXAMIC ACID	
HYDROXYACETOPHENONE	HYDROXYACETOPHENONE	0.8-0.88
BUTYLENE GLYCOL	BUTYLENE GLYCOL	
AQUA	AQUA	
DIMETHICONE	DIMETHICONE	0.5-0.55
GLYCERYL STEARATE SE	GLYCERYL STEARATE SE	0.5-0.55
AQUA	AQUA	
GLYCERIN	GLYCERIN	
DENDROBIUM NOBILE STEM EXTRACT	DENDROBIUM NOBILE STEM EXTRACT	
ALOE BARBADENSIS LEAF EXTRACT	ALOE BARBADENSIS LEAF EXTRACT	
SOPHORA FLAVESCENS ROOT EXTRACT	SOPHORA FLAVESCENS ROOT EXTRACT	0.5-1
LYCIUM BARBARUM FRUIT EXTRACT	LYCIUM BARBARUM FRUIT EXTRACT	
ECHINACEA PURPUREA EXTRACT	ECHINACEA PURPUREA EXTRACT	
PHENOXYETHANOL	PHENOXYETHANOL	
ETHYLHEXYLGLYCERIN	ETHYLHEXYLGLYCERIN	
GLYCERIN	GLYCERIN	
AQUA	AQUA	
BUTYLENE GLYCOL	BUTYLENE GLYCOL	
CARBOMER	CARBOMER	
POLYSORBATE 20	POLYSORBATE 20	0.5-1
PALMITOYL TRIPEPTIDE-1	PALMITOYL TRIPEPTIDE-1	
PALMITOYL TETRAPEPTIDE-7	PALMITOYL TETRAPEPTIDE-7	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER	AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER	0.26-0.36
BUTYROSPERMUM PARKII (SHEA) BUTTER	BUTYROSPERMUM PARKII (SHEA) BUTTER	0.2-0.3
CARNOSINE	CARNOSINE	0.2-0.3

STEARETH-21	STEARETH-21	0.15-0.165
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER	ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER	0.12-0.15
TOCOPHERYL ACETATE	TOCOPHERYL ACETATE	0.1-0.2
DISODIUM EDTA	DISODIUM EDTA	0.1-0.2
BISABOLOL	BISABOLOL	0.1-0.2
ZINGIBER OFFICINALE (GINGER) ROOT OIL	ZINGIBER OFFICINALE (GINGER) ROOT OIL	
ARGININE	ARGININE	0.08-0.088
XANTHAN GUM	XANTHAN GUM	0.05-0.055
SODIUM HYALURONATE	SODIUM HYALURONATE	0.03-0.033

Product: SQT Firming Rejuvenation Essence

Chemical Name	Trade Name	Concentration (%)
AQUA	AQUA	45.8-62.78
GLYCERIN	GLYCERIN	8-11
AQUA	AQUA	8-11
GLYCERIN	GLYCERIN	
GLYCERYL POLYMETHACRYLATE	GLYCERYL POLYMETHACRYLATE	
PROPYLENE GLYCOL	PROPYLENE GLYCOL	
PVM/MA COPOLYMER	PVM/MA COPOLYMER	
METHYLPARABEN	METHYLPARABEN	
PROPYLPARABEN	PROPYLPARABEN	
BUTYLENE GLYCOL	BUTYLENE GLYCOL	5-6
PROPANEDIOL	PROPANEDIOL	4-5
DIPEPTIDE DIAMINOBUTYROYL BENZYLAMIDE DIACETATE	DIPEPTIDE DIAMINOBUTYROYL BENZYLAMIDE DIACETATE	3-5
BUTYLENE GLYCOL	BUTYLENE GLYCOL	
PENTYLENE GLYCOL	PENTYLENE GLYCOL	
AQUA	AQUA	
AQUA	AQUA	2.5-4
PROPANEDIOL	PROPANEDIOL	
FIBRONECTIN	FIBRONECTIN	
GLYCERIN	GLYCERIN	
DISODIUM PHOSPHATE	DISODIUM PHOSPHATE	
SODIUM PHOSPHATE	SODIUM PHOSPHATE	

