Cosmetic Product Safety Report

SQT Spongilla Recovery Set

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	88.87063	100	88.87063	7732-18-5	231-791-2
GLYCERIN	9.67742	100	9.67742	56-81-5 / 8013-25-0	200-289-5
MANNITOL	0.24194	100	.24194	69-65-8	200-711-8
TREHALOSE	0.04839	100	.04839	99-20-7	202-739-6
BETA-GLUCAN	0.29032	100	.29032	26874-89-5 /53238-80-5 /55965-23-6	258-443-2/ 310-127-6
1,2-HEXANEDIOL	0.29032	100	.29032	6920-22-5	230-029-6
HYDROXYACETOPHENONE	0.19355	100	.19355	99-93-4	202-802-8 (I)
SODIUM POLYGLUTAMATE	0.19355	100	.19355	28829-38-1	POLYMER
HYDROLYZED SODIUM HYALURONATE	0.04839	100	.04839	-	-
CAPRYLHYDROXAMIC ACID	0.04839	100	.04839	7377-03-9	230-936-7
ETHYLHEXYLGLYCERIN	0.04839	100	.04839	70445-33-9	408-080-2
PROPYLENE GLYCOL	0.04839	100	.04839	57-55-6	200-338-0
SOLUBLE COLLAGEN	0.00016	100	.00016	1375784-79-4/ 9007-34-5 / 9064-67-9	-
FIBRONECTIN0.00016	0.00016	100	.00016	86088-83-7	289-149-2

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

LABELLED WARNINGS & INSTRUCTIONS OF USE

CONSUMER EXPOSURE

Product Class: Face serum
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: Liquid
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 product is composed of two parts, one part is SQT antiallergy repair lyophilized powder(100 mg), the other part is SQT antiallergy repair liquid solvent(3 ml), they will blend together form a serum intended for facial skin care. The final formulation contains solvent, moisturizers and skin conditioners.
None of the ingredients is on the prohibition list of the Cosmetic Regulation (EC) No. 1223/ 2009. Most of the ingredients are commonly used in cosmetic products and reviewed by CIR Panel. Based on the available NOAEL, the lowest MoS is more than 100 from glycerin. In addition, CIR confirmed that trehalose, 1,2-hexanediol, hydrolyzed sodium hyaluronate, caprylhydroxamic acid and soluble collagen are safe for use at the current level. 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).
Due to the absence of preservatives, production according to Good Manufacturing Practices is considered appropriate to minimize the risk of microbiological hazard.
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: 24 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
Melting Point: 0
Boiling Point: 100

Appearance: Liquid
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: 22.81012 No NOAEL Available
SED Child mg/kg bw/day: 81.95255 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
Melting Point: ~18°C
Boiling Point: 290°C
Vapour Pressure: <0.01 mm Hg @ 20°C

Appearance: liquid
Log Kow: -1.76
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: 2.48387 MoS - Adult 60kg: 1843.8
SED Child mg/kg bw/day: 8.92408 MoS - Child 16.7kg: 513.2
SED Baby mg/kg bw/day: 25.25970 MoS - Baby 5.9kg: 181.3

NOAEL mg/kg bw day: 4580
NOAEL test method: 90-day oral

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: MANNITOL

EU INCI NAME:MANNITOL

CAS: 69-65-8
EINECS 200-711-8

Function: binders / humectants
Melting Point: 166-168 deg C (ChemIDplus, 2014)
Boiling Point: 290-295 deg C at 3.5 mm Hg (ChemIDplus, 2014)

Appearance: crystalline powder or free flowing granules (ChemIDplus, 2014)
Log Kow: -3.10 (measured) (ChemIDplus, 2014)
Water Solubility: Soluble in water (JECFA, 2014)

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: 0.06209 MoS - Adult 60kg: 80517.9
SED Child mg/kg bw/day: 0.22310 MoS - Child 16.7kg: 22410.8
SED Baby mg/kg bw/day: 0.63150 MoS - Baby 5.9kg: 7917.6

NOAEL mg/kg bw day: 5000
NOAEL test method: 13 weeks oral in rats

Toxicological Summary:

A simple and ubiquitous sugar alcohol similar in structure to sorbitol and xylitol with low irritancy and no allergenic potential. Not toxic, non irritating to the skin and eyes though the granular sugar may cause mechanical eye irritation. Will not permeate the skin. When used as a cosmetic ingredient use should be uneventful taking into account the toxicological profile of this chemical.

