Cosmetic Product Safety Report

SQT Anti-Aging Rejuvenation Set-SQT Firming Rejuvenation 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: NA

Buyer/Final Retailer: NA

Manufacturer: NA

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	56.785	100	56.785	7732-18-5	231-791-2
GLYCERIN	6.3	100	6.3	56-81-5 / 8013-25-0	200-289-5
PROPANEDIOL	3.9	100	3.9	504-63-2	207-997-3
PENTAERYTHRITYL TETRAETHYLHEXANOATE	3.3	100	3.3	UNKNOWN	
CETEARYL ALCOHOL	3	100	3	67762-27-0 / 8005-44-5	267-008-6
HYDROGENATED POLYISOBUTENE	2.2	100	2.2	40921-86-6 / 61693-08-1 / 68937-10-0	POLYMER
PENTYLENE GLYCOL	2.2	100	2.2	5343-92-0	226-285-3
TREHALOSE	2.2	100	2.2	99-20-7	202-739-6
DIMETHICONE	1.95	100	1.95	9006-65-9 / 63148-62-9 / 9016-00-6	205-491-7 / 205-492-2
BIFIDA FERMENT LYSATE	1.65	100	1.65	MIXTURE	
CYCLOPENTASILOXANE	1.3	100	1.3	541-02-6	208-764-9
BUTYLENE GLYCOL	1.3	100	1.3	107-88-0	203-529-7
CANDELILLA/JOJOBA/RICE BRAN POLYGLYCERYL-3 ESTERS	1.5	100	1.5	-	-
CYCLOHEXASILOXANE	1.2	100	1.2	540-97-6	208-762-8
GLYCERYL STEARATE	1	100	1	123-94-4 / 31566-31-1/11099-07-3	204-664-4 / 250-705-4
BUTYROSPERMUM PARKII (SHEA) BUTTER	1	100	1	91080-23-8/ 68920-03-6/ 194043-92-0/ 68424-60-2	293-515-7/-/-/270-311-6
JOJOBA ESTERS	1	100	1	61789-91-1	307-350-6
SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL	1	100	1	61789-91-1/90045-98-0	289-964-3
SILICA	0.5	100	.5	7631-86-9 / 112945-52-5 / 60676-86-0 /63231-67-4	231-545-4/ -/ 262-373-8
TOCOPHERYL ACETATE	0.5	100	.5	7695-91-2 / 58-95-7	231-710-0 / 200-405-4
ACACIA DECURRENS FLOWER WAX	0.5	100	.5	98903-76-5	308-877-4
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX	0.5	100	.5	1286686-34-7	-
LACTOBACILLUS/RICE FERMENT	0.5	100	.5	-	-
BIOSACCHARIDE GUM-1	0.5	100	.5	194237-89-3	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE	0.5	100	.5	-	-
CAPRYLHYDROXAMIC ACID	0.35	100	.35	7377-03-9	230-936-7
GLYCERYLAMIDOETHYL METHACRYLATE/STEARYL METHACRYLATE COPOLYMER	0.3	100	.3	-	-
GLYCERYL CAPRYLATE	0.3	100	.3	26402-26-6	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER	0.2	100	.2	111286-86-3	-
POLYETHYLENE	0.2	100	.2	9002-88-4	200-815-3
POLYSORBATE 60	0.2	100	.2	9005-67-8	500-020-4
SACCHAROMYCES/SOY PROTEIN FERMENT	0.2	100	.2	-	-
PHENOXYETHANOL	0.15	100	.15	122-99-6	204-589-7
ALLANTOIN	0.15	100	.15	97-59-6	202-592-8
CARNOSINE	0.15	100	.15	305-84-0	206-169-9
MALTITOL	0.1	100	.1	585-88-6	
POLYGLYCERIN-3	0.1	100	.1	259-986-8	56090-54-1/25618-55-7 (GENERIC)
SODIUM STEAROYL LACTYLATE	0.1	100	.1	25383-99-7	246-929-7
FUCOSE	0.1	100	.1	219-452-7	2438-80-4 (L-)/3615-37-0 (D-)
GLYCOSAMINOGLYCANS	0.1	100	.1	94945-04-7	305-682-6
HYDROXYACETOPHENONE	0.1	100	.1	99-93-4	202-802-8 (I)
PEG/PPG-20/15 DIMETHICONE	0.1	100	.1	POLYMER	POLYMER

SERINE	0.1	100	.1	302-84-1	206-130-6
SODIUM POLYGLUTAMATE	0.1	100	.1	28829-38-1	POLYMER
SORBITAN ISOSTEARATE	0.1	100	.1	71902-01-7	276-171-2
PALMITOYL TRIPEPTIDE-8	0.05	100	.05	N/A	
BETA-GLUCAN	0.05	100	.05	26874-89-5 /53238-80-5 /55965-23-6	258-443-2/ 310-127-6
SODIUM HYALURONATE	0.05	100	.05	9067-32-7	-
1,2-HEXANEDIOL	0.05	100	.05	6920-22-5	230-029-6
ARGININE	0.05	100	.05	74-79-3 / 7200-25-1	200-811-1 / 230-571-3
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
PALMITOYL TETRAPEPTIDE-7	0.05	100	.05	POLYMER	POLYMER
PALMITOYL TRIPEPTIDE-1	0.05	100	.05	147732-56-7/	-
PHENYL METHICONE	0.05	100	.05	55066-49-4	
POLYSORBATE 20	0.05	100	.05	9005-64-5	500-018-3
DISODIUM PHOSPHATE	0.005	100	.005	7558-79-4/7782-85-6/10028-24-7	231-448-7
FIBRONECTIN	0.005	100	.005	86088-83-7	289-149-2
SODIUM PHOSPHATE	0.005	100	.005	7558-80-7/ 7632-05-5/10049-21-5	231-449-2/ 231-558-5

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

This cream contains solvent, moisturizers, skin conditionesr, emollients and preservative and is use for facial skin care.
None of the ingredients is on the prohibition list of the Cosmetic Regulation (EC) No. 1223/ 2009. Phenoxyethanol used as preservative is legally permitted for use under Cosmetic Regulation.
Most of the ingredients are commonly used in cosmetic products and reviewed by CIR Panel. Based on the available NOAEL, the lowest MoS is more than 100 from hydroxyacetophenone. In addition, CIR confirmed that pentaerythrityl tetraethylhexanoate, cetearyl alcohol, trehalose, jojoba esters, simmondsia chinensis (jojoba) seed oil, helianthus annuus (sunflower) seed wax, glyceryl caprylate, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, allantoin, maltitol, fucose, PEG/PPG-20/15 dimethicone, serine, sorbitan isostearate, 1,2-hexanediol and arginine are safe for use at the current level. CIR also concluded that candelilla/jojoba/rice bran polyglyceryl-3 esters and sodium stearoyl lactylate when formulated to be non-irritating and non-sensitizing. Fibronectin has a high number molecular weight (Da > 200,000), which is sufficiently high to prevent passage across biological membranes, so the permeation and absorption may not occur in intact skin. Sodium polyglutamate is the organic compound, used as a skin conditioning agent this polymer if a naturally occurring amino acid is not expected to present any risks to health when used in cosmetics.
Manufacturer should ensure the grade of glycerin being used containing low level of diethylene glycol impurities (e.g. pharmaceutical grade).Manufacturer should ensure the grade of carbomer being used be benzene-free to minimize the risk of carcinogenic potential.
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.

The raw materials used to formulate this product are all well known ingredients. They are present at typical concentrations where they are unlikely to cause irritation or allergy.

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

If used as directed, use of this product should be uneventful.

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 urity 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, Hengqin 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

EU INCI NAME:AQUA

CAS: 7732-18-5
EINECS 231-791-2

Function: Solvent

Appearance: Liquid

Melting Point: 0

Boiling Point: 100

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: 14.57481 No NOAEL Available
SED Child mg/kg bw/day: 52.36461 No NOAEL Available
SED Baby mg/kg bw/day: No NOAEL Available

Toxicological Summary:

Cosmetic function : Solvent. 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 deionised 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
EINECS 200-289-5

Function: Denaturant / Humectant / Perfuming / Solvent / Fragrance Ingredient / Hair & Skin Conditioning Agent / Oral Care Agent / Skin Protectant / Viscosity Decreasing Agent

Appearance: liquid

Log Kow: -1.76

Melting Point: ~18°C

Boiling Point: 290°C

Vapour Pressure: <0.01 mm Hg @ 20°C

Water Solubility: miscible with water

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: 1.61700 MoS - Adult 60kg: 2832.4 NOAEL mg/kg bw day: 4580
SED Child mg/kg bw/day: 5.80958 MoS - Child 16.7kg: 788.3 NOAEL test method: 90-day oral
SED Baby mg/kg bw/day: 16.44406 MoS - Baby 5.9kg: 278.5

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
EINECS 207-997-3

Function: Solvent

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: 1.00100 MoS - Adult 60kg: 832500.8 NOAEL mg/kg bw day: 1000
SED Child mg/kg bw/day: 3.59640 MoS - Child 16.7kg: 231712.7 NOAEL test method: 13-week rat study (developmental)
SED Baby mg/kg bw/day: 10.17966 MoS - Baby 5.9kg: 81862.5

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: PENTAERYTHRITYL TETRAETHYLHEXANOATE

EU INCI NAME:PENTAERYTHRITYL TETRAETHYLHEXANOATE

CAS: unknown Function: Antioxidant

Regulatory Summary:

EU DSD/DPD Classification› unclassified

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.84700 No NOAEL Available
SED Child mg/kg bw/day: 3.04311 No NOAEL Available
SED Baby mg/kg bw/day: 8.61355 No NOAEL Available

Toxicological Summary:

The substance as supplied may cause mild/moderate but transient eye irritation and may cause minimal skin irritation. When diluted in cosmetic products it is unlikely to cause irritation. It is not expected to cause skin sensitisation.