PEG/PPG/POLYBUTYLENE GLYCOL-8/5/3 GLYCERIN	PEG/PPG/POLYBUTYLENE GLYCOL-8/5/3 GLYCERIN	2-4
GLYCERIN	GLYCERIN	2-3
AQUA	AQUA	
BUTYLENE GLYCOL	BUTYLENE GLYCOL	
CARBOMER	CARBOMER	
POLYSORBATE 20	POLYSORBATE 20	
PALMITOYL TRIPEPTIDE-1	PALMITOYL TRIPEPTIDE-1	
PALMITOYL TETRAPEPTIDE-7	PALMITOYL TETRAPEPTIDE-7	
CAPRYLHYDROXAMIC ACID	CAPRYLHYDROXAMIC ACID	0.8-1.0
ETHYLHEXYLGLYCERIN	ETHYLHEXYLGLYCERIN	
1,2-HEXANEDIOL	1,2-HEXANEDIOL	
PROPYLENE GLYCOL	PROPYLENE GLYCOL	
AQUA	AQUA	
BACILLUS/SOYBEAN FERMENT EXTRACT	BACILLUS/SOYBEAN FERMENT EXTRACT	0.5-0.8
AQUA	AQUA	
BUTYLENE GLYCOL	BUTYLENE GLYCOL	
FOLIC ACID	FOLIC ACID	
1,2-HEXANEDIOL	1,2-HEXANEDIOL	
SODIUM HYALURONATE	SODIUM HYALURONATE	
LACTOBACILLUS/BEAN SEED EXTRACT/SODIUM GLUTAMATE FERMENT FILTRATE	LACTOBACILLUS/BEAN SEED EXTRACT/SODIUM GLUTAMATE FERMENT FILTRATE	0.5-0.8
BUTYLENE GLYCOL	BUTYLENE GLYCOL	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER	AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER	0.1-0.3
CARNOSINE	CARNOSINE	0.2-0.4
HYDROLYZED SODIUM HYALURONATE	HYDROLYZED SODIUM HYALURONATE	0.15-0.3
SODIUM HYALURONATE	SODIUM HYALURONATE	0.1-0.3
CENTELLA ASIATICA EXTRACT	CENTELLA ASIATICA EXTRACT	0.1-0.3
BETA-GLUCAN	BETA-GLUCAN	0.1-0.3
XANTHAN GUM	XANTHAN GUM	0.05-0.2
HYDROLYZED SCLEROTIUM GUM	HYDROLYZED SCLEROTIUM GUM	0.05-0.2

CITRIC ACID	CITRIC ACID	0.03-0.1
SODIUM POLYGLUTAMATE	SODIUM POLYGLUTAMATE	0.02-0.1
SODIUM HYALURONATE	SODIUM HYALURONATE	0.02-0.1

Product: SQT Firming Repair Mask

Chemical Name	Trade Name	Concentration (%)
AQUA	AQUA	81.6-91.55
GLYCERIN	GLYCERIN	5-10
AQUA	AQUA	1-2
PROPANEDIOL	PROPANEDIOL	
FIBRONECTIN	FIBRONECTIN	
GLYCERIN	GLYCERIN	
DISODIUM PHOSPHATE	DISODIUM PHOSPHATE	
SODIUM PHOSPHATE	SODIUM PHOSPHATE	
BETA-GLUCAN	BETA-GLUCAN	1-2
AQUA	AQUA	
1,2-HEXANEDIOL	1,2-HEXANEDIOL	
HYDROXYACETOPHENONE	HYDROXYACETOPHENONE	
PANTHENOL	PANTHENOL	0.5-2
CAPRYLHYDROXAMIC ACID	CAPRYLHYDROXAMIC ACID	0.5-1
ETHYLHEXYLGLYCERIN	ETHYLHEXYLGLYCERIN	
1,2-HEXANEDIOL	1,2-HEXANEDIOL	
PROPYLENE GLYCOL	PROPYLENE GLYCOL	
AQUA	AQUA	
XANTHAN GUM	XANTHAN GUM	0.1-0.3
TREMELLA FUCIFORMIS SPOROCARP EXTRACT	TREMELLA FUCIFORMIS SPOROCARP EXTRACT	0.1-0.3
CARBOXYMETHYL CHITOSAN	CARBOXYMETHYL CHITOSAN	0.1-0.3
SODIUM POLYGLUTAMATE	SODIUM POLYGLUTAMATE	0.1-0.3
HYDROLYZED SODIUM HYALURONATE	HYDROLYZED SODIUM HYALURONATE	0.05-0.2