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: 0.01242 No NOAEL Available
SED Child mg/kg bw/day: 0.04462 No NOAEL Available
SED Baby mg/kg bw/day: 0.12630 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: 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: 0.07451 MoS - Adult 60kg: 100650.2 NOAEL mg/kg bw day: 7500
SED Child mg/kg bw/day: 0.26772 MoS - Child 16.7kg: 28014.3 NOAEL test method: 99-114 wks in mice by oral
SED Baby mg/kg bw/day: 0.75778 MoS - Baby 5.9kg: 9897.2

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: 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: 0.07451 No NOAEL Available
SED Child mg/kg bw/day: 0.26772 No NOAEL Available
SED Baby mg/kg bw/day: 0.75778 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: 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: 0.04967 MoS - Adult 60kg: 905.8 NOAEL mg/kg bw day: 45
SED Child mg/kg bw/day: 0.17848 MoS - Child 16.7kg: 252.1 NOAEL test method: 90 day to rats by oral
SED Baby mg/kg bw/day: 0.50519 MoS - Baby 5.9kg: 89.0

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: 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: 0.04967 No NOAEL Available
SED Child mg/kg bw/day: 0.17848 No NOAEL Available
SED Baby mg/kg bw/day: 0.50519 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: HYDROLYZED SODIUM HYALURONATE

CAS: -
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: 0.01242 No NOAEL Available
SED Child mg/kg bw/day: 0.04462 No NOAEL Available
SED Baby mg/kg bw/day: 0.12630 No NOAEL Available

Toxicological Summary:

Functions: skin conditioning

Hydrolyzed Sodium Hyaluronate is the hydrolysate of Sodium Hyaluronate derived by acid, enzyme or other method of hydrolysis and it is not classified by CLP.

Chemical Substance: CAPRYLHYDROXAMIC ACID

EU INCI NAME:CAPRYLHYDROXAMIC ACID
CAS: 7377-03-9
EINECS 230-936-7

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

EU DSD/DPD Classification›

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01242 No NOAEL Available NOAEL mg/kg bw day: -
SED Child mg/kg bw/day: 0.04462 No NOAEL Available
SED Baby mg/kg bw/day: 0.12630 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: ETHYLHEXYLGLYCERIN

EU INCI NAME:OCTOXYGLYCERIN
CAS: 70445-33-9 Function: Skin conditioning agent/ preservative
EINECS 408-080-2

Appearance: Solid

Log Kow: 2.4 +/- 0.55

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification› R41-52/53

EU CLP Harmonised Classification› Eye Dam. 1

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.01242 MoS - Adult 60kg: 4025.7 NOAEL mg/kg bw day: 50
SED Child mg/kg bw/day: 0.04462 MoS - Child 16.7kg: 1120.4 NOAEL test method: subchronic oral toxicity study
SED Baby mg/kg bw/day: 0.12630 MoS - Baby 5.9kg: 395.8

Toxicological Summary:

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

Chemical Substance: PROPYLENE GLYCOL

EU INCI NAME:PROPYLENE GLYCOL

CAS: 57-55-6
EINECS 200-338-0

Function: Humectant/Solvent
Skin Conditioning/Viscosity Controlling

Appearance: liquid
Log Kow: -0.78
Water Solubility: miscible

Melting Point: -60°C
Boiling Point: 187°C
Vapour Pressure: 0.07 mm/Hg

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: 0.01242	MoS - Adult 60kg: 239710.8	NOAEL mg/kg bw day: 1700
SED Child mg/kg bw/day: 0.04462	MoS - Child 16.7kg: 66719.5	NOAEL test method: Chronic oral Toxicity to rat
SED Baby mg/kg bw/day: 0.12630	MoS - Baby 5.9kg: 23571.5	

Toxicological Summary:

The ingredient is not acutely toxic, mutagenic, a reproductive toxicant, and is not carcinogenic. It is not a dermal irritant based on in vivo animal tests and clinical trials with human subjects. It causes minimal eye irritation according to OECD 405 test. 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: SOLUBLE COLLAGEN

EU INCI NAME:SOLUBLE COLLAGEN

CAS: 1375784-79-4/ 9007-34-5 / 9064-67-9
EINECS -

Function: Moisturiser/ Skin conditioning agent

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: 0.00004	No NOAEL Available	NOAEL mg/kg bw day: -
SED Child mg/kg bw/day: 0.00014	No NOAEL Available	NOAEL test method: -
SED Baby mg/kg bw/day: 0.00041	No NOAEL Available	

Toxicological Summary:

Non-hydrolysed protein with a low potential to irritate the skin and eye not orally acutely toxic.

Chemical Substance: FIBRONECTIN0.00016

EU INCI NAME:FIBRONECTIN

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: 0.00004	No NOAEL Available
SED Child mg/kg bw/day: 0.00014	No NOAEL Available
SED Baby mg/kg bw/day: 0.00041	No NOAEL Available

Toxicological Summary:

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 Spongilla Recovery Set

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 Spongilla Recovery Set)

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Identification of the substance or preparation:

Product Name: SQT Spongilla Recovery 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: Mannitol
Purity: 99%
ELINCS #: N/A
CAS#:N/A

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: GZHH00472012

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 Spongilla Recovery 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.
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Test Report Number: GZHH00472012

Tests Conducted

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

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

Test component(s):
(1) Transparent liquid
(2) White solid

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 in closed bottle.