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: 0.77000 No NOAEL Available NOAEL mg/kg bw day: -
SED Child mg/kg bw/day: 2.76646 No NOAEL Available NOAEL test method: -
SED Baby mg/kg bw/day: 7.83050 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: HYDROGENATED POLYISOBUTENE

EU INCI NAME:HYDROGENATED POLYISOBUTENE

CAS: 40921-86-6 / 61693-08-1 / 68937-10-0 Function: Emollient/Skin Conditioning
EINECS polymer

Appearance: Colourless liquid

Log Kow: 13.27

Water Solubility: 5.6 x 10(-3) ng/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: 0.56466 MoS - Adult 60kg: 1770.9 NOAEL mg/kg bw day: 1000
SED Child mg/kg bw/day: 2.02874 MoS - Child 16.7kg: 492.9 NOAEL test method: two year repeat dose study in rats
SED Baby mg/kg bw/day: 5.74237 MoS - Baby 5.9kg: 174.1

Toxicological Summary:

The ingredient is not acutely toxic by oral administration. It is not a skin irritant nor a skin sensitizer; however it is non-irritating to irritating to the eyes. It is not carcinogenic, a reproductive toxicant, bioaccumulative, nor phototoxic. Evidence for genotoxicity was inconclusive. 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: PENTYLENE GLYCOL

EU INCI NAME:PENTYLENE GLYCOL

CAS: 5343-92-0 Function: Moisturiser

EINECS 226-285-3 Melting Point: -40

Appearance: Liquid Boiling Point: 209.4 (99.4% purity)

Log Kow: 0.06 (at 25 °C) / -0.28

Water Solubility: 1000 (at 20 °C) Vapour Pressure: 1.46 (at 20 °C)

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> Xi; R41

EU CLP Harmonised Classification> H318; Eye damage

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.56466	MoS - Adult 60kg: 1770.9	NOAEL mg/kg bw day: 1000	
SED Child mg/kg bw/day: 2.02874	MoS - Child 16.7kg: 492.9	NOAEL test method:	Read across to 1,2-hexanediol; daily dermal application on rats for 91-93 days
SED Baby mg/kg bw/day: 5.74237	MoS - Baby 5.9kg: 174.1		

Toxicological Summary:

1,2-pentanediol is a colourless liquid that is readily soluble in water and organic solvents. A glycol compound with a C3 side chain which will enhance its properties as a binding agent to water. Glycols are a class of compounds characterised by two hydroxyl (OH-) groups on separate carbons of an organic structure, usually linear and aliphatic. The most common sub-classification of glycols is the 1,2-diols in which propylene glycol is one of the most important members. Glycols are widely used in cosmetics, foods and in topical pharmaceutical applications as solvent/humectant. Pentylene glycol improves the water-binding capability of the skin and increases the degree of hydration, as such, acts as moisturiser when included in topical application. It is an efficient dermal absorption enhancer as demonstrated in a number of published peer-reviewed reports. Has been shown in vitro to have growth inhibitory effects on bacterial strains and putatively considered to have antimicrobial activities against bacteria, fungi and viruses.
Pentylene glycol is used as an alternative to propylene glycol because it is considered to be less irritating and allergenic. It has low acute toxicity. A single oral administration to rat induced signs of toxicity indicative of mild CNS effects with no changes observed in gross pathology. Oral LD50 was greater than 5000 mg/kg. Erythema was seen at the site of application in acute dermal study and clinical signs of toxicity including sedation, dyspnoea and exophthalamus were reported. No mortality or gross pathological effect were reported; the dermal LD50 > 2000 mg/kg. LC50 from inhalation of the aerosol was > 7015 mg/m3 (4h). Pentylene glycol has mild irritation potential. No erythema or edema (score =0) were seen on application of 100% solution to the skin of rabbits under semi-occlusive conditions; primary irritation index of 1.85. No irritation was reported in human volunteers (n=50) in a 48-hour occluded patch test with 10% pentylene glycol in aqua. However, pentylene glycol is irritating to the eye. Instillation of 100% solution in the eyes of rabbit resulted in conjunctiva redness and/or swelling and slight corneal opacity that has not resolved within 21 days (Primary irritation index of 31.7 and 25.5 for unrinsed and rinsed eyes, respectively). Thus, it has been classified with R41/H318 (Causes serious eye damage). Skin sensitisation potential were not noted in animal (GPMT; topical challenge dose of 10%) and in 53 human volunteers (HRIPT; 50% solution). However, there have been few case reports of allergic contact dermatitis to pentylene glycol in emollient creams which suggest that it may be a weak skin sensitiser. Pentylene glycol is not genotoxic; negative results reported in a battery of standard in vitro tests (bacteria mutation, chromosome aberration and mammalian cell gene mutation assays). Although, there is no specific investigation conducted, no evidence of phototoxicity potential has been noted from its application in topical products.
Repeated dose toxicity of pentylene glycol has not been investigated. Available data on structural closely, related substances, 1,3-butanediol, 1,2-propanediol and 1,2-hexanediol, indicates that it will show little systemic adverse effects. Propylene glycol (1,2-propanediol) has been used for years in many applications and is "Generally Recognized as Safe" (GRAS) in food. Repeated exposures of rats to propylene glycol in drinking water or feed did not result in adverse effects at levels up to 10% in water (estimated at about 10 g/kg bw/day) or 5% in feed (dosage reported as 2.5 g/kg bw/day) for periods up to 2 years. Species-specific haematological effects were seen in cat in 90-day oral studies with the NOAEL/LOAEL determined as 80/443 mg/kg bw/d (OECD SIDS Initial Assessment Report for 1,2-dihydroxypropane; 2001).
In a 42-day developmental study with butylene glycol administered by oral gavage at doses of 40,200 or 1000 mg/kg bw/d, no mortality or significant toxicity effects were noted. Transient hypolocomotion and hypopnea which indicate mild CNS effects were observed at 1000 mg/kg bw/d, which was considered to be the NOAEL. Daily dermal application of hexylene glycol (0, 350, 700, 1000 mg/kg bw/d) to rat skin for 91-93 days resulted in local effects of skin irritation, reduction in body weight and increase in organ weight (kidney, heart) of treated animal group. Treated skin changes included low incidence of slight focal erythema / thickening and minimal epidermal hyperplasia and hyperkeratosis. The study author concluded that the observed microscopic changes are not likely to progress to chronic skin damage or ulceration. The effect on organ weight was not associated with any pathological findings. Based on these slight changes, NOAEL for local and systemic effect are considered to be 700 and 1000 mg/kg bw/d, respectively. The data on the analogous compounds indicate that pentylene glycol has low carcinogenicity potential, and not likely to induce reproductive/developmental toxicity effects.

References:
(Faergemann J et al., Acta Derm. Venereol. 2005; 85(3): 203-5; abstract information).
(Gallo et al., 2003: Allergic contact dermatitis from pentylene glycol in an emollient cream with possible co-sensitisation to resveratrol. Contact Dermatitis; 48 (3): 176-7. Kerre S. (2008): Allergic contact dermatitis to pentylene glycol in a cosmetic cream. Contact Dermatitis; 58: 122-3; Arnado A et al.: Contact dermatitis to pentylene glycol in a prescription cream case report. Arch. Dermatol. 2008, 144: 810 -2)

Chemical Substance: TREHALOSE

EU INCI NAME:TREHALOSE

CAS: 99-20-7 Function: Moisturiser

EINECS 202-739-6

Regulatory Summary:

EU DSD/DPD Classification> UNclassified

EU CLP Harmonised Classification>

Systemic Exposure Dosage / Margin of Safety:

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

Toxicological Summary:

Cosmetic Functions : Humectant / Moisturising / Flavoring Agent. A disaccharide with the empirical formula $C_{12}H_{22}O_{11}$. Also known as Ergot sugar, materials of this type are not associated with adverse effects. Use as a cosmetic ingredient should be uneventful.

