Product Information File (PIF)

Awesome Cosmetics

Base Gel

Status: Final-restricted

SkinConsult Safety Assessment

Issued: 23-8-2019, Reportversion: V2,0

- Raw material impurities and/or cosmetic suitability
- Raw material declaration of non-animal use
- CPNP registration

SkinConsult

Index, Product Information File (PIF)
Awesome Cosmetics, Base Gel

Index

Part 1 Product Administrative Information

Awesome Cosmetics, Base Gel

Product responsible

Company name	Awesome Cosmetics
Adress	Langehof 3
City	Schagen
Telephone	0612989329
Website	[redacted]
Company representative	
File coordinator	

Manufacturer of the product

Company name	Heyuan MissGel New Material Co., Ltd.
Adress	2/F, Bldg. A2 Xinhuafeng Tech. Park, Hudieling Ind. Zone
City	Heyuan City, Guandong Province
Telephone	[redacted]
Website	http://www.missgelish.com/
Company representative	

Packager of the product

Company name	Heyuan MissGel New Material Co., Ltd.
Adress	2/F, Bldg. A2 Xinhuafeng Tech. Park, Hudieling Ind. Zone
City	Heyuan City, Guandong Province
Telephone	[redacted]
Website	http://www.missgelish.com/

Safety Assessor

Company name	SkinConsult B.V.
Adress	J.H. van der Heideplein 6
City	Maarssen
Telephone	+31 (0) 88 555 4600
Website	www.skinconsult.com
Company representative	F. Blok
Function	Chemist and Dermatologist

Part 2 Product Description
Awesome Cosmetics, Base Gel

Product Description

Product name	Base Gel
Formula code	no product code
Date	23-7-2019
Product type	nail care
IFRA category	8
Product Description	The product is a nail care product. It is intended for daily stay on use on the nails of fingers and toes. Normal product use is gentle application of the product. Average standard product use will be 250 mg in 1-3 days. Nail products have stay on characteristics with a retention factor of 10%. In the exposure dose calculations a retention factor of 10% is used. The typical daily exposure to the product can occur for months up to years. The target user is the general population from 3 years and up. Unwanted and accidental short-time contact with mucous membranes of eye and mouth is unlikely. Unwanted exposure to oral mucosa could only occur by direct oral contact with the treated nails. Direct exposure to the oral mucosa is estimated to be very low << 1%, as applied product will almost all retain on the nails. Unwanted exposure the eyes is also expected to be very low for the same reasons. Contactallergy for acrylates and other allergens in nail care products applied on the nails have been described on the periungual skin but also the eyelids. In the case of contact dermatitis the product should be discontinued.
Addtional product description	no additional information

Part 3 Ingredient Declaration (INCI)

Awesome Cosmetics, Base Gel

Ingredient Declaration (INCI)

Acrylates Copolymer
Ethyl Methacrylate
Ethyl Acetate
Butyl Acetate
Dimethicone
Microcrystalline Wax
CI 77891

Part 4 Product Type & Product Exposure

Awesome Cosmetics, Base Gel

Product Type

ProductType	nail care
Product category (IFRA QRA)	8
Product use	stay on

Product Exposure

Site of application	Nail
Route	Dermal
Dosing per application (mg)	250
Frequency per day	1
Daily exposure dose (mg/dy)	250
Duration of use	Prolonged exposure, mostly daily use, months to years
Target population	General population from 3 years and up

Part 5 Ingredient formula INCI

Awesome Cosmetics, Base Gel

Identities of the ingredients

Ingredient (INCI)	Mol. formula	CasNo	CasNo2	EinecsNo	Molar mass (g/mol)	Function	Conc %
Acrylates Copolymer	Mixture	25133-97-5				see part A7	54,76000
Ethyl Methacrylate	C6H10O2	97-63-2			114.1	see part A7	31,51000
Ethyl Acetate	C4H8O2	141-78-6		205-500-4	88.1	see part A7	5,20000
Butyl Acetate	C6-H12-O2	123-86-4		204-658-1	116.1	see part A7	3,30000
Dimethicone	Mixture	9006-65-9	63148-62-9			see part A7	2,89000
Microcrystalline Wax	Mixture	63231-60-7		264-038-1		see part A7	2,24000
CI 77891	TiO2	13463-67-7		236-675-5	79.8	see part A7	0,10000

In this table cosmetic functions as intended by the formulator are listed.