Product: SQT Firming Rejuvenation Cream

Chemical Name	Trade Name	Concentration (%)
AQUA	AQUA	40.72-54.15

GLYCERIN	GLYCERIN	5.0-5.5
CANDELILLA/JOJOBA/RICE BRAN POLYGLYCERYL-3 ESTERS	CANDELILLA/JOJOBA/RICE BRAN POLYGLYCERYL-3 ESTERS	3.0-3.3
GLYCERYL STEARATE	GLYCERYL STEARATE	
CETEARYL ALCOHOL	CETEARYL ALCOHOL	
SODIUM STEAROYL LACTYLATE	SODIUM STEAROYL LACTYLATE	
PENTAERYTHRITYL TETRAETHYLHEXANOATE	PENTAERYTHRITYL TETRAETHYLHEXANOATE	3.0-3.3
PROPANEDIOL	PROPANEDIOL	3.0-3.3
AQUA	AQUA	2.5-3.5
BUTYLENE GLYCOL	BUTYLENE GLYCOL	
PALMITOYL TRIPEPTIDE-8	PALMITOYL TRIPEPTIDE-8	
CETEARYL ALCOHOL	CETEARYL ALCOHOL	2.0-2.2
HYDROGENATED POLYISOBUTENE	HYDROGENATED POLYISOBUTENE	2.0-2.2
JOJOBA ESTERS	JOJOBA ESTERS	2.0-2.5
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX	HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX	
ACACIA DECURRENS FLOWER WAX	ACACIA DECURRENS FLOWER WAX	
POLYGLYCERIN-3	POLYGLYCERIN-3	
CYCLOPENTASILOXANE	CYCLOPENTASILOXANE	2.0-2.5
CYCLOHEXASILOXANE	CYCLOHEXASILOXANE	
TREHALOSE	TREHALOSE	2.0-2.2
PENTYLENE GLYCOL	PENTYLENE GLYCOL	2.0-2.2
BIFIDA FERMENT LYSATE	BIFIDA FERMENT LYSATE	2.0-3.0
BUTYLENE GLYCOL	BUTYLENE GLYCOL	
GLYCERIN	GLYCERIN	2.0-3.0
AQUA	AQUA	
BUTYLENE GLYCOL	BUTYLENE GLYCOL	
CARBOMER	CARBOMER	
POLYSORBATE 20	POLYSORBATE 20	
PALMITOYL TRIPEPTIDE-1	PALMITOYL TRIPEPTIDE-1	
PALMITOYL TETRAPEPTIDE-7	PALMITOYL TETRAPEPTIDE-7	
AQUA	AQUA	1.5-2.5
BIOSACCHARIDE GUM-1	BIOSACCHARIDE GUM-1	

PHENOXYETHANOL	PHENOXYETHANOL	
AQUA	AQUA	2.0-3.0
PROPANEDIOL	PROPANEDIOL	
FIBRONECTIN	FIBRONECTIN	
GLYCERIN	GLYCERIN	
DISODIUM PHOSPHATE	DISODIUM PHOSPHATE	
SODIUM PHOSPHATE	SODIUM PHOSPHATE	
DIMETHICONE	DIMETHICONE	1.5-1.75
BUTYROSPERMUM PARKII (SHEA) BUTTER	BUTYROSPERMUM PARKII (SHEA) BUTTER	1.0-1.5
SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL	SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL	1.0-1.5
CYCLOPENTASILOXANE	CYCLOPENTASILOXANE	1.0-1.1
POLYETHYLENE	POLYETHYLENE	
DIMETHICONE	DIMETHICONE	
PEG/PPG-20/15 DIMETHICONE	PEG/PPG-20/15 DIMETHICONE	
PHENYL METHICONE	PHENYL METHICONE	
AQUA	AQUA	1.0-2.0
SACCHAROMYCES/SOY PROTEIN FERMENT	SACCHAROMYCES/SOY PROTEIN FERMENT	
SERINE	SERINE	
FUCOSE	FUCOSE	
GLYCOSAMINOGLYCANS	GLYCOSAMINOGLYCANS	
CAPRYLHYDROXAMIC ACID	CAPRYLHYDROXAMIC ACID	
PROPANEDIOL	PROPANEDIOL	
1,2-HEXANEDIOL	1,2-HEXANEDIOL	
PHENOXYETHANOL	PHENOXYETHANOL	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER	HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER	0.5-1.0
POLYSORBATE 60	POLYSORBATE 60	
SORBITAN ISOSTEARATE	SORBITAN ISOSTEARATE	
AQUA	AQUA	
GLYCERYL CAPRYLATE	GLYCERYL CAPRYLATE	0.8-0.88
CAPRYLHYDROXAMIC ACID	CAPRYLHYDROXAMIC ACID	
HYDROXYACETOPHENONE	HYDROXYACETOPHENONE	