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: 0.50050	MoS - Adult 60kg: 99900.0	NOAEL mg/kg bw day: 5000	
SED Child mg/kg bw/day: 1.79820	MoS - Child 16.7kg: 27805.5	NOAEL test method:	90 days in rats
SED Baby mg/kg bw/day: 5.08983	MoS - Baby 5.9kg: 9823.5		

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: BIFIDA FERMENT LYSATE

CAS: Mixture Function: Additive

Appearance: Slightly yellow Liquid

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.42350 No NOAEL Available
SED Child mg/kg bw/day: 1.52155 No NOAEL Available
SED Baby mg/kg bw/day: 4.30677 No NOAEL Available

Toxicological Summary:

This skin conditioning agent is a biological product derived by lysing the fermentation product of Bifida. It is unlikely to produce adverse effects when incorporated into a product at a concentration of 5% or less.

Toxicological data below derived from Bifida except using phenonip as preservtaive as opposed to sodium benzoate and phenoxyethanol. The general toxicological profile from read across can be used.
LD50/LC50 values that are relevant for classification
LD50 (oral, rat) > 20 ml/kg - not toxic; Non Irritating to eyes (Rabbit) Draize test (10 % in water); Non Irritating to skin (Rabbit) Draize test (10 % in water); Non Irritating to skin (human) Patch test (10% in o/w-cream); Not sensitizing - Buehler (10 % in water)
Cancerogenic and mutagenic effects, risks to reproduction - Salmonella typhimurium, 5 strains - Negative in Ames test; Mohn test - Non mutagenic in E. coli 343/113/PKM 101 and 3 mutation systems.

Chemical Substance: CYCLOPENTASILOXANE

EU INCI NAME:CYCLOPENTASILOXANE

CAS: 541-02-6 Function: Hair & Skin Conditioning
EINECS 208-764-9

Cosmetic Regulatory Summary:

EU Cosmetics Status: Controlled

Regulatory Summary:

EU DSD/DPD Classification› Unclassified

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.33366 MoS - Adult 60kg: 2997.0 NOAEL mg/kg bw day: 1000
SED Child mg/kg bw/day: 1.19880 MoS - Child 16.7kg: 834.1
SED Baby mg/kg bw/day: 3.39322 MoS - Baby 5.9kg: 294.7

Toxicological Summary:

Cosmetic functions: Antistatic / emollient / humectant / solvent / viscosity controlling / hair conditioning agents. They are widely versatile and well used in leave on cosmetic products. Classified as a category 3 reprotoxin. The SCCS has since reviewed the available toxicological data and concluded that Cyclotetrasiloxane D4 (OctamethylCyclotetrasiloxane) and cyclopentasiloxane D5. Decamethylcyclopentasiloxane Cyclopentasiloxane, decamethyl, is safe for use in cosmetic products. Not a skin sensitizer/non irritating to the skin (Old study), rapidly absorbed orally when administered in corn oil, lipid soluble & would preferentially deposit in fat and highly lipophilic tissues. Very low acute oral, inhalation and dermal toxicity, mild irritant to the respiratory tract, reproductive toxicity in rats. A very low oral acute toxicity (LD50: (rat) >20,000 mg/k) and low inhalation toxicity (LC50: (rat) >6722 mg/L) have been reported for Cyclopentasiloxane (Fiabila, France). NOAEL of 300 ppm for reproductive toxicity of D4 is higher than the NOAEL of 150 ppm derived from the chronic/carcinogenicity studies. When inhaled, approximately 5% D4 in rat and 12% D4 in humans is absorbed. Dermal absorption of these are estimated as 0.5% (Conservative estimate). NOAEL (Male rat) 17.8 mg/kg bw/day, SED 0.1 mg/kg bw/day. Margin of Safety (cosmetic products except sunscreens) NOAEL / SED = 178. Margin of Safety (sunscreen products) NOAEL / SED = 89. SCCS/1241/10. Canada: Government proposed on Jan 30th 2009 regulation to set a concentration limit for D4. There is no evidence that the inhalation of cyclomethicone vapour is likely to produce adverse effects, provided the product is not sprayed directly into the face and the Cosmetic Review Safety Panel Report on cyclomethicones published in 1991 concluded that cyclomethicone is a safe ingredient for cosmetic products under present usage. Since then, in a rat nose-only inhalation toxicology study on the cyclomethicone D4 vapour, published in 2002 it was reported that at high exposure levels some minor lung changes were seen (macrophage accumulation, interstitial inflammation and eosinophil infiltration) but that other studies at similar dose levels failed to produce this. Cosmetic Ingredients Review Panel (1991) Final report on the safety assessment of cyclomethicone. J. Am. Coll. Toxicol. 10: 7-19. 3. Burns-Naas L.A., Meeks R.G., Kolesar G.B., Mast R.W., Elwell M.R., Hardisty J.F. and Thevenaz P (2002) Inhalation toxicology of octamethylcyclotetrasiloxane (D4) following a 3-month nose-only exposure in Fischer 344 rats. Int. J. Toxicol. 21: 39 -53. Its adverse in young children was noted in six case reports of ingestion of emollient cosmetic products in which were identified paraffinic hydrocarbons or silicone derivatives (including Cyclopentasiloxane) as factors in aspiration hazards producing signs and symptoms of pulmonary aspiration in paediatrics (ages ages 13 months to 2 years) (Burda A *et al*., Aspiration Hazards of Emollient Cosmetic Products. 2004. *J Toxicol Clin Toxicol ;42*(5):729-30. Abstract)

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: 0.33366 MoS - Adult 60kg: 21407.1 NOAEL mg/kg bw day: 6000
SED Child mg/kg bw/day: 1.19880 MoS - Child 16.7kg: 5958.3 NOAEL test method: 90-days toxicity study to dogs
SED Baby mg/kg bw/day: 3.39322 MoS - Baby 5.9kg: 2105.0

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: CANDELILLA/JOJOBA/RICE BRAN POLYGLYCERYL-3 ESTERS

EU DSD/DPD Classification›

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:

Candelilla/Jojoba/Rice Bran Polyglyceryl-3 Esters is a product obtained by the transesterification of Polyglycerin-3 (q.v.) and Euphorbia Cerifera (Candelilla) Wax (q.v.), and Simmondsia Chinensis (Jojoba) Seed Wax (q.v.) and Oryza Sativa (Rice) Bran Wax (q.v.).

Chemical Substance: CYCLOHEXASILOXANE

EU INCI NAME:CYCLOHEXASILOXANE

CAS: 540-97-6 Function: Film former

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: 0.30800	MoS - Adult 60kg: 4870.1	NOAEL mg/kg bw day: 1500
SED Child mg/kg bw/day: 1.10658	MoS - Child 16.7kg: 1355.5	
SED Baby mg/kg bw/day: 3.13220	MoS - Baby 5.9kg: 478.8	

Toxicological Summary:

Function:Skin/hair conditioning. This silicone derivative is a mixture of straight chain but predominantly ring compounds. As supplied is a mild eye irritant but is unlikely to cause eye irritation when incorporated into a product. It is unlikely to give rise to skin irritation or allergy when incorporated into a product. As per CIR Compendium and references therein, cyclohexasiloxane exhibits minimal percutaneous absorption and therefore systemic exposure and the available data do not suggest skin irritation or sensitization potential. No developmental or reprotoxic effect are expected with cyclohexasiloxane (D6). The CIR panel also noted that whilst cyclopentasiloxane could be ingested when used in lip products, the effects are unlikely to be higher than any effects from inhalation or dermal routes. Reproductive and developmental toxic effects were observed in rats after inhalation exposure to D3 at a high concentration. D3 however does not form part of cyclomethicone which consists of D4-D7 only. The panel determined that Cyclomethicone and D6 can be used safely in hair sprays, because the ingredient particle size is not respirable. The Panel reasoned that the particle size of aerosol hair sprays (~38 µm) and pump hair sprays (>80 µm) is large, compared to respirable particulate sizes (≤10 µm).