PART A - COSMETIC PRODUCT SAFETY INFORMATION

INTRODUCTION

SGS is requested to review the safety of the product formula BASE GEL for consumer health and no other part of the product. The product is for EU market and intended for application on nail plates then light-cured for changing appearance by adults. This product is not a finished consumer product as it is indicated to be supplied to other manufacturers for re-packaging. The client and the manufacturers are drawn to the attention that the finished consumer product should be assessed individually and a separate safety report is required.

The net weight of this product (The formulation under assessment) is 1 kg or 5 kg per consumer product. Detailed formulation is submitted by the client as in Section 1.

LITERATURE SOURCES

This review was compiled by using information gathered from raw material suppliers and various online databases including the EU Scientific Committee on Consumer Safety (SCCS) opinions, Cosmetic Ingredients Review (CIR); detailed references are not reported here but are recorded in the SGS Scientific Archives.

1 Quantitative and qualitative composition of cosmetic product under assessment

INCI or Chemical Name	CAS No.	EINECS/ ELINCS	Conc. %	Intended Function
Acrylates Copolymer	25035-69-2	N/A	54.7600	Antistatic / binding / film forming
Ethyl Methacrylate	97-63-2	202-597-5	31.5100	Viscosity controlling
Ethyl Acetate	141-78-6	205-500-4	5.2000	Perfuming / solvent
Butyl Acetate	123-86-4	204-658-1	3.3000	Masking / solvent
Dimethicone	9016-00-6	N/A	2.8900	Antifoaming / emollient / skin conditioning / skin protecting
Microcrystalline Wax	63231-60-7	264-038-1	2.2400	Binding / bulking / emulsion stabilising / viscosity controlling
Colouring Agent				
CI 77891	13463-67-7	236-675-5	0.1000	Cosmetic colorant / opacifying / UV absorber / UV filter

FRAGRANCE ALLERGENS

No parfum is present in the formulation.

2 Physical/chemical characteristics and stability of the formulation

2.1 The product is a colourless liquid, with pH value 5.8 – 6.1, and viscosity 5300 – 5700 mpa/s.

2.2 The stability test result on formulation, by in house method of manufacturer Dongyuan MissGel Chemical Limited Company, on product name Base Gel (Batch no. 15111601), with a testing period Nov 17, 2015 – Feb 16, 2016, was submitted and reviewed. It is the responsibility of the manufacturer and responsible person to determine the product's minimum durability and period-after-opening (PAO), if applicable, using the available data.

Testing conditions : 25℃, 40±1℃, and -5 ~ -15℃ for 12 weeks

Testing parameters : Appearance, odour, pH value, and viscosity

Conclusion: The stability of the formulation is acceptable for this application.

Part 6 Ingredient formula Raw Materials

Awesome Cosmetics, Base Gel

Quantitative composition of the product: identities of the raw materials with impurities

Code, tradename and supplier	Conc %	Ingredient or impurity	CasNo	EinecsNo	Component	Conc. in tradename Min %	Conc. in tradename Max %	Total product conc. Min %	Total product conc. Max %
- Acrylates Copolymer, Acrylates Copolymer [Zhaoqing Powerdream Chemical Co., Ltd.], Zhaoqing Powerdream Chemical Co., Ltd.	54,76	Acrylates Copolymer	25133-97-5		Ingredient	0	100	0	54.76
- Ethyl Methacrylate, Ethyl Methacrylate [Sigma Aldrich], Sigma-Aldrich	31,51	Ethyl Methacrylate	97-63-2		Ingredient	96.5	100	30.40715	31.51
		p-Hydroxyanisole	150-76-5	205-769-8	Addition	0	0.025	0	0.0078775
- Ethyl Acetate, Ethyl Acetate [Lily Group Co., Ltd.], Lily Group Co. Ltd.	5,2								
- Butyl Acetate, Butyl Acetate [Sigma-Aldrich], Sigma-Aldrich	3,3								
- Dimethicone, Dimethicone [Lily Group Co., Ltd.], Lily Group Co. Ltd.	2,89								
- Microcrystalline Wax, Microcrystalline Wax [Lily Group Co., Ltd.], Lily Group Co. Ltd.	2,24	Microcrystalline Wax	63231-60-7	264-038-1	Ingredient	99	100	2.2176	2.24
- Titanium Dioxide, CI 77891 [Lily Group Co., Ltd.], Lily Group Co. Ltd.	0,1	CI 77891	13463-67-7	236-675-5	Ingredient	97	100	0.097	0.1

PART A - COSMETIC PRODUCT SAFETY INFORMATION

INTRODUCTION

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Testing parameters : Appearance, odour, pH value, and viscosity

Conclusion: The stability of the formulation is acceptable for this application.