Note:
Because the above samples had been mixed and tested as one testing item as requested by the applicant, the testing result is for the mixed samples, instead of any individual one.

****

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Test Report Number: GZHH00472012

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) (1+2)	Reporting Limit (ppm)	Limit# (ppm)
Total Antimony (Sb)	ND	0.1	10
Total Arsenic (As)	ND	0.1	5
Total Cadmium (Cd)	ND	0.1	5
Total Lead (Pb)	ND	0.1	20
Total Mercury (Hg)	ND	0.1	1
Soluble Nickel (Ni)	ND	0.1	10

Test component(s):
(1) Transparent liquid
(2) White solid

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

****

End of report

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

See below report(s) if available

SQT Spongilla Recovery Set Stability Test Report

Inspection number：CP2022070302

Product Name	SQT Antiallergy Repair Lyophilized Powder + SQT Antiallergy Repair Liquid Solvent	Batch Number	2111G11111+2112G11121
Specification	100mg/vial + 3ml/vial	Source	Production Department
Representative Amount	21040 vials + 21062 vials	Sampling Date	July 03, 2022
Sampling Amount	17 vials + 17 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	Powder	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	Clear 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	6.0	6.1	6.2	6.1	6.0	6.1	6.0
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

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

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Total Quality. Assured.

Test Report Number: GZHH00472093

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) 3ml clear 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

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Test Report Number: GZHH00472093

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)	62.6	12.9	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)	62.6	12.9	--	100

Tested Component(s):
(1) Transparent glass bottle
(2) Gray 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.
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Appendix 5- Serious/ Undesirable Effects of Cosmetic Product Declaration or Report

See below report(s) if available

LETTER OF DECLARATION

To Whom It May Concern:

Product Name: SQT Spongilla Recovery Set

Product: SQT Antiallergy Repair Lyophilized Powder

Chemical Name	Trade Name	Concentration (%)
AQUA	AQUA	83.664-92.96
MANNITOL	MANNITOL	6-7.5
TREHALOSE	TREHALOSE	1-1.5
AQUA	AQUA	0.04-0.05
SOLUBLE COLLAGEN	SOLUBLE COLLAGEN	
FIBRONECTIN	FIBRONECTIN	

Product: SQT Antiallergy Repair Liquid Solvent

Chemical Name	Trade Name	Concentration (%)
AQUA	AQUA	80-90
GLYCERIN	GLYCERIN	8-10
BETA-GLUCAN	BETA-GLUCAN	1-2
AQUA	AQUA	
1,2-HEXANEDIOL	1,2-HEXANEDIOL	
HYDROXYACETOPHENONE	HYDROXYACETOPHENONE	
CAPRYLHYDROXAMIC ACID	CAPRYLHYDROXAMIC ACID	0.75-1.0
ETHYLHEXYLGLYCERIN	ETHYLHEXYLGLYCERIN	
1,2-HEXANEDIOL	1,2-HEXANEDIOL	
PROPYLENE GLYCOL	PROPYLENE GLYCOL	
AQUA	AQUA	
SODIUM POLYGLUTAMATE	SODIUM POLYGLUTAMATE	0.12-0.2
HYDROLYZED SODIUM HYALURONATE	HYDROLYZED SODIUM HYALURONATE	0.05-0.06

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: GZHH00472012

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 Spongilla Recovery 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

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Test Report Number: GZHH00472012

Tests Conducted

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

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

Test component(s):
(1) Transparent liquid
(2) White solid

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 in closed bottle.

Note:
Because the above samples had been mixed and tested as one testing item as requested by the applicant, the testing result is for the mixed samples, instead of any individual one.

****

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www.intertek.com

Test Report Number: GZHH00472012

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) (1+2)	Reporting Limit (ppm)	Limit# (ppm)
Total Antimony (Sb)	ND	0.1	10
Total Arsenic (As)	ND	0.1	5
Total Cadmium (Cd)	ND	0.1	5
Total Lead (Pb)	ND	0.1	20
Total Mercury (Hg)	ND	0.1	1
Soluble Nickel (Ni)	ND	0.1	10

Test component(s):
(1) Transparent liquid
(2) White solid

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

****

End of report

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

1. Human volunteers study for the cosmetic product

No existing studies from human volunteers for finish product were provided

2. Human volunteers study for raw material

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

Appendix 9- Assessor's credentials

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

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Journal Reviewers

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

Funding Support

1. 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

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EUROPEAN REGISTERED TOXICOLOGIST

whilst registered with the

UK

Register of Toxicology

Signature

June 26, 2018

Date

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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
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The American Board of Toxicology

hereby declares that

Leshuai Zhang

having fulfilled all the Board's requirements is

Certified in General Toxicology

October 29, 2015

president

corporate secretary

AMERICAN BOARD OF TOXICOLOGY, INC.

August 2019

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

Dear Dr. Zhang:

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

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

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

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

Sincerely,

Susie Masten
Executive Director

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