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: 0.25666	MoS - Adult 60kg: 29220.7	NOAEL mg/kg bw day: 7500	
SED Child mg/kg bw/day: 0.92215	MoS - Child 16.7kg: 8133.1	NOAEL test method:	three consecutive generations study
SED Baby mg/kg bw/day: 2.61016	MoS - Baby 5.9kg: 2873.3		

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: BUTYROSPERMUM PARKII (SHEA) BUTTER

EU INCI NAME:BUTYROSPERMUM PARKII BUTTER

CAS: 91080-23-8/ 68920-03-6/ 194043-92-0/ 68424-60-2 Function: Skin conditioning/viscosity controlling/ emulsifying/emulsion stabilising/surfactant/viscosity controlling

EINECS 293-515-7/-/-/270-311-6

Appearance: White-light yellow soft fat

Water Solubility: Insoluble

Cosmetic Regulatory Summary:

Regulatory Summary:

EU DSD/DPD Classification> Unclassified

EU CLP Harmonised Classification> Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.25666	MoS - Adult 60kg: 4005.1	NOAEL mg/kg bw day: 1028	
SED Child mg/kg bw/day: 0.92215	MoS - Child 16.7kg: 1114.7	NOAEL test method:	reproductive/ developmental toxicity study
SED Baby mg/kg bw/day: 2.61016	MoS - Baby 5.9kg: 393.8		

Toxicological Summary:

Cosmetic Functions : Skin Conditioning / Viscosity Controlling. A mixture of fatty acid/fatty alcohol esters (triacylglycerol) with low potential to irritate the skin or eye. Fat from the fruit of Butyrospermum Parkii, Shea or Shea nut tree. In Africa also used as a food source for dietary fat. Allergic contact dermatitis have been rarely reported with this ingredient. However a recent Belgian report (2011) of a 10 year study (2000 - 2010) on the role of non-fragrance allergens in specific cosmetic products in people who have presented with adverse reactions, identified a few (4 people in 4 years) allergic contact dermatitis reaction to Butyrospermum Parkii when used as a vehicle component. The reaction was found to be particular to skin care products in contrast to the other 10 categories of product areas such as hair care, sun care, body-cleansing and facial cleansers investigated (1. Travassos, AR, Claes ,L, Boey, L, Drieghe, J and Goossens, A. 2011. *Non-fragrance allergens in specific cosmetic products. Contact Dermatitis, 65*, 276–285). This report indicate that reactions to this ingredient does occur but it is not very common.

Chemical Substance: JOJOBA ESTERS

EU INCI NAME:JOJOBA ESTERS

CAS: 61789-91-1 Function: Exfoliating agent

EINECS 307-350-6

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: 0.25666	No NOAEL Available
SED Child mg/kg bw/day: 0.92215	No NOAEL Available
SED Baby mg/kg bw/day: 2.61016	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: SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL

EU INCI NAME:SIMMONDSIA CHINENSIS OIL

CAS: 61789-91-1/90045-98-0 Function: Botanical

EINECS 289-964-3

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: 0.25666 No NOAEL Available

SED Child mg/kg bw/day: 0.92215 No NOAEL Available

SED Baby mg/kg bw/day: 2.61016 No NOAEL Available

Toxicological Summary:

Cosmetic Functions : Emollient / Hair & Skin Conditioning. Jojoba oil, a non-ionic surfactant is expressed or extracted from the seed of the Jojoba tree/shrub. It is technically a liquid wax ester with long unsaturated carbon chains. Chemically similar to spermaceti oil and human sebum, Jojoba oil is hypoallergenic and has been used as a folk remedy by native North Americans. Jojoba waxes/oils have been reviewed by the CIR expert panel and found to be safe for use at present practices. jojoba oil which is expressed from seeds and is composed almost completely (97%) of wax esters of monounsaturated, straight-chain fatty acids and alcohols with high-molecular weights has been found safe for use upto 100% in cosmetic leave on products such as body creams and oils. Not an acute toxicant LD50>5g/kg. Not toxic dermally in animal experiments. Non irritating to slightly irriting to the eye (white rabbit). Hydrolyzed Jojoba Esters (20%) to be non-irritating to guinea pigs. Seed Wax was moderately comedogenic in tests using rabbits, but Jojoba Esters was non comedogenic, and Jojoba Esters were non- to slightly- comedogenic. Non mutagenic in the Ames test. Seed Oil was neither a significant dermal irritant, nor a sensitizer. not phototoxic. Non sensitizing in repeat insult patch test at induction or challenge. Ingredient particle size is cosmetic aerosols is not respirable in aerosols or pump sprays. None of the tested ingredients were genotoxic and there were no structural alerts for carcinogenicity. These ingredients can enhance the penetration of other ingredients through the skin (e.g. fluconazole and aminophylline). This data was compiled from the CIR Compendium 2010.

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: 0.12833 MoS - Adult 60kg: 69974.0 NOAEL mg/kg bw day: 8980

SED Child mg/kg bw/day: 0.46107 MoS - Child 16.7kg: 19476.1 NOAEL test method: 6 months oral in rats

SED Baby mg/kg bw/day: 1.30508 MoS - Baby 5.9kg: 6880.7

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: 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: 0.12833 MoS - Adult 60kg: 974.0 NOAEL mg/kg bw day: 125

SED Child mg/kg bw/day: 0.46107 MoS - Child 16.7kg: 271.1 NOAEL test method: oral study in rat

SED Baby mg/kg bw/day: 1.30508 MoS - Baby 5.9kg: 95.7

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: 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: 0.12833 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:

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: HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

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:

Helianthus Annuus (Sunflower) Seed Wax is the wax obtained from the seed of the sunflower,?Helianthus annuus.

Chemical Substance: LACTOBACILLUS/RICE FERMENT

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

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:

Lactobacillus/Rice Ferment is the product obtained by the fermentation of Oryza Sativa (rice) by the microorganism,?Lactobacillus.

Chemical Substance: BIOSACCHARIDE GUM-1

EU INCI NAME:BIOSACCHARIDE GUM-1
CAS: 194237-89-3 Function: Biological

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

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:

Biosaccharide Gum -1 (Fucogel): Biologically produced polysaccharide. It is obtained by microbial fermentation from vegetal raw materials. The carbon base is derived from corn and the nitrogen base is derived from soybean hydrolysis. Because it is a blend of polysaccharides it is able to provide the skin with a double hydration effect. Its immediate action is from its excellent substantivity or film forming power on the skin. It is able to retain water in the same manner as hyaluronic acid, a very popular and efficient humectant commonly used in cosmetics. Displays anti-adhesive properties (deodorant properties). The anti-adhesive biosaccharide gum-1 is able to bind with bacteria instead of bacteria binding to the skin and causing odor. Unlikely to cause problems in use.

Chemical Substance: PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE

CAS: -
EINECS -

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

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:

Phytosteryl/Octyldodecyl Lauroyl Glutamate is the mixed ester of phytosterol and Octyldodecanol (q.v.) with Lauroyl Glutamic Acid (q.v.).

Chemical Substance: CAPRYLHYDROXAMIC ACID

EU INCI NAME:CAPRYLHYDROXAMIC ACID
CAS: 7377-03-9
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: 0.08983 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: GLYCERYLAMIDOETHYL METHACRYLATE/STEARYL METHACRYLATE COPOLYMER

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:

Glycerylamidoethyl Methacrylate/Stearyl Methacrylate Copolymer is a copolymer of glycerylamidoethyl methacrylate and?Stearyl Methacrylate?(q.v.) monomers.

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: 0.07700 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:

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: HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER

CAS: 111286-86-3
EINECS -

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.05133 No NOAEL Available
SED Child mg/kg bw/day: 0.18443 No NOAEL Available
SED Baby mg/kg bw/day: 0.52203 No NOAEL Available

Toxicological Summary:

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer is a copolymer of sodium hydroxyethyl acrylate and acryloyldimethyl taurate monomers.

Chemical Substance: POLYETHYLENE

EU INCI NAME:POLYETHYLENE

CAS: 9002-88-4 Function: antistatic agents / binders / emulsion stabilisers / film formers / viscosity controlling agents
EINECS 200-815-3

Appearance: solid Melting Point: 85 - 90 (+/- 5 °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: 0.05133 MoS - Adult 60kg: 97402.5 NOAEL mg/kg bw day: 5000
SED Child mg/kg bw/day: 0.18443 MoS - Child 16.7kg: 27110.3 NOAEL test method: 90 day dietary study
SED Baby mg/kg bw/day: 0.52203 MoS - Baby 5.9kg: 9577.9

Toxicological Summary:

The ingredient is not acutely toxic by oral administration or inhalation. Undiluted polyethylene is mildly irritating to the skin at molecular weights of 655 Da, but not at 450 Da. Undiluted polyethylene is mildly irritating to the eyes. It is not skin sensitizing or mutagenic. It is not carcinogenic when used in cosmetics. It is non-bioaccumulative. No data was available for reproductive toxicity or phototoxicity. 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: POLYSORBATE 60

EU INCI NAME:POLYSORBATE 60

CAS: 9005-67-8 Function: emulsifying agents / surfactants

EINECS 500-020-4

Log Kow: 5.63 (calculated)

Water Solubility: Slightly soluble in water

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: 0.05133	MoS - Adult 60kg: 9740.2	NOAEL mg/kg bw day: 500	
SED Child mg/kg bw/day: 0.18443	MoS - Child 16.7kg: 2711.0	NOAEL test method:	developmental toxicology test; rats
SED Baby mg/kg bw/day: 0.52203	MoS - Baby 5.9kg: 957.7		

Toxicological Summary:

Cosmetic Function : Emulsifying / Surfactant. A hydrophilic, nonionic surfactant used in a variety of cosmetic products. CIR Compendium 2009:- Polysorbate 80 was shown to be nonmutagenic in the Ames and micronucleus tests. The Polysorbates were noncarcinogenic in laboratory animals and low order of oral toxicity. Clinical skin testing showed little potential for human skin irritation or evidence of skin sensitization or phototoxicity. The FDA has approved Polysorbates 20 and 80 at up to 1% in ophthalmic preparations and Polysorbate 60 at up to 4.5% in foods. Overall low potential to irritate the skin or eyes or cause skin sensitisation or allergy by skin contact. On the basis of the available data, the Panel concludes that Polysorbates-20, -21, -40, -60, -61, -65, -80, -81, and -85 are safe as cosmetic ingredients in the concentration of present use (5-10%).