Part 7 Product specification
Awesome Cosmetics, Base Gel

Product specification, physical & chemical characteristics

Physical appearance	Liquid
Colour	Colorless
Odour	Typical
Product use	stay on
Viscosity (cP)	5300-5700
Density (g/ml)	No data
pH value	5,8-6,1
Melting point	Not applicable
Flammability	No data
Other aspects	No data

PART A - COSMETIC PRODUCT SAFETY INFORMATION

INTRODUCTION

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Testing conditions : 25℃, 40±1℃, and -5 ~ -15℃ for 12 weeks

Testing parameters : Appearance, odour, pH value, and viscosity

Conclusion: The stability of the formulation is acceptable for this application.

GUANGZHOU MISS GEL LIMITED COMPANY
ROOM A329, THE 3RD FLOOR, YIFA PLAZA, NO.118-122,124-164,166-182 AIRPORT ROAD, BAIYUN DISTRICT, GUANGZHOU

The following sample was submitted and identified by the client as BASE GEL (1 formulation).

Net Weight	:	1 kg or 5 kg per consumer product
SGS Report No.	:	HKHC1607004332HC
SGS Case No.	:	HKHC160700002090 – 103 (GZCPCH160501162)
Region of Origin	:	China
Region of Destination	:	EU
Sample Receiving Date	:	Jul 04 – 19, 2016
Test Period	:	Jul 04 – 29, 2016

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.

Summary
It is my opinion that this cosmetic formulation is safe for professional use when used as directed.
This assessment takes account of:

a) The general toxicological profile of each ingredient used.
b) The chemical structure of each ingredient.
c) The level of exposure of each ingredient.
d) The specific exposure characteristics of each ingredient on the areas on which the cosmetic product will be applied.
e) The specific exposure characteristics of the class of individuals for which the cosmetic product is intended.

If there is an adverse reaction from using this formulation then the undersigned should be informed so that the formulation can be further reviewed.

Signed for and on behalf of
SGS Hong Kong Ltd.

Lee Chun Ngai, Gerald
BSc(Hons), MSc, MRSB, MBTS
Cosmetic Safety Assessor

PART A - COSMETIC PRODUCT SAFETY INFORMATION

INTRODUCTION

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FRAGRANCE ALLERGENS

No parfum is present in the formulation.

2 Physical/chemical characteristics and stability of the formulation

2.1 The product is a colourless liquid, with pH value 5.8 – 6.1, and viscosity 5300 – 5700 mpa/s.

2.2 The stability test result on formulation, by in house method of manufacturer Dongyuan MissGel Chemical Limited Company, on product name Base Gel (Batch no. 15111601), with a testing period Nov 17, 2015 – Feb 16, 2016, was submitted and reviewed. It is the responsibility of the manufacturer and responsible person to determine the product's minimum durability and period-after-opening (PAO), if applicable, using the available data.

Testing conditions : 25℃, 40±1℃, and -5 ~ -15℃ for 12 weeks

Testing parameters : Appearance, odour, pH value, and viscosity

Conclusion: The stability of the formulation is acceptable for this application.

3 Microbiological quality

3.1 The microbiological test result on formulation, with reference to European Pharmacopeia 8.0 2.6.12 & 2.6.13, by third party laboratory (SGS report no. GZCPCH160501162E-1.3), with testing period May 24 – Jun 02, 2016, was submitted and reviewed based on following criteria.

Product Category of this product: 2

Micro-organisms	Total viable count and Total yeast and mold	*P.aeruginosa*, *S.aureus* and *C.albicans*
Category 1: Products specifically intended for children under 3 years, to be used in the eye area and on mucous membranes	≤ 100 cfu/g or 100 cfu/ml	not detectable in 1g or 1 ml
Category 2: Other products	≤ 1000 cfu/g or 1000 cfu/ml	not detectable in 0.1g or 0.1 ml

Conclusion: The microbiological quality of the formulation is acceptable for this application.

3.2 The preservation efficacy test result on formulation, with reference to European Pharmacopeia 8.0 5.1.3, by third party laboratory (SGS report no. GZCPCH160501162E-1.5), with testing period May 24 – Jul 11, 2016, was submitted and reviewed based on following criteria.

