COSMETIC PRODUCT SAFETY REPORT

Company Name:	**Shantou Oralhoe Biotechnology Co., Ltd.**
Company Address:	**Room 101, 1st Floor, Building 8-2, (Shenzhen Shantou Digital Science and Technology Innovation Industrial Park) No. 22 Qiaoyun Road, Longhu District, Shantou City,515000**
Product Name:	**ORALHOE Teeth Restoration Mineral Powder**
Net weight:	**50G/1.76OZ per consumer product**
Region of Origin:	**China**
Region of Destination:	**EU**
Version:	**1.0**
Date:	**2025-05-27**
Test Requested:	**This Cosmetic Product Safety Report (CPSR) is carried out according to Regulation (EC) No. 1223/2009 and its amendments.**
Test Results:	**Please refer to the following pages**

上海量远检测技术有限公司
上海市闵行区莲花南路2899
号 莲谷科技园1号楼10层
电话: 021-64788791
传真: 021-64788791
网址: www.greatesting.com
电邮: info@greatesting.com

Greatesting Service Shanghai Co.,Ltd
NO. 2899, 10th Floor,1# Building,No.2899 South
Lianhua Road,Minhang District,Shanghai
Tel: +0862164788791
Fax: +0862164788791
Web: www.greatesting.com
Email: info@greatesting.com

Table of Contents

PART A – Cosmetic product safety information

A.1 Quantitative and Qualitative Composition of Products

A.1.1 Nominal Composition

The table below shows the aggregated break-down components of all raw materials from the product. Substances may have more than one function in the product. If so, the main function is given.

INCI Name	CAS No.	Concentration (%)	Funtion
SODIUM BICARBONATE	144-55-8	89.5	SOLVENT
PPG-10 SORBITOL	-	4	SOLVENT
TRITICUM VULGARE (WHEAT) STARCH	-	3	SOLVENT
MAGNESIUM STEARATE	557-04-0	3	SOLVENT
POTASSIUM SORBATE	590-00-1	0.5	SOLVENT

A.2 Physical chemical characteristics and stability of the cosmetic product

A.2.1 Physical/chemical characteristics of Raw Materials

The raw materials specifications are available upon request.

A.2.2 Physical chemical specifications of the end product

The finished product specifications are available upon request.

A.2.3 End product stability

The stability evaluation of the above formula was conducted under different operating conditions in an appropriate packaging at 0 ± 1 °C, room condition, and 40 ± 2 °C, 60±5% humdity for 3 months. The appearance, odor, pH value and packaging apperance examinations were carried out.

The compatibility between the formula and the packaging was also evaluated.

The overall results of these examinations allow it to be stated that the stability tests and compatibility tests are acceptable.

A.2.4 Durability (PAO)

It lies with the responsibility of manufacturer or responsible person to determine the product's minimum durability and perid-after-opening (PAO) based on the above results from the product stabitity testing.

A.3 Microbiological quality

A.3.1 The microbiological specifications of the substance or mixture

The microbiological specifications of all raw materials are available upon request.

A.3.2 The microbiological testing results of end product

The microbiological testing results of end product according to European Pharmacopoeia 10.0 2.6.12 & 2.6.13 were listed below.

Items	**Testing Results**	**Unit**
Aerobic Plate Count	<10	CFU/g
Yeasts and Moulds	<10	CFU/g
E. Coli, P. aeruginosa, S. aureus, C. albicans, bile-tolerant gram-negative bacteria,S. typhimurium,C.tetani	Undetected	/g

According to Appedix 9 of the 11th Revision of the NoG (SCCS/1628/21), the microbiological quality of this product was considered as acceptable for Category 1 products.

A.3.3 Results of preservation challenge test

The preservation challenge test result of this formulation according to European Pharmacopoeia 10.0 5.1.3 was listed below.

Micoorganisms	**24H**	**7D**	**D14**	**D28**
	Log reduction values			
Escherichia coli	2.9	4.4	-	NI
Staphylococcus aureus	2.7	4.3	-	NI
Pseudomonas aeruginosa	2.7	4.4	-	NI
Candida albicans	-		1.8	NI
Aspergillus niger	-		2.0	NI

Note: NI=No increase in number of viable micro-organisms compared to the previous reading

According to European Pharmacopoeia 10.0 5.1.3 Table 5.1.3-1. Criteria B, the preservation challenge test result of this formulation was considered as acceptable.