Chemical Substance: SACCHAROMYCES/SOY PROTEIN FERMENT

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.05133	No NOAEL Available
SED Child mg/kg bw/day: 0.18443	No NOAEL Available
SED Baby mg/kg bw/day: 0.52203	No NOAEL Available

Toxicological Summary:

Saccharomyces/Soy Protein Ferment is a product obtained by the fermentation of soy protein by the microorganism,?Saccharomyces.

Chemical Substance: PHENOXYETHANOL

EU INCI NAME:PHENOXYETHANOL

CAS: 122-99-6 Function: preservatives

EINECS -

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: 0.03850	MoS - Adult 60kg: 21645.0	NOAEL mg/kg bw day: 500	
SED Child mg/kg bw/day: 0.13832	MoS - Child 16.7kg: 6024.5	NOAEL test method:	GLP 90-day repeated-dose sub-chronic dermal toxicity study
SED Baby mg/kg bw/day: 0.39152	MoS - Baby 5.9kg: 2128.4		

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: ALLANTOIN

EU INCI NAME:ALLANTOIN

CAS: 97-59-6 Function: Skin conditioning agent

EINECS 202-592-8

Appearance: white odorless powder

Water Solubility: 5260 mg/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: 0.03850	No NOAEL Available	NOAEL mg/kg bw day: -	
SED Child mg/kg bw/day: 0.13832	No NOAEL Available	NOAEL test method:	-
SED Baby mg/kg bw/day: 0.39152	No NOAEL Available		

Toxicological Summary:

Cosmetic functions : Skin Conditioning / Skin Protecting / Soothing. Low acute toxicity and minimal potential to irritate the skin and eyes, not a skin sensitiser. Also negative Ames test data. Suppliers data also states hazardous properties are relatively improbable and no description of any toxic symptoms. Unlikely to produce any adverse effects when used at typical concentrations in cosmetic products.

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: 0.03850 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 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: MALTITOL

EU INCI NAME:MALTITOL

CAS: 585-88-6

Regulatory Summary:

EU DSD/DPD Classification› unclassified

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:

A disaccharide obtained by the hydrogenation of maltose. Unlikely to cause harm, irritation or allergy.

Chemical Substance: POLYGLYCERIN-3

EINECS 2438-80-4 (L-)/3615-37-0 (D-)

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:

Polyglycerin-3 is a glycerin polymer containing 3 glycerin units.

Chemical Substance: SODIUM STEAROYL LACTYLATE

EU INCI NAME:SODIUM STEAROYL LACTYLATE

CAS: 25383-99-7 Function: emulsifying agents

EINECS 246-929-7

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: 0.02566 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:

As supplied not classified as Dangerous according to the CHIP Health criteria. Claimed to have low potential to cause irritancy. Unlikely to cause problems if used at up to 2% in a cosmetic product.

Chemical Substance: FUCOSE

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:

Fucose is a deoxyhexose that is present in a wide ?variety of organisms;?unlike most sugars, fucose occurs in ?nature as the L-form and lacks a hydroxyl group on the carbon ?at the 6-position (C-6).

Chemical Substance: GLYCOSAMINOGLYCANS

EU INCI NAME:GLYCOSAMINOGLYCANS

CAS: 94945-04-7 Function: emollients / film formers
EINECS 56090-54-1/25618-55-7 (generic)

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:

This skin conditioning agent is a mixture of mucopolysaccharides prepared from shark cartilage (MSDS). Unlikely to give rise to skin irritation or allergy when incorporated into a cosmetic product.

Chemical Substance: HYDROXYACETOPHENONE

EU INCI NAME:HYDROXYACETOPHENONE

CAS: 99-93-4 Melting Point: 109 °C (REACH Dossiers, 2017)
EINECS 202-802-8 (I) 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: 0.02566 MoS - Adult 60kg: 1753.2 NOAEL mg/kg bw day: 45
SED Child mg/kg bw/day: 0.09221 MoS - Child 16.7kg: 487.9 NOAEL test method: 90 day to rats by oral
SED Baby mg/kg bw/day: 0.26101 MoS - Baby 5.9kg: 172.4

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: PEG/PPG-20/15 DIMETHICONE

CAS: polymer Function: Emollient/Hair & Skin Conditioning
EINECS polymer

Regulatory Summary:

EU DSD/DPD Classification› Unclassified

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:

A water soluble polymer of dimethylsiloxane with polyoxyethylene and polyoxypropylene side chains. This silicone derivative has little potential to irritate the skin or eye and is not a sensitiser.

Chemical Substance: SERINE

EU INCI NAME:SERINE

CAS: 302-84-1 Function: antistatic agents
EINECS 206-130-6

Cosmetic Regulatory Summary:

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:

An amino acid used for its moisturising and antistatic properties. At typical levels of use, unlikely to cause allergy or irritation.

Chemical Substance: SODIUM POLYGLUTAMATE

EU INCI NAME:SODIUM POLYGLUTAMATE

CAS: 28829-38-1 Function: humectants

EINECS polymer

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:

Synthetic polymer formed by the polymerization of glutamic acid. Used as a skin and hair conditioning agent this polymer if a naturally occurring amino acid is not expected to present any risks to health when used in cosmetics.

Chemical Substance: SORBITAN ISOSTEARATE

EU INCI NAME:SORBITAN ISOSTEARATE

CAS: 71902-01-7 Function: emulsifying agents

EINECS 276-171-2

Regulatory Summary:

EU DSD/DPD Classification› unclassified

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: Surfactant/Emulsifier. Sorbitan ester are waxy solids or viscous liquids. These esters are mono-, di-, and triesters of fatty acids and sorbitol. They are used in a variety of products including skin care products, moisturizers, cleansing products, and eye and facial makeup. The sorbitan esters are produced by reacting the polyol, sorbitol, with a fatty acids (caprylic, coconut oil-derived fatty acids, isostearic, oleic, stearic, isostearic, olive oil-derived fatty acids). Sorbitol and the fatty acids are naturally occurring chemicals and are used in cosmetic products. Used as thickeners in food and cosmetics and is FDA approved. Low potential to cause skin or eye irritancy. Low oral toxicity (LD50, rat >5000 mg/kg). The CIR have completed an authoritative review on the use of sorbitan laurate and other sorbitan esters for their suitability in cosmetic products. Sorbitan esters show low toxicity by oral and dermal routes and subchronic and chronic toxicity is low. They are metabolized back to sorbitan and commons esters and then excreted. The lowest LD50 was 31,000 mg/kg for sorbitan stearate. The rat LD50 values from acute toxicity studies of sorbitan laurate ranged from 33,600 mg/kg to 41,500 mgkg (CIR 2000). Not a dermal irritant and not reported as a dermal toxicant. Chronic studies in animal produced no effects when the ester concentration in the diet was 40% (CIR 1985). Not reported as a skin sensitizer on intact skin but may cause sensitization on damaged skin . May induce cutaneous irritation in humans. Not reported as photosensitizers. Little potential for reproductive and developmental effects and do not show carcinogenic or mutagenic effects. At high concentration, cocarcinogenicity and tumour promotion (10% in mice) in dermal studies is observed but these concentrations are higher than what would be used in cosmetic products (typically 5%)
Inhalation is not expected to be a route of exposure given their high molecular weight, volatility and melting point.