BUTYLENE GLYCOL	BUTYLENE GLYCOL	
AQUA	AQUA	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE	PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE	0.5-0.55
TOCOPHERYL ACETATE	TOCOPHERYL ACETATE	0.5-1.0
GLYCERYLAMIDOETHYL METHACRYLATE/STEARYL METHACRYLATE COPOLYMER	GLYCERYLAMIDOETHYL METHACRYLATE/STEARYL METHACRYLATE COPOLYMER	0.5-1.0
GLYCERIN	GLYCERIN	
BUTYLENE GLYCOL	BUTYLENE GLYCOL	
LACTOBACILLUS/RICE FERMENT	LACTOBACILLUS/RICE FERMENT	0.5-1.0
MALTITOL	MALTITOL	
ARGININE	ARGININE	
SILICA	SILICA	0.5-1.0
ALLANTOIN	ALLANTOIN	0.15-0.2
CARNOSINE	CARNOSINE	0.15-0.2
SODIUM POLYGLUTAMATE	SODIUM POLYGLUTAMATE	0.1-0.2
BETA-GLUCAN	BETA-GLUCAN	0.05-0.1
SODIUM HYALURONATE	SODIUM HYALURONATE	0.05-0.1

1. Animal testing and toxicity studies:

The raw material(s) used in the product and the finish product itself have not been subjected to any animals testing in order to meet the requirements of EU Cosmetic Regulation (EC) No 1223/2009.

2. Undesirable effects (UEs) and serious undesirable effects (SUEs)

The product or, where relevant, other cosmetic products have not been involved to any undesirable effects or serious undesirable effects as defined in the Article 21 of Regulation (EC) No 1223/2009.

Undesirable effects (UEs): "adverse reactions for human health attributable to the normal or reasonably foreseeable use of a cosmetic product."
Serious Undesirable effects (SUEs): "undesirable effects which result in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death."

I hereby confirmed that all the above information is complete and accurate and agree to immediately notify in writing of any changes to the above details.

Name: Qin Hao

Position: CEO

Date: Sept 29,2022

Company Address: Building E7, Lugu Yuyuan, No.27, Wenxuan Road, High-Tech Development Zone, Changsha, Hunan, China, 410000

Appendix 6- Fragrance

This formulation does not contain a synthetic fragrance and therefore a fragrance safety evaluation as per IFRA code of practice is not available to this product.

Appendix 7- Heavy Metal Test Report of Cosmetic Product

See below report(s) if available

Test Report Number: GZHH00472057

Applicant: Hunan Sunshine Bio-Tech Co., Ltd
Building E7, Lugu Yuyuan, No.27, Wenxuan Road, High-Tech Development Zone, Changsha, Hunan, China, 410000

Date: Nov 01, 2022

Sample Description:

One (1) style of submitted sample said to be :

Item Name	:	**SQT Anti-Aging Rejuvenation Set.**
Country of Origin	:	China.
Date Sample Received	:	Oct 20, 2022
Testing Period	:	Oct 20, 2022 to Nov 01, 2022

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Tests conducted:

As requested by the applicant, refer to attached page(s) for details.

****

Conclusion:

Tested Sample	Standard	Result
Tested component(s) of submitted sample(s)	The European Cosmetic Regulation (EC) No.1223/2009 Annex I Part A 3, Microbiological control criteria of the cosmetic products.	Pass
	With reference to the Notification of the German Federal Health Office Centre (BGA) up to 1996 on toxic elements analysis for cosmetics	Meet

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Intertek GM Testing Service Zhuhai Co. Ltd.

Maggie Liu
Technical Supervisor
Healthcare and Beauty Products

Intertek GM Testing Service Zhuhai Co. Ltd.
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Test Report Number: GZHH00472057

Tests Conducted

1 Microbiological examination of non-sterile products : Microbial Enumeration Tests and tests for specified microorganisms of submitted sample

With reference to British Pharmacopoeia (2020), Appendix XVI B2 & B1 and European Pharmacopoeia 10.0 Edition, Chapter 2.6.12 & 2.6.13.