		Day 2	Day 7	Day 14	Day 28
Criteria A	*E.coli, P.aeruginosa, S.aureus*	2	3	/	NI
	C. albicans	/	/	2	NI
	A. brasiliensis (niger)	/	/	2	NI
Criteria B	*E.coli, P.aeruginosa, S.aureus*	/	/	3	NI
	C. albicans	/	/	1	NI
	A. brasiliensis (niger)	/	/	1	NI

NI: No increase

Conclusion: The preservative efficacy of the formulation achieved B criteria and is acceptable for this application.

4 Impurities, traces and information about the formulation and the packaging material

4.1 The heavy metal test result on formulation, by third party laboratory (SGS report no. GZCPCH160501162E-1.2), with testing period May 24 – 31, 2016, was submitted and reviewed based on following criteria.

	German Health Authority BgA (Recommendation from German Health Journal No. 28, July 1985) and The German Health Journal No. 7/1992, Session 45 from November 14, 1991					
Test items	As	Hg	Pb	Sb	Cd	Ni (soluble)
Limit (mg/kg)	≤5	≤1	≤20	≤10	≤5	≤10

Conclusion: The heavy metal content of the formulation is acceptable for this application.

4.2 The determination of phthalates Benzyl Butyl Phthalate (BBP), Bis(2-Ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Bis(2-Methoxyethyl) Phthalate (DMEP), Di-n-Pentyl Phthalate (DnPP), Diisopentylphthalate (DIPP), and N-pentyl iso-pentyl phthalate (PIPP), by third party laboratory (SGS report no.GZCPCH160501162E-1.1) with testing period May 24 – 31, 2016, indicates total tested phthalates is not detected, with a detection limit of 5 mg/kg.

Conclusion: The phthalates content of the formulation is acceptable.

4.3 The determination of hydroquinone, with reference to Hygienic Standard for Cosmetics 2007, by third party laboratory (SGS report no.GZCPCH160501162E-1.4) with testing period May 24 – Jun 03, 2016, indicates hydroquinone is not detected, with a detection limit of 7 µg/kg.

Conclusion: The hydroquinone content of the formulation is acceptable.

4.4 The client has supplied the following list of packaging parts for this product as the immediate container.

No.	Immediate Container	Material
1.	Bottle & Cap	PE

4.5 For packaging material, test result of lead, cadmium, mercury and chromium (VI) on immediate container by third party laboratory (SGS report no. GZCPCH160501162E-2) with testing period May 24 – Jun 03, 2016, indicates the total amount is less than 100ppm.
Conclusion: The heavy metal content of the packaging material is acceptable.

4.6 Packaging compatibility test result on packaging material, by in house method of manufacturer Dongyuan MissGel Chemical Limited Company, on product name Base Gel (Batch no. 15111601), with a testing period Nov 17, 2015 – Feb 16, 2016, was submitted and reviewed.
Testing conditions : 25℃, 40±1℃, and -5 ~ -15℃ for 12 weeks
Testing parameters : Packing condition
Conclusion: The stability of the packaging material is acceptable.

5 Normal and reasonably foreseeable use

The normal use of this product is for application on nail plates then light-cured by adults. Application of this product to other parts of the body is unlikely. Ingestion of this product would be a misuse.

6 Exposure to the cosmetic product

Product type: Makeup cosmetics
Use category: Nail gel
Physical form: Liquid
The site(s) of application: Nail plates
The surface area(s) of application: 4 square centimeter
The amount per application: 0.25 g
The duration of exposure: 3360 minutes
The frequency of use: 52 times per year
The normal and reasonably foreseeable exposure route(s): Primarily via dermal contact
The targeted (or exposed) population(s): Adults
The body weight: 60 kg
Estimated daily amount applied: 36 mg/day

7 Exposure and toxicological profile of the substances

There are no nanoparticles indicated to be used in this formulation.
For toxicological profile of ingredients, refer to Annex 1.
All the ingredients were found to be present at levels that were permitted by the Cosmetic Regulation. Margins of safety (MOS) have been calculated, where applicable, based on systemic NOAEL when data is in the present stage of knowledge.

8 Undesirable effects and serious undesirable effects

No data on any undesirable effects associated with this product has been supplied.