In an addendum to their original report the CIR added that the sorbitan esters were to be relatively nontoxic via ingestion in acute and long-term studies, minimal to mild skin irritants. Sorbitan esters did not act as sensitizing agents. The fatty acid component, tested alone, typically caused only slight irritation and sensitization, and was not photosensitizing. Sorbitan esters were not ocular irritants. These esters and their corresponding fatty acids were not mutagenic. In clinical tests, sorbitan esters were generally minimal to mild skin irritants and were nonsensitizing, but Sorbitan Sesquioleate did produce an allergic reaction in fewer than 1% of patients with suspected contact dermatitis and addition of Sorbitan Sesquioleate to the components of a fragrance mix used in patch testing increased both irritant and allergic reactions to the fragrance mix. The CIR expert panel considered the use of sorbitan esters safe for use up to 20% in cosmetic formulations. They concluded that the cocarcinogenisis potential of sorbitan laurate was not relevant when considering the likely exposures and quantities in cosmetic formulations.

Cosmetic Ingredient Review (CIR) Expert panel3 (1984, 1985,2000,2002),
Joint FAOIWHO (Food and Agriculture Organization/World Health Organization)(JECFA)
The High Production Volume (HPV) Chemical Challenge Program's
Test Plan for the Sorbitan Esters Category of the Aliphatic Esters Chemicals prepared by the American
Chemistry Council (ACC) in November, 2003.

Chemical Substance: PALMITOYL TRIPEPTIDE-8

EU INCI NAME:PALMITOYL TRIPEPTIDE-8

CAS: n/a Function: Conditioning agent

Appearance: Limpid solution

Water Solubility: miscible at r.t.

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: 0.01283	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:

Cosmetic function: skin conditioning. Palmitoyl Tripeptide-8 is the product obtained by the reaction of Palmitic acid and Tripeptide-8. It is a modified peptide aqueous/glycol/sugar solution used in cosmetic products to maintains the skin in good condition. The typical use in cosmetic products is unlikely to result in irritation or allergy.

Chemical Substance: BETA-GLUCAN

EU INCI NAME:BETA-GLUCAN

CAS: 26874-89-5 /53238-80-5 /55965-23-6 Function: Skin conditioning agent

EINECS 258-443-2/ 310-127-6 Boiling Point: 865.2 °C at 760 mmHg

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: 0.01283	MoS - Adult 60kg: 584415.5	NOAEL mg/kg bw day: 7500	
SED Child mg/kg bw/day: 0.04610	MoS - Child 16.7kg: 162662.3	NOAEL test method:	99-114 wks in mice by oral
SED Baby mg/kg bw/day: 0.13050	MoS - Baby 5.9kg: 57467.5		

Toxicological Summary:

Cosmetic function: skin conditioning. A polysaccharide consisting of b(1-3) linked glucose chains carrying b(1-6) linked glucose sidechains. Used to enhance the immune system and to lower blood cholesterol levels. When use in cosmetic products should be uneventful.

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: 0.01283	MoS - Adult 60kg: 4675.3	NOAEL mg/kg bw day: 60	
SED Child mg/kg bw/day: 0.04610	MoS - Child 16.7kg: 1301.2	NOAEL test method:	Reproductive / Developmental Toxicity study
SED Baby mg/kg bw/day: 0.13050	MoS - Baby 5.9kg: 459.7		

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.

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: 0.01283	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 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: 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: 0.01283	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:

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: 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: PALMITOYL TETRAPEPTIDE-7

EU INCI NAME:PALMITOYL TETRAPEPTIDE-7

CAS: polymer
EINECS polymer

Function: Emollient/Hair & Skin Conditioning

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: PALMITOYL TRIPEPTIDE-1

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:

Palmitoyl Tripeptide-1 is the reaction product of palmitic acid and Tripeptide-1 (q.v.).

Chemical Substance: PHENYL METHICONE

EU INCI NAME:PHENYL METHICONE

CAS: 55066-49-4
EINECS -

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:

Only slightly irritating to the skin and eyes, unlikely to give rise to skin sensitisation. Use of this raw material is unlikely to cause adverse effects on health when included in a cosmetic product.

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: DISODIUM PHOSPHATE

EU INCI NAME:DISODIUM PHOSPHATE

CAS: 7558-79-4/7782-85-6/10028-24-7 Function: Buffering/Masking/Anticorrosive

EINECS 231-448-7 Melting Point: > 723 K

Appearance: Solid

Water Solubility: > 10000 mg/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: 0.00128	MoS - Adult 60kg: 251532.4	NOAEL mg/kg bw day: 322.8	
SED Child mg/kg bw/day: 0.00461	MoS - Child 16.7kg: 70009.8	NOAEL test method:	90-day oral in rats
SED Baby mg/kg bw/day: 0.01305	MoS - Baby 5.9kg: 24734.0		

Toxicological Summary:

The ingredient is not acutely toxic, a skin irritant, an eye irritant, a skin sensitizer, mutagenic, a reproductive toxicant and bioaccumulative. No information available for phototoxic. 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: FIBRONECTIN

EU INCI NAME:FIBRONECTIN

CAS: 86088-83-7

EINECS 289-149-2

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: 0.00128	No NOAEL Available
SED Child mg/kg bw/day: 0.00461	No NOAEL Available
SED Baby mg/kg bw/day: 0.01305	No NOAEL Available

Toxicological Summary:

Fibronectin is a glycoprotein found in connective tissues, basement membranes, in plasma and other body fluids.

Chemical Substance: SODIUM PHOSPHATE

EU INCI NAME:SODIUM PHOSPHATE

CAS: 7558-80-7/ 7632-05-5/10049-21-5 Function: Buffering/Masking/Anticorrosive

EINECS 231-449-2/ 231-558-5 Melting Point: > 723 K

Appearance: Solid

Water Solubility: > 10000 mg/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: 0.00128	MoS - Adult 60kg: 292207.7	NOAEL mg/kg bw day: 375	
SED Child mg/kg bw/day: 0.00461	MoS - Child 16.7kg: 81331.1	NOAEL test method:	90- day oral in rats
SED Baby mg/kg bw/day: 0.01305	MoS - Baby 5.9kg: 28733.7		

Toxicological Summary:

The ingredient is not acutely toxic, a skin irritant, an eye irritant, a skin sensitizer. It is not mutagenic toxic, not a reproductive toxicant. The bioaccumulative potential could not be judged. No information on its carcinogenic and phototoxic potential. But it is a permitted food additive by WHO with MTDI of 70 mg/kg bw (as P) (JECFA, 2015). 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 Firming Rejuvenation 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

601, R&D and Testing Building, Guangdong-Macau Medical Science and Technology Industrial Park, No.2682 HuanDao North Road, HengQin New Area,Zhuhai,GD,China,519031
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	-

****

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

601, R&D and Testing Building, Guangdong-Macau Medical Science and Technology Industrial Park, No.2682 HuanDao North Road, HengQin New Area,Zhuhai,GD,China,519031
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

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.

****

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

601, R&D and Testing Building, Guangdong-Macau Medical Science and Technology Industrial Park, No.2682 HuanDao North Road, HengQin New Area,Zhuhai,GD,China,519031
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

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.
珠海天祥粤澳质量技术服务有限公司

601, R&D and Testing Building, Guangdong-Macau Medical Science and Technology Industrial Park, No.2682 HuanDao North Road, HengQin New Area,Zhuhai,GD,China,519031
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

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

See below report(s) if available

2. Outer Packaging material

See below report(s) if available

intertek
Total Quality. Assured.

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.

****

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

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

601, R&D and Testing Building, Guangdong-Macau Medical Science and Technology Industrial Park, No.2682 HuanDao North Road, HengQin New Area,Zhuhai,GD,China,519031
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: 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.

****

End of report

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

601, R&D and Testing Building, Guangdong-Macau Medical Science and Technology Industrial Park, No.2682 HuanDao North Road, HengQin New Area,Zhuhai,GD,China,519031
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

intertek
Total Quality. Assured.

Test Report Number: GZHH00472087

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) 5ml brown soda lime glass vial** **(2) Butyl 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.

****

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

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

601, R&D and Testing Building, Guangdong-Macau Medical Science and Technology Industrial Park, No.2682 HuanDao North Road, HengQin New Area,Zhuhai,GD,China,519031
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: GZHH00472087

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	11.0	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	11.0	--	100

Tested Component(s):
(1) Brown glass bottle with orange printing
(2) Black 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.