Test Item		Result		Limit
		(1)	(2)	
(I)	Total Aerobic Microbial Count (per g)	＜10 CFU#	＜10 CFU#	Category (B): (I) + (II) should be ≤1,000 CFU
(II)	Moulds and Yeasts Count (per g)	＜10 CFU#	＜10 CFU#	
(III)	*Escherichia coli* (per g)	Absence	Absence	Absence
(IV)	*Pseudomonas aeruginosa* (per g)	Absence	Absence	Absence
(V)	*Staphylococcus aureus* (per g)	Absence	Absence	Absence
(VI)	*Candida albicans* (per g)	Absence	Absence	Absence
(VII)	Bile-Tolerant Gram-Negative Bacteria (per g)	Absence	Absence	-
(VIII)	*Salmonella sp.* (per 10g)	Absence	Absence	-
(IX)	*Clostridia sp.* (per g)	Absence	Absence	-

Test Item		Result		Limit
		(3)	(4)	
(I)	Total Aerobic Microbial Count (per g)	＜10 CFU#	＜10 CFU#	Category (B): (I) + (II) should be ≤1,000 CFU
(II)	Moulds and Yeasts Count (per g)	＜10 CFU#	＜10 CFU#	
(III)	*Escherichia coli* (per g)	Absence	Absence	Absence
(IV)	*Pseudomonas aeruginosa* (per g)	Absence	Absence	Absence
(V)	*Staphylococcus aureus* (per g)	Absence	Absence	Absence
(VI)	*Candida albicans* (per g)	Absence	Absence	Absence
(VII)	Bile-Tolerant Gram-Negative Bacteria (per g)	Absence	Absence	-
(VIII)	*Salmonella sp.* (per 10g)	Absence	Absence	-
(IX)	*Clostridia sp.* (per g)	Absence	Absence	-

****

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Test Report Number: GZHH00472057

Tests Conducted

Test component(s):
(1) White cream (4-1)
(2) Yellow liquid (4-2)
(3) Transparent liquid attached to white non-woven cloth (4-3)
(4) White cream (4-4)

Remark :

#	=	No colony was detected at the one-tenth dilution of the sample
CFU	=	Colony Forming Unit
<	=	Less than
≤	=	Less than or equal to

The limit for test item (I) and (II) is with reference to the notes of guidelines on microbiological quality of the finished cosmetic products adopted by Scientific Committee on Consumer Safety (SCCS, 11th Rev., 2021) of the European Commission, Microbiological Quantitative Limits for Category B Cosmetic Products.

Category A: Cosmetic products specifically intended for children under 3 years, eye area and mucous membranes.
Category B: Other cosmetic products.

Sample received condition: sample (1)、(2)、(4) in closed bottle, sample (3) in unopened container.

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Test Report Number: GZHH00472057

Tests Conducted

2 Toxic Element Analysis (Cosmetics)

Acid digestion for Antimony (Sb), Arsenic (As), Cadmium (Cd), Lead (Pb) and Mercury (Hg) and perspiration simulant extraction for Soluble Nickel (Ni), follow by Inductively Coupled Plasma Mass Spectrometry analysis.

Element	Result (ppm) Test component(s)				Reporting Limit (ppm)	Limit# (ppm)
	(1)	(2)	(3)	(4)		
Total Antimony (Sb)	ND	ND	ND	ND	0.1	10
Total Arsenic (As)	ND	ND	ND	ND	0.1	5
Total Cadmium (Cd)	ND	ND	ND	ND	0.1	5
Total Lead (Pb)	ND	ND	ND	ND	0.1	20
Total Mercury (Hg)	ND	ND	ND	ND	0.1	1
Soluble Nickel (Ni)	ND	ND	ND	ND	0.1	10

Test component(s):
(1) White cream (4-1)
(2) Yellow liquid (4-2)
(3) Transparent liquid attached to white non-woven cloth (4-3)
(4) White cream (4-4)

Remark :
ppm = parts per million = mg/kg
# = The limit is with reference to the Notification of the German Federal Health Office (BGA), Pg 28, No. 7, July 1985 and No. 7/1992 and No. 4/1996 for cosmetics
ND = Not detected (less than reporting limit)

****

End of report

Intertek GM Testing Service Zhuhai Co. Ltd.
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Appendix 8- Human Volunteers Studies