9 Information on the cosmetic product

The product is indicated to be manufactured by Dongyuan MissGel Chemical Limited Company in a manufacturing setting according to ISO 22716: 2007 with scope of compliance on manufacturing of cosmetics for nail art, including nail gel, by third party laboratory (Intertek Certificate No. SZ1506A1 which is valid until May 31, 2018).

PART B - COSMETIC PRODUCT SAFETY ASSESSMENT

1. Assessment conclusion

The product complies with the Regulation (EC) No. 1223/2009 and its subsequent amendments for professional use when used as directed.
Provided the manufacturer's instructions are followed and skin contact is avoided, it is considered that, in the present state of knowledge, the submitted formulation put on the market is unlikely to pose a significant risk to the health of intended consumer under normal and reasonably foreseeable conditions of use. However, due to the presence of hazardous substance, p-Hydroxyanisole (MEHQ), the product should be labelled to provide clear instruction of use as well as warnings and cautionary statements to alert the consumer and professional the potential hazard if misused and to keep the product out of reach of children and avoid skin contact.

2. Labelled warnings and instructions of use

For professional use only. ***(Mandatory)***
Read directions for use carefully. ***(Mandatory)***
Avoid skin contact. ***(Mandatory)***
Keep away from heat and avoid direct sunlight.
Keep out of reach of children.
Avoid contact with eyes, mouth and skin. Rinse them immediately should the product comes into contact with them. If there is any incident, contact the poison center immediately.
May cause sensitization by skin contact. Avoid contact with skin. Rinse off immediately in case of contact. Stop using the product if redness and itching develop. If symptom persists, consult a doctor.

3. Reasoning

The potential interactions between ingredients have been considered. The submitted test results indicate the product will be safe for intended use concerning the impurity, stability, microbiological quality, and preservative efficacy, while the product was manufactured in accordance with ISO 22716:2007 Cosmetic GMP.
This product is a UV-cured nail gel which hardens on the nail plates under the influence of UV-light. It is expected to cause irritation if contact with skin and eyes. The product contains hazardous substance p-Hydroxyanisole (MEHQ) (CAS No. 150-76-5), as polymerization inhibitor, at a level of 69.64 ppm (0.006964%) that requires this product to be used by professional only, as the product is expected to cause sensitization by skin contact. However, provided the manufacturer's instructions are followed and skin contact is avoided, the formulation is not expected to pose a significant risk under normal and reasonably foreseeable conditions of use. The product should be labelled to provide clear instruction of use as well as warnings and cautionary statements to alert the consumer and professional the potential hazard if misused and to keep the product out of reach of children and avoid skin contact. It is manufacturer's responsibility to ensure that the MEHQ content does not exceed 0.02% (after mixing for use) in each batch of product in order to substantiate the safety of the product and its compliance with the EU Cosmetic Regulation.
This product is not a finished consumer product as it is indicated to be supplied to other manufacturers for re-packaging. The client and the manufacturers are drawn to the attention that the finished consumer product should be assessed individually and a separate safety report is required.

4. Assessor's credentials and approval of Part B
Date: Jul 29, 2016

Chun-Ngai Lee, Gerald BSc(Hons), MSc, MRSB, MBTS

The validity of this review depends on the validity of disclosure by both the manufacturer of the components and that of the finished products. Best professional capabilities are used in performing this review and if the client wishes to use this opinion with any alternations to the submitted formula, SGS (HK) Ltd. or any of its employees will not be held liable for any injury or damage resulting from this product. This review will need to be updated upon reformulation or upon change of the new significant safety information.

******** End of Report ********

ANNEX 1 TOXICOLOGICAL PROFILE OF INDIVIDUAL INGREDIENT

1. Acrylates Copolymer

CAS No.: 25133-97-5 / 25035-69-2 / 25212-88-8 / 159666-35-0 / 25685-29-4
EINECS/ELINCS: N/A
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe for use when formulated to avoid irritation
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.3250594 mg/kg bw/day
MOS: --
Acrylates Copolymer is a copolymer of two or more monomers consisting of acrylic acid, methacrylic acid or one of their simple esters. Acrylates Copolymers are considered similar in that they are uniformly produced in chemical reactions that leave very little residual monomer. While residual acrylic acid may be as high as 1500 ppm, typical levels are 10-1000 ppm. There is sufficient odor if residual monomers are present to cause producers to keep levels as low as possible. These ingredients function in cosmetics as binders, film formers, and antistatic agent. Concentrations may be as high as 25% if used as a binder, film former, or fixative. These very large polymers exhibit little toxicity. In rabbits and guinea pigs, Acrylates Copolymer did produce irritation, but no evidence of sensitization was found. The principle concern regarding the use of Acrylates Copolymer is the presence of toxic residual monomers. However the levels that would be found in cosmetic formulations are not considered presenting a safety risk. Accordingly, the CIR Expert Panel concludes that Acrylate Copolymers are considered safe for use in cosmetic formulations when formulated to avoid irritation, in addition to containing technically unavoidable trace amount of residual monomers.