****

End of report

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

601, R&D and Testing Building, Guangdong-Macau Medical Science and Technology Industrial Park, No.2682 HuanDao North Road, HengQin New Area,Zhuhai,GD,China,519031
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

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	0.8-0.88
CAPRYLHYDROXAMIC ACID	CAPRYLHYDROXAMIC ACID	
HYDROXYACETOPHENONE	HYDROXYACETOPHENONE	
BUTYLENE GLYCOL	BUTYLENE GLYCOL	
AQUA	AQUA	
DIMETHICONE	DIMETHICONE	0.5-0.55
GLYCERYL STEARATE SE	GLYCERYL STEARATE SE	0.5-0.55
AQUA	AQUA	0.5-1
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	
LYCIUM BARBARUM FRUIT EXTRACT	LYCIUM BARBARUM FRUIT EXTRACT	
ECHINACEA PURPUREA EXTRACT	ECHINACEA PURPUREA EXTRACT	
PHENOXYETHANOL	PHENOXYETHANOL	
ETHYLHEXYLGLYCERIN	ETHYLHEXYLGLYCERIN	
GLYCERIN	GLYCERIN	0.5-1
AQUA	AQUA	
BUTYLENE GLYCOL	BUTYLENE GLYCOL	
CARBOMER	CARBOMER	
POLYSORBATE 20	POLYSORBATE 20	
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

****

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

601, R&D and Testing Building, Guangdong-Macau Medical Science and Technology Industrial Park, No.2682 HuanDao North Road, HengQin New Area,Zhuhai,GD,China,519031
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	-

****

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

601, R&D and Testing Building, Guangdong-Macau Medical Science and Technology Industrial Park, No.2682 HuanDao North Road, HengQin New Area,Zhuhai,GD,China,519031
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

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.

****

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

601, R&D and Testing Building, Guangdong-Macau Medical Science and Technology Industrial Park, No.2682 HuanDao North Road, HengQin New Area,Zhuhai,GD,China,519031
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

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.
珠海天祥粤澳质量技术服务有限公司

601, R&D and Testing Building, Guangdong-Macau Medical Science and Technology Industrial Park, No.2682 HuanDao North Road, HengQin New Area,Zhuhai,GD,China,519031
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

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, DCST

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

DCST, Diplomat of Certified Toxicologist CST	**Apr 2021**
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 > 1600

1. Pang G, Liu Y, Wang Y, Wang Y, Wang F, Zhao J, **Zhang LW***. Endotoxin contamination in ovalbumin as viewed from a nano-immunotherapy perspective. Wiley Interdiscip Rev Nanomed Nanobiotechnol. 2021 Aug 10:e1747.

2. Jiang T, Guo H, Xia YN, Liu Y, Chen D, Pang G, Feng Y, Yu H, Wu Y, Zhang S, Wang Y, Wang Y, Wen H*, **Zhang LW***. Hepatotoxicity of copper sulfide nanoparticles towards hepatocyte spheroids using a novel multi-concave agarose chip method. Nanomedicine (Lond). 2021 Jul;16(17):1487-1504.

3. Wu Y, Gu J, Zhang S, Gu Y, Ma J, Wang Y, **Zhang LW**, Wang Y. Iodinated BSA Nanoparticles for Macrophage-Mediated CT Imaging and Repair of Gastritis. Anal Chem. 2021 Apr 27;93(16):6414-6420.

4. Wang Q, Zhang QH, Wen HR, Guo HX, **Zhang L***, Ma SC*. [Study on potential hepatotoxicity of main monomers of Polygonum multiflorum based on liver micro-tissue]. Zhongguo Zhong Yao Za Zhi. 2020 Jun;45(12):2954-2959.

5. Zhang X, Jiang T, Chen D, Wang Q*, **Zhang L***. Three-dimensional liver models: state of the art and their application for hepatotoxicity evaluation. Crit Rev Toxicol. 2020 Apr;50(4):279-309.

6. Pang G, Chen C, Liu Y, Jiang T, Yu H, Wu Y, Wang Y, Wang FJ*, Liu Z*, **Zhang L***. Bioactive Polysaccharide Nanoparticles Improve Radiation-Induced Abscopal Effect through Manipulation of Dendritic Cells. ACS Appl Mater Interfaces. 2019 Nov 13;11(45):42661-42670.

7. Wang J, Chen XY, Zhao Y, Yang Y, Wang W, Wu C, Yang B, Zhang Z, **Zhang L**, Liu Y, Du X, Li W, Qiu L, Jiang P, Mou XZ, Li YQ. pH-Switchable Antimicrobial Nanofiber Networks of Hydrogel Eradicate Biofilm and Rescue Stalled Healing in Chronic Wounds. ACS Nano. 2019 Oct 22;13(10):11686-11697.

8. Yu H, Yang Y, Jiang T, Zhang X, Zhao Y, Pang G, Feng Y, Zhang S, Wang F, Wang Y, Wang Y*, **Zhang L***. Effective Radiotherapy in Tumor Assisted by Ganoderma lucidum Polysaccharide-Conjugated Bismuth Sulfide Nanoparticles through Radiosensitization and Dendritic Cell Activation. ACS Appl Mater Interfaces. 2019 Aug 7;11(31):27536-27547.

9. Cao Y, Huang H, Chen L, Du H, Cui J, **Zhang L***, Lee B, Cao Q*. 2019. Enhanced Lysosomal Escape of pH-Responsive PEI-Betaine Functionalized Carbon Nanotube for the Co-delivery of Survivin siRNA and Doxorubicin. ACS Applied Materials & Interfaces 11(10):9763-9776.

10. Pang G, Zhang S, Yu H, Wu Y, Jiang T, Wang F*, Wang Y*, **Zhang L***. 2019. Immunoactive Astragalus Polysaccharide Functionalized Gold Nanocomposites Promote Dendritic Cell Stimulation and Anti-tumor Effect with Elicited Memory T-cell Responses. Nanomedicine 14(10):1291-1306.

11. Zhang S, Pang G, Chen C, Qin J, Yu H, Liu Y, Zhang X, Song G, Zhao J, Wang F*, Wang Y*, **Zhang L***. 2019. Effective Cancer Immunotherapy by Ganoderma Lucidum Polysaccharide-Gold Nanocomposites through Dendritic Cell Activation and Memory T cell Response. Carbohydrate Polymer 205:192-202.

12. Yan R, Chen J, Wang J, Rao J, Du X, Liu Y, **Zhang L**, Qiu L, Liu B, Zhao YD, Jiang P, Chen C, Li YQ. 2018. A NanoFlare-Based Strategy for In Situ Tumor Margin Demarcation and Neoadjuvant Gene/Photothermal Therapy. Small. e1802745.

13. **Zhang L***, Monteiro-Riviere NA Toxicity Assessment of Six Titanium Dioxide Nanoparticles in Human Epidermal Keratinocytes. 2018. Cutaneous and Ocular Toxicology. 2018 Sep 28:1-29. doi: 10.1080/15569527.2018.1527848.

14. Song ZT, **Zhang L**, Fan LQ, Kong JW, Mao JH, Zhao J, Wang FJ. 2018. Enhanced anticancer effect of MAP30-S3 by cyclosproin A through endosomal escape. Anti-cancer Drugs 29(8):736-747.

15. Pan G, Wang F*, **Zhang L***. 2018. Direct Killing or Immunoregulatory Effects of Natural Polysaccharides in Cancer Treatment. Carbohydrate Polymer 195: 243–256.