A.4 Impurities, traces and Information about the Packaging Material

A.4.1 Impurities and Traces of prohibited substances

The potential impurities and traces relevant for the raw materials were controlled via the raw material specifications. And the raw material specification are available upon request. This product does not contain any relevant impurity at significant levels, and the analytical testing results of heavy metals (below table) indicated the content of As, Hg, Pb, Sb, Cd and Ni (soluble) in this product were undetected and considred to be acceptable according to Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) (published online: 06 Oct 2016) and German Health Authority BgA recommendations. Furthermore, in conformity with the article 3 of the regulation, the safety evaluation of this impurity and trace of prohibited substances is part of the safety evaluation of the cosmetic product.

Items	**Testing Results**	**BVL (published online: 06 Oct 2016)**	**BgA recommendations**

Pb	<0.01	≤2.0a	-
Hg	<0.001	≤0.1	-
As	<0.005	≤0.5b	-
Sb	<0.005	≤0.5	-
Cd	<0.01	≤0.1	-
Ni (soluble)	<2	-	10

a For the product make-up powder, rough, eyeshadow, eyeliner, kajal, as well as theater, fan or carnival make-up: 5 mg/kg

b For theater, fan or carnival make-up: 2.5 mg/kg

A.4.2 Information about the Packaging Material

The relevant characteristics of packaging material and in depth knowledge of its raw materials, is based on supplier data. The material information of packaging was listed below.

No.	Part	Material
1	Bottle	PET
2	Cap	ABS
3	Inner plug	PE

The analytical testing results of immediate container indicated Pb, Cd, Hg and Cr (VI) were undetected with total amount less than 10 ppm.

A.5 Normal and Reasonably Foreseeable Use

The normal use and reasonably foreseeable uses of the product are described for the product type and determine the exposure and hazards used in the safety assessment. Product misuse is not considered.

A.5.1 Normal use and reasonably foreseeable use conditions:

The normal use of this product is to apply this product as makeup remover for face or eyes. Application of this product to other parts of body is not foreseeable.

A.5.2 Warning and other explanation in the product labelling of the product category relevant for safety evaluation

As the printed instructions of use and warning is clear to describe the product usage and appropriate enough to avoid misuse, no special warnings or instructions of use are further required.

A.6 Exposure to the product

The exposure to the cosmetic product is described by the following items:

A.6.1 Product Type

This cosmetic product is applied as

Product Type: leave-on with retention factor of 0.1

A.6.2 Target Group

The target users for this product are: Adult. And the default adult body weight is 60 kg.

A.6.3 Area of application

The following exposure areas have been used in the Exposure calculations:

Area of application: skin

Application Surface area: 565 cm2

A.6.4 Routes of Exposure

The following exposure routes have been used in the Exposure calculations:

Routes of Exposure: Dermal

A.6.5 Amount per application

The following product quantity used per application has been used in the Exposure calculations:

Product Exposure: 5 g

A.6.6 Duration and Frequency

The following product use conditions have been used in the Exposure calculations:

Frequency of use: once per day

Exposure duration: 60 minutes

A.7 Exposure to the substances/impurities

Exposure to the substances/impurities has been calculated taking into account the potential expousure of product and the concentration of substances/impurities in the product. And exposure to aqua and sea water is not calculated as it is an innocuous and ubiquitous substance.

A.7.1 Exposure to the substance

INCI Name	Inclusion level (% w/w)	Total Systemic (SED) mg/kg bw/day	Local Dermal (CEL) µg/cm2
SODIUM BICARBONATE	89.5	2.0825	221.25
PPG-10 SORBITOL	4	0.41650833	44.250885
TRITICUM VULGARE (WHEAT) STARCH	3	0.4165	44.25
MAGNESIUM STEARATE	3	0.4165	44.25
POTASSIUM SORBATE	0.5	0.064134586	6.81381855

A.7.2 Exposure to impurities

As there is no impurity at significant levels, there is no exposure calculation.

A.8 Toxicological Profile of the Substances

Toxicological Profiles are provided for all substances apart from those that are fragrances, regulated ingredients, substances assessed by external authoritative body (for example Cosmetic Ingredient Review (CIR), SCCS, etc), aqua or substances present at levels below a threshold of toxicological concern.

Accordingly, toxicological profiles of PARAFFINUM LIQUIDUM and SODIUM CHLORIDE are included here.