2. Ethyl Methacrylate

CAS No.: 97-63-2
EINECS/ELINCS: 202-597-5
CLP Classification: Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; Eye Irrit. 2, H319; STOT SE 3, H335
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: safe as used when application is accompanied by directions to avoid skin contact because of the sensitizing potential
Food additive recommendation: None
Toxicological profile by chemical supplier: Flammable liquids (Category 2), H225; Skin irritation (Category 2), H315; Eye irritation (Category 2), H319; Skin sensitisation (Category 1), H317; Specific target organ toxicity - single exposure (Category 3), Respiratory system, H335
NOAEL: --
SED: 0.1870457 mg/kg bw/day
MOS: --
Ethyl Methacrylate (EMA) is the ester of ethyl alcohol and methacrylic acid. It conforms to the formula $C_6H_{11}O_2$. It can function as viscosity controlling agent in cosmetics. EMA is also used as the major

structural monomer of commercial and retail artificial fingernail formulations that are cross-linked with one or more multifunctional methacrylates. It is used as a substitute for methyl methacrylate. The oral LD50 for rats ranged between 12.70 and 18.14g/kg. The LC50/24 for rats was 8,300 ppm with ocular, nasal and respiratory tract irritation was observed, while the lungs, trachea, and bronchi of the rats were observed to be markedly congested, edematous and spotted in another study. The CIR Expert Panel concluded that, although individuals can become sensitized to EMA, the risk of that happening as a result of the use of artificial nail products is low. In order to minimize any exposure to free monomer, t he Panel also recommends that commercial fingernails enhancement products containing EMA should be applied by trained individuals and that skin contact be avoided. Therefore, EMA is safe as used as a cosmetic ingredient when application is accompanied by directions to avoid skin contact because of the sensitizing potential of EMA.
On the other hand, based on the estimates of potency derived from local lymph node essay (LLNA) data, the results of guinea pig assays, data derived from in silico methods and in vitro approaches, and human studies and clinical experience, it was concluded that EMA is a contact allergen resulting in allergic contact dermatitis (ACD) but the available evidence indicated that it has only modest (weak) skin sensitization potency.
The submitted Certificate of Analysis (COA) of this ingredient, as supplied by Sigma-Aldrich (Shanghai) Trading Co., Ltd., indicated that the purity was determined to be 98%, and it contains 221 ppm of MEHQ as inhibitor.

3. Ethyl Acetate
CAS No.: 141-78-6
EINECS/ELINCS: 205-500-4
CLP Classification: Flam. Liq. 2 H225; Eye Irrit. 2 H319; STOT SE 3 H336
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used at concentration more than 50%
Food additive recommendation: None
Toxicological profile by chemical supplier: Flam.Liq. 2 H225
NOAEL: 1000 mg/kg bw/day
SED: 0.0308676 mg/kg bw/day
MOS: 16198.21
Ethyl Acetate is the ester of ethyl alcohol and acetic acid and conforms to the formula $C_4H_8O_2$. It is a clear liquid which is miscible with water, alcohols, acetone, chloroform and ether, and is used as perfuming and solvent in cosmetics such as nail polish, nail polish removers, basecoats and other manicuring preparations. LD50 and ND50 (quantity that produced stupor and loss of voluntary movements in half of the experimental animals) in rabbits was reported to be 4.9 g/kg and 4.5 g/kg respectively. A nail polish containing 10% Ethyl Acetate was a moderate to severe irritant in unrinsed rabbit eyes and a mild irritant in rinsed rabbit eyes. Ethyl Acetate was non-mutagenic when tested by the Ames procedure, Rec-assay, and micronucleus assay. It did not induce mitotic aneuploidy in yeast and chromosomal aberrations in Chinese hamster fibroblasts. Ethyl Acetate was a mild skin irritant but was not sensitizing to human, it was neither phototoxic nor photo-allergenic in human clinical tests. The CIR Expert Panel concluded that Ethyl Acetate is safe as cosmetic ingredients in the present practices of use and concentration.
The occupational exposure limits are set: TLV: 400 ppm as TWA; (ACGIH 2004); MAK: 400 ppm, 1500 mg/m3; Peak limitation category: I(2); Pregnancy risk group: C; (DFG 2004).OSHA PEL: TWA 400 ppm (1400 mg/m^3); NIOSH REL: TWA 400 ppm (1400 mg/m^3); NIOSH IDLH: 2000 ppm 10% LEL.