16. Liu Y, Yu H, Zhang X, Wang Y, Zhao J, Shi H, Li R, Wang Y*, **Zhang L***. 2018. The Protective Role of Autophagy in Nephrotoxicity Induced by Bismuth Nanoparticles Through AMPK/mTOR Pathway. Nanotoxicology 6:1-16.
17. Zhang X, Yang L, Liu Y, Song Z, Zhao J, Chen D, Yu Huan, Li R, Wang Y, Yang K, Chen Y, Xia M, **Zhang L***. 2018. Detection of Nanocarrier Potentiation on Drug Induced Phospholipidosis in Cultured Cells and Primary Hepatocyte Spheroids by High Content Imaging and Analysis. Toxicology and Applied Pharmacology 348: 54–66.
18. Chen D, Yang L, Chen X, Zhang X, Liu Y, Guo Z*, **Zhang L***. 2018. Automated contour analysis of multi-cellular spheroids spreading through high content imaging. Physical Biology 24: 15:026006
19. Liu Y, Shen C, Zhang X, Yu H, Wang F, Wang Y*, **Zhang L***. 2018. Exposure and Nephrotoxicity Concern of Bismuth with the Occurrence of Autophagy. Toxicology and Industrial Health 34:188–199
20. Yue C, Ji C, Zhang H, **Zhang L**, Tong J, Jiang Y, Chen T*. 2017. Protective effects of folic acid on PM2.5-induced cardiac developmental toxicity in zebrafish embryos by targeting AhR and Wnt/β-catenin signal pathways. Environmental Toxicology. 32:2316-2322.
21. Pei W, Tao L, **Zhang L**, Zhang S, Cao J, Jiao Y, Tong J* and Nie J*. 2017. Circular RNA profiles in mouse lung tissue induced by radon. Environmental Health and Preventive Medicine 22:36.
22. Li J, He X, Zou Y, Chen D, Yang L, Rao J, Chen H, Chan M CW, Guo Z*, **Zhang L***, Chen C. 2017. Mitochondria-Targeted Platinum(II) Complex: Dual Inhibitory Activities on Tumor Cell Proliferation and Migration/Invasion via Intracellular Trafficking of β-catenin. Metallomics 9:726-733.
23. Liu Y, Zhuang J, Zhang X, Le C, Zhu N, Yang L, Wang Y, Chen T, Wang Y*, **Zhang L*** 2017. Autophagy Associated Cytotoxicity and Cellular Uptake Mechanisms of Bismuth Nanoparticles in Human Kidney Cells. Toxicology Letters 275: 39-48.
24. Chen D, Monteiro-Riviere NA, **Zhang L***. 2017. Intracellular imaging of quantum dots, gold, and iron oxide nanoparticles with associated endocytic pathways. WIREs Nanomedicine and Nanobiotechnology 9(2).
25. Yang L, Zhong X, Li Q, Zhang X, Wang Y, Yang K, **Zhang L***. 2017. From the Cover: Potentiation of Drug-Induced Phospholipidosis In Vitro through PEGlyated Graphene Oxide as the Nanocarrier. Toxicological Sciences 156:39–53.
26. Wang Y, Liu Y, Wu Y, Shen J, Lv L, Li L, Yang L, Zeng J, Wang Y, **Zhang L***, Li Z*, Gao M*, Chai Z. 2016. BSA-Mediated Synthesis of Bismuth Sulfide Nanotheranostic Agents for Tumor Multimodal Imaging and Thermoradiotherapy. Advanced Functional Materials 26: 5335–5344.
27. Zhu N, Lv X, Wang Y, Li J, Liu Y, Lu W, Yang L, Zhao J, Wang F, **Zhang L***. 2016. Comparison of immunoregulatory effects of polysaccharides from three natural herbs and cellular uptake in dendritic cells. International Journal of Biological Macromolecules 93:940–951.
28. Wang Y*, Zhu L, Wang Y, Li L, Lu Y, Shen L*, **Zhang L***. 2016. Ultrasensitive GSH-Responsive Ditelluride-Containing Poly(ether-urethane) Nanoparticles for Controlled Drug Release. ACS Applied Materials & Interfaces 8: 35106–35113
29. Lv X, Chen D, Yang L, Zhu N, Li J, Zhao J, Hu Z, Wang F*, **Zhang L***. 2016. Comparative Studies on the Immunoregulatory Effects of Three Polysaccharides Using High Content Imaging System. International Journal of Biological Macromolecules 86:28–42.
30. Xin L, Wang J, **Zhang L**, Che B, Dong G, Fan G, Cheng K. 2016. Development of HSPA1A promoter-driven luciferase reporter gene assays in human cells for assessing the oxidative damage induced by silver nanoparticles. Toxicology and Applied Pharmacology 304:9–17.
31. **Zhang L**, Koci J, Brett J, Riviere JE, Monteiro-Riviere NA. 2015. Safety Assessment of Potential Food Ingredients in Canine Hepatocytes. Food and Chemical Toxicology 78:105–15.

32. Rouse RL, **Zhang L**, Shea K, Zhou H, Xu L, Sharron S, Rosenzweig B, Zhang J. 2014. Extended Exenatide Administration Enhances Lipid Metabolism and Exacerbates Pancreatic Injury in Mice on a High Fat, High Carbohydrate Diet. PLOS ONE. 9(10):e109477

33. Tobin GA, Zhang J, Goodwin D, Stewart S, Xu L, Knapton A, González C, Bancos S, **Zhang L**, Lawton MP, Enerson BE, Weaver JL. 2014. The role of eNOS phosphorylation in causing drug-induced vascular injury. Toxicologic Pathology 42(4):709–24.

34. **Zhang L**, Shea KI, Xu L, Stewart S, Zhang J, Rouse RL. 2014. Autophagy in pancreatic acinar cells in caerulein treated mice: Immunolocalization of related proteins and their potential as markers of pancreatitis. *Toxicologic Pathology* 42, 435–457.

35. **Zhang L**, Monteiro-Riviere NA. 2013. Use of confocal microscopy for nanoparticle drug delivery through skin. Journal of Biomedical Optics. 18(6):061214

36. **Zhang L**, McMahon Tobin GA, Rouse RL. 2012. Oleic acid and glucose regulate glucagon-like peptide 1 receptor expression in a rat pancreatic ductal cell line. *Toxicology and Applied Pharmacology* 264: 274–283.

37. **Zhang L**, Bäumer W, Monteiro-Riviere NA. 2011. Cellular uptake mechanisms and toxicity of quantum dots in dendritic cells. *Nanomedicine*. 6: 777–791.

38. **Zhang L**, Monteiro-Riviere NA. 2010. Lectins modulate multi-walled carbon nanotubes cellular uptake in human epidermal keratinocytes. *Toxicology In Vitro* 24: 546–555.

39. **Zhang L**, Yang J, Barron AR, Monteiro-Riviere NA. 2009. Endocytic mechanisms and toxicity of a functionalized fullerene in human cells. *Toxicology Letters* 191: 149–157.

40. **Zhang L**, Monteiro-Riviere NA. 2009. Mechanisms of quantum dot nanoparticle cellular uptake. *Toxicological Sciences*. 110: 138–155.

41. Chen T, Li M, Ding Y, **Zhang L**, Xi Y, Pan WJ, Tao DL, Wang JY, Li L. 2009. Identification of zinc-finger bed domain containing 3 (ZBED3) as a novel axin-interacting protein that activates WNT/beta –catenin signalling. The *Journal of Biological Chemistry* 284: 6683–6689.

42. Monteiro-Riviere NA, Inman Al, **Zhang L.** 2009. Limitations and relative utility of screening assays to assess nanoparticle toxicity in a human cell line. *Toxicology and Applied Pharmacology* 234: 222–235.

43. **Zhang L**, Monteiro-Riviere NA. 2008. Assessment of quantum dot penetration into intact, tape-stripped, abraded and flexed rat skin. *Skin Pharmacology and Physiology* 21:166 –180.

44. **Zhang L**, Yu WW, Colvin VL, Monteiro-Riviere NA. 2008. Biological interactions of quantum dot nanoparticles in skin and in human epidermal keratinocytes. *Toxicology and Applied Pharmacology* 228:200–211.

45. **Zhang L**, Zeng L, Barron AR, Monteiro-Riviere NA. 2007. Biological interactions of functionalized single-wall carbon nanotubes in human epidermal keratinocytes. *International Journal of Toxicology* 26:103–113.

46. 李菁玲,曹建平,陈春英,郭正清,**张乐帅**. 新型铂配合物 Mor-platin 导致细胞凋亡及抑制细胞迁移. 科学通报, 2017, 62(4), 270–278.

47. 朱宁, **张乐帅,**王富军. 中药多糖类活性成份的纳米化应用. 中国新药杂志,2017, (01):60-65.

48. 吕小成, **张乐帅,**王富军. 中药多糖的免疫调节作用及研究进展. 上海中医药大学学报, 2016, (03): 97-101.

49. **张乐帅,**赵健.MST1 的酵母双杂交及与 Salvador 体外结合的研究[J].华东理工大学学报（自然科学版）,2006,32(4):407–410.

Book and Chapters

Zhang L, Chen D. 2017. Chapter 7. Cellular uptake mechanisms of nanoparticles for biomedical imaging. In Shi D, Zhang B (eds.): Nano Imaging: From Fundamental Principles to Translational Medical Applications. The World Scientific Encyclopedia of Nanomedicine and Bioengineering I. World Scientific., pp. 241-272.

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

Monteiro-Riviere NA, **Zhang LW**. 2008. Assessment of quantum dot penetration into skin in different species under different mechanical actions. In Linkov I, Steevens J (eds.): Nanomaterials: Risks and Benefits. Springer, Dordrecht, Netherlands, pp. 41-52.

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. Design of cell backpacks by micro contact printing and their applications in tumor immunotherapy. National Natural Science Foundation of China #32171403, 2022/01-2025/12
2. Hepatotoxicity of copper sulfide nanoparticles. National Natural Science Foundation of China #31971319, 2020/01-2023/12
3. Bismuth nanomaterials and nephrotoxicity, National Natural Science Foundation of China #31771104，2018/01-2021/12
4. Influence of Graphene oxide Derivatives on phospholipidosis, National Natural Science Foundation of China #81401511，2015/01- 2017/12
5. Immunoregulatory function on herbal polysaccharide on dendritic cells, National Natural Science Foundation of China #81373950，2014/01 - 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

2021 – Present Editor Board Member, Toxicology Research and Applications

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

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

P. O. Box 97786, Raleigh, NC 27624
(919) 841-5022
E-Mail: info@abtox.org