1. Human volunteers study for the cosmetic product

No existing studies from human volunteers for finish product were provided

2. Human volunteers study for raw material

No existing studies from human volunteers for raw material(s) were provided

Appendix 9- Assessor's credentials

Leshuai Zhang, Toxicologist, Intertek China
Professor, PhD, DABT, ERT, UKRT

Education

Ph. D., Comparative Biomedical Sciences **Aug 2005 – May 2010**
Center for Chemical Toxicology Research and Pharmacokinetics, College of Veterinary Medicine, North Carolina State University, Raleigh, North Carolina, USA

M. S., Molecular Biology **Sept 2002 – June 2005**
Department of applied Biology, East China University of Science and Technology &
Institute of Biochemistry and Cell Biology, Shanghai Institutes for Biological Sciences, Chinese Academy of Science, Shanghai, China

B. S., Biochemistry **Sept 1998 – June 2002**
Department of applied Biology, East China University of Science and Technology

Certificate

ERT, Europe Registered Toxicologist **Aug 2018**

UKRT, UK Registered Toxicologist **Aug 2018**

DABT, Diplomate of American Board of Toxicology **Oct 2015**

Career Experience

Mar 2021 – Present, Toxicologist, Intertek China

February 2014 – Present, Professor in School of Radiation Medicine and Protection (SRMP), Soochow University, Suzhou, Jiangsu Province, China

Research Interests: Polysaccharides from traditional medical herbs and tumor immunotherapy; Bismuth compounds and nephrotoxicity; Hepatotoxicity and phospholipidosis by liver spheroids (3D cell culture); Microcontact printing technology and cell backpack based drug delivery system

November 2012 – January 2014, Research Assistant Professor in the Nanotechnology Innovation Center of Kansas State University.

Research Interests:Food safety (toxicity) on primary hepatocytes; Nanocorona and Nanotoxicology studies

June 2010 – June 2012, Research Fellow in the Division for Drug Safety Research, Center for Drug Evaluation and Research, Food and Drug Administration, supported by the Oak Ridge Institute of Science and Education Fellowship Program. Under the supervision of Dr. Rodney Rouse and Dr.Thomas Colatsky.

Research Description: Drug induced pancreatitis in vivo, biomarker evaluation and toxicity mechanisms; Nanoparticle toxicity prediction in vitro; Calcium signaling in drug induced cardiovascular injury

Aug 2005 – June 2010, Graduate Research Assistant, Center for Chemical Toxicology Research and Pharmacokinetics, Department of Clinical Sciences, College of Veterinary Medicine, North Carolina State University, Raleigh, North Carolina. Under the supervision of Nancy A. Monteiro-Riviere.

Research Description: Quantum dot nanoparticle penetration and absorption in skin; Cytotoxicity of nanoparticles via MTT/Cell Titer Blue/Cell Titer 96AQ/LDH assays, live/dead fluorescence markers and apoptosis/necrosis markers, inflammatory factors release and reactive oxygen species (ROS); Nanoparticle cellular uptake and mechanisms by human epidermal keratinocytes, dendritic cells and mesenchymal stem cell derived adipose cells

Publications Citation > 1500

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Book and Chapters

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Zhang L，Z Xuan, Xing T：Experimental Techniques for Radiation Nanomedicine and Nanotoxicology, 2016. ISBN 978-7-5605-9318-0.

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Journal Reviewers

Journal Name	IF	Review #
Biomaterials	10.3	2
ACS Applied Materials & Interfaces	8.5	9
Nanoscale	7	3
Particle and Fibre Toxicology	6.6	2
Wiley Interdisciplinary Reviews-Nanomedicine and Nanobiotechnology	6.1	8
Carbohydrate Polymer	6	4
Nanotoxicology	6	1
Biomacromolecules	5.7	1
Nanomedicine-Nanotechnology Biology and Medicine	5.6	8
Science of the Total Environment	5.6	1
International Journal of Biological Macromolecules	4.8	7
ACS Biomaterials Science & Engineering	4.5	1
International Journal of Nanomedicine	4.5	23
Scientific Reports	4	3
Toxicological Sciences	3.6	2
Metallomics	3.6	1
Toxicology	3.5	6
Toxicology letters	3.5	22
Cellular Immunology	3.3	3
Toxicology in vitro	3.1	31
Journal of Applied Toxicology	3.1	1
Archives of Pharmacal Research	2.5	1
Cancer Management and Research	2.2	1
Frontiers in Veterinary Science	2	1
IET Nanobiotechnology	1.9	1
Toxicology and Industrial Health	1.6	20
Toxicologic Pathology	1.4	3
Animal Biotechnology	1.3	1
International Journal of Toxicology	1.2	16
Journal of Nanoscience and Nanotechnology	1.1	1
Cutaneous and Ocular Toxicology	1.1	2
Nanoimpact		3
Nanotoday		2
Nanoscale Advances		1
Applied In Vitro Toxicology		1
Theranostics		1
Total		**195**