Toxicological profile of Paraffinum Liquidum（CAS# 8042-47-5）

Toxicological endpoints:

Acute toxicity: Its acute toxicity was practically non-toxic with oral LD50 > 5000 mg/kg bw in rats and dermal LD50 > 2000 mg/kg bw in rabbits[1] .

Skin irritation: According to acute irritation test in rabbits, it was found to be non-irritating to rabbit skin[1] .

Eye irritation: According to acute irritation test in rabbits, it was found to be non-irritating to eyes [1] .

Skin sensitization: Weight of evidence indicated it was not a skin sensitizer.

Repeated dose toxicity: No studies were available to evaluate the repeated exposure to mineral oils through dermal route. However, based upon the fact that there is no evidence to suggest significant percutaneous absorption, adverse effects are not expected following repeated dermal exposure . An ADI of 12 mg/kg bw/d for medium viscosity white mineral oils (kinematic viscosity between 8.5 - 11 mm^2/s at 100 oC) based on a 2-year feeding study in the rats with NOAEL of 1200 mg/kg bw/d[2] .

Mutagenicity/Genotoxicity: Highly refined Mineral Oils are not considered as being mutagenic/ genotoxicl[1] .

Carcinogenicity: It was found not to be carcinogneic in chroinc feeding study in rats [2] .

Reproductive toxicity: The data available from short-term and long-term studies in

experimental animals exposed to mineral oil via oral, inhalation or skin exposure routes provide no evidence of reproduction/ developmental toxicity. Moreover, Mineral oil has not been detected in reproductive organs [1] .

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	1200 mg/kg bw/d
Exposure Estimate	0.42 mg/kg bw/d
Margin of Safety (MoS)	2857

Regulatory Status - Not regulated in (EC) No 1223/2009 and without the assessment opinion from SCCS or CIR.

Conclusion

It was highly refined white mineral oil that are removed aromatic hydrocarbon during the refinery process, which complies with purity requirements of USP/NF/BP/JP/Ph.Eur. for Mineral Oil. And it is concluded that the currently available data is sufficient to consider it safe to be used as intended in this product.

Reference list:

[1] ECHA. Registration dossier of White mineral oil (petroleum) (CAS No. 8042-47-5). Last accessed on 2022-10-22@ https://echa.europa.eu/registration-dossier/-/registered - dossier/15514.

[2] EFSA. Scientific opinion on the safety assessment of medium viscosity white mineral oils with a kinematic viscosity between 8.5 - 11 mm²/s at 100 °C for the proposed uses as a food additive. EFSA Journal 2013;11(1):3073.

Toxicological profile of SODIUM CHLORIDE (CAS# 7647-14-5)

Toxicological endpoints:

Acute toxicity: It was recognzied to be of none acute toxicity based on animal experimental data and human usage experience[1] .

Skin irritation: At physiological concentrations (0.9%) sodium chloride is not irritating to the eyes or skin. However, as concentration increases it can become moderately irritating to the eyes and skin, especially abraded skin[1] .

Eye irritation: At physiological concentrations (0.9%) sodium chloride is not irritating to the eyes or skin. However, as concentration increases it can become moderately irritating to the eyes and skin, especially abraded skin[1] .

Skin sensitization: It was not recognized to be a skin sensitiser based on animal experimental data and human usage experience [1] .

Phototoxicity: No data. But it was considered acceptable as it was demonstrated not to have significant UV absorpition capacity[1] .

Repeated dose toxicity: Salt, also known as sodium chloride, is regulated by U.S. Food and Drug Administration (FDA) as a “generally recognized as safe” (GRAS) ingredient. A “GRAS” substance is one that has a long history of safe, common use in foods, or that is determined to be safe, for the intended use, based on proven science. The major adverse effect of increased sodium intake is elevated blood pressure. Higher blood pressure is an acknowledged risk factor for ischaemic heart disease, stroke and renal disease. For sodium, EFSA considers that 2.0 g sodium/day is a safe and adequate intake for the general adults. A salt intake of less than 5 grams (approximately 2g sodium) per person per day is recommended by WHO for the prevention of cardiovascular diseases, the leading cause of death globally [2] .

Mutagenicity/Genotoxicity: It is not mutagenic in vitro or in vivo [1] .

Carcinogenicity: It was not recognzied as a human carcinogen [1] .

Reproductive toxicity: It was not recognzied as a specific reproductive or developmental toxicant [1] .