4. Butyl Acetate
CAS No.:123-86-4
EINECS/ELINCS: 204-658-1
CLP Classification: Flam. Liq. 3, H226; STOT SE 3, H336
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 72%
Food additive recommendation: None
Toxicological profile by chemical supplier: Flam Liq. 3 H226; STOT SE3, H336
NOAEL: --
SED: 0.0195890 mg/kg bw/day
MOS: --
Butyl Acetate is the ester of butyl alcohol and acetic acid. It conforms to the formula of $C_6H_{12}O_2$. Butyl Acetate is used as solvents in nail polish, nail polish removers, basecoats, and other manicuring preparations. Butyl Acetate was relatively nontoxic when administered orally, dermally or by inhalation to rabbits, rats, mice and guinea pigs. A nail polish containing 25 percent Ethyl Acetate was a moderate to severe irritant in unrinsed rabbit eyes and a mild irritant in rinsed rabbit eyes. Butyl Acetate was not a sensitizer in either mice or guinea pigs. It was nonmutagenic when tested by the Ames procedure, Rec-assay, and micronucleus assay. It did not induce mitotic aneuploidy in yeast and chromosomal aberrations in Chinese hamster fibroblasts. Butyl Acetate was nonmutagenic in all these assays and was not teratogenic when inhaled. Butyl Acetate was mild skin irritants but not sensitizers to humans. The CIR Expert Panel concludes that Butyl Acetate is safe as cosmetic ingredients in the present practices of use and concentration.

5. Dimethicone
CAS No.: 63148-62-9 / 9006-65-9 / 9016-00-6 / 141-62-8 / 141-63-9
EINECS/ELINCS: N/A
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 80% in hair preparations; and up to 24% in makeup
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.0171553 mg/kg bw/day
MOS: --
Dimethicone is a mixture of fully methylated linear siloxane polymers end blocked with trimethylsiloxy units and with a formula as $(C_2H_6OSi)_xC_4H_{12}Si$. It is used as antifoaming, emollient, skin conditioning and skin protecting. It was indicated to cause minimum irritation in most dermal irritation studies and a mild to minimal irritation in ocular irritation studies, all in rabbits.

6. Microcrystalline Wax
CAS No.: 63231-60-7
EINECS/ELINCS: 264-038-1
CLP Classification: N/A
EU Cosmetic Regulation: None

SCCS opinion: None
CIR recommendation: Safe to be used up to 50%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 1100 mg/kg bw/day
SED: 0.0132968 mg/kg bw/day
MOS: 41363.34
Microcrystalline Wax is a wax derived from petroleum and characterized by the fineness of its crystals in contrast to the larger crystals of paraffin wax. It consists of high molecular weight saturated aliphatic hydrocarbons. It is used as emulsion stabilizers, viscosity controlling, binding and bulking agents in cosmetics. Based on the available documented animal and clinical test data, the CIR concluded that it is safe for use as cosmetic ingredients in the present practices of concentration and use.

7. CI 77891
CAS No.: 13463-67-7
EINECS/ELINCS: 236-675-5
CLP Classification: N/A
EU Cosmetic Regulation: Annex IV; Annex VI: Maximum concentration in ready for use preparation is 25% as UV filter (sum of Titanium Dioxide and Titanium Dioxide (nano))
SCCS opinion: No
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 2500 mg/kg bw/day
SED: 0.0005936 mg/kg bw/day
MOS: 2105795.15
Titanium dioxide is the inorganic oxide with an empirical formula O_2Ti. It functions as opacifier, UV absorber, UV filter and colorant in cosmetics. INCI name CI 77891 should be used when it functions as colorant. CI 77891 is generally used as white colorant and allowed in cosmetic products according to EU Cosmetic Regulation and should fulfill the purity criteria as set out in Commission Directive 95/45/EC (E171). IARC concluded that there