Funding Support

1. Hepatotoxicity of copper sulfide nanoparticles. 31971319, 2020/01-2023/12
2. Bismuth nanomaterials and nephrotoxicity, 31771104，National Natural Science Foundation of China，2018/01-2021/12
3. Influence of Graphene oxide Derivatives on phospholipidosis, 81401511，National Natural Science Foundation of China，2015/01- 2017/12

4. Immunoregulatory function on herbal polysaccharide on dendritic cells, 81373950，National Natural Science Foundation of China，2014/01 - 2017/12

Awards and Scholarships

1. Outstanding young scholars awarded by Chinese Society of Toxicology (2020)
2. Battelle Memorial Research Award of the Dermal Toxicology Specialty Section at the 48th Annual Meeting of the National Society of Toxicology (SOT), Baltimore, MD, 2009. Research Proposal “Inhibition of multi-walled carbon nanotubes in human epidermal keratinocytes by lectin or niacinamide”, $2500.
3. First place award for the MB Research Award, at the 47th Annual Meeting of the National Society of Toxicology (SOT), Seattle, Washington, 2008.
4. Third place for best poster at the In Vitro and Alternative Methods Specialty Section at the 47th Annual Meeting of the National Society of Toxicology (SOT), Seattle, Washington, 2008.
5. Toxicology and Applied Pharmacology, Certificate of Recognition for one of Elsevier’s Top 10 Cited Articles on Scopus 2007-2008.

Professional Associations and Activities

2021 – Present Associate Editor, Journal of Nanobiotechnology

2016 – Present Officer, Nanotoxicology Specialty Section, Chinese Society of Toxicology

2012 – Present Associate Editor, Toxicology and Industrial Health

2012 – 2015 Education Committee Officer, US Society of Toxicology

2011 – 2012 Officer, Nanotoxicology Specialty Section, US Society of Toxicology

2009 – Present Full membership, Sigma Xi Scientific Research Society

2006 – Present Membership in US Society of Toxicology

Teaching and Training Experiences

2016.9 – Present, specialized optional course for overseas undergraduates “ Skin Toxicology and Chemicals”

2017.9 – Present, General Course “Photography – Remarkableness from ordinary lives”

EUROTOX

This is to Certify that

LESHUAI ZHANG

may use the title

ERT

EUROPEAN REGISTERED TOXICOLOGIST

whilst registered with the

UK

Register of Toxicology

Signature

June 26, 2018

Date

EUROTOX

Basle, SWITZERLAND

bts
THE BRITISH TOXICOLOGY SOCIETY

Royal Society of Biology

This is to certify that

Leshuai Zhang

has been registered with the

UK Register of Toxicologists

and is bound by the codes of conduct of the

Royal Society of Biology
and
British Toxicology Society

for the period

21st May 2018 to 20th May 2023

Dr Lesley Stanley, ERT
(Panel Chair)

Incorporated by Royal Charter
Registered Charity No: 277981

The American Board of Toxicology

hereby declares that

Leshuai Zhang

having fulfilled all the Board's requirements is

Certified in General Toxicology

October 29, 2015

president

corporate secretary

AMERICAN BOARD OF TOXICOLOGY, INC.

August 2019

Dr. Leshuai Zhang
Guoliyuan Xincun 76-202
Nantong, 226001
China

Dear Dr. Zhang:

This letter is to inform you of the status of your recertification application.

Your application is in order and you passed the Literature Review assessment. Therefore, nothing further is required. In December of 2020 (**NOT 2019)** you will receive a letter and sticker affirming your recertification for five years.

Please note, Diplomates are strongly encouraged to record activities related to recertification on an ongoing basis via the ABT website.

If you have any questions, please contact the ABT office.

Sincerely,

Susie Masten
Executive Director

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(919) 841-5022
E-Mail: info@abtox.org