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	83 mg/kg bw/d
Exposure Estimate	0.03 mg/kg bw/d
Margin of Safety (MoS)	2767

Regulatory Status – Not regulated in (EC) No 1223/2009 and without the assessment opinion from SCCS or CIR.

Conclusion

opinion from SCCS or CIR.Hence, based on the large safety margin, it can be concluded it is safe to be used as intended

in this product. Reference list:

[1] ECHA. Regsitration dossier of Sodium chloride (CAS No. 7647-14-5). Last accessed on 2022-09-28@https://echa.europa.eu/registration-dossier/-/registered-dossier/15467.

[2] WHO. Last accessed on 2022-09-28@ https://www.who.int/data/gho/indicator-metadata-registry/imr-details/3082.

A.9 Undesirable effects and serious undesirable effects

As at the date of this report the product has not yet been commercialized, therefore there are no data available from post marketing surveillance on undesirable effects or serious undesirable effects to the cosmetic product.

No relevant data on other cosmetic product are available.

A.10 Information on the Cosmetic Product

This product will be produced using Good Manufacturing Practice for Cosmetics according to US FDA CFSAN Cosmetic Good Manufacturing Practice Guidelines with DEKRA Certificate DH2022GMP (D)0056.

PART B – Cosmetic Product Safety Assessment

B.1 Assessment conclusion

After overall evaluating the information in part A, this product can be assessed as safe for normal and reasonably foreseeable use in accordance with the European Cosmetics Regulation (EC) No 1223/2009.

The formulation does not contain forbidden or banned ingredients per Regulation (EC) No. 1223/2009 of the European Parliament and of the Council 30 November 2009 on Cosmetic Products and its amendments, and the safety assessment has been carried out in accordance with this regulation.

B.2 Labelled warnings and instructions of use

As the printed instructions of use and warning is clear to describe the product usage and appropriate enough to avoid misuse, no special warnings or instructions of use are further required.

B.3 Reasoning

B.3.1 Safety Evaluation of the Substances

All of the following ingredients have been assessed as safe for human health under normal and reasonably foreseeable conditions of use.

Substance Name	Inclusion Level (%)	Max.Use conc. (%)	Margin of Safety	Assessment Conclusion	Reference
SODIUM BICARBONATE	89.5	90	NA	Conforms to accepted external review in a product.	CIR Expert Panel.Safety assessment of ingredients usedin cosmetics. IJT31(Suppl. 3): 269-295, 2012.
PPG-10 SORBITOL	4	79.2	NA	Conforms to accepted external review in a product.	CIR Expert Panel.Safety assessment of ingredients usedin cosmetics.IJT 38(Suppl. 3): 6-22, 2019.

Substance Name	Inclusion Level (%)	Max.Use conc. (%)	Margin of Safety	Assessment Conclusion	Reference
TRITICUM VULGARE (WHEAT) STARCH	3	77.3	NA	Conforms to accepted external review in a product.	CIR Expert Panel.Safety assessment of ingredients used in Cosmetics. IJT 34(Suppl. 2): 5-69, 2015.
MAGNESIUM STEARATE	3	2857	NA	Conforms to accepted external review in a product.	See Section A.8
POTASSIUM SORBATE	0.5	10	NA	Conforms to accepted external review in a product.	See Section A.8

B.3.2 Safety Evaluation of the Product

This product along with all substances contained within the formulation of the product has been evaluated and found to be safe for its normal and reasonably foreseeable use based on submitted product information and other information pubicly available.

The product will be produced with certified Good Manufacturing Practices for cosmetics. And the stability, microbiological quality, packaging, warnings and use instructions have been considered and taken into account as part of safety evaluation of this product. These aspects are covered under Sections A2, A3, A4 & A5 of the report.

Based upon the information supplied, unless otherwise stated in this report, it was assumed that neither this product, nor the ingredients used in the product, contained any impurities/contaminants that would cause harm to the health of a consumer. And this evaluation result is vailid only to the conditions described herein. And any deviation from the above disclosed conditions will necessitate a new evaluaiton. Furthermone, if any serious undesirable effects attributed to the use of this product occurred, the safety assessor shall be informed immediatedly. Under such circumstances, a new safety assessment will be conducted, and conclusions may be revised.

B.4 Assessor´s credentials and approval of part B

Dr. Raul Xin, EUROTOX Registered Toxicologist (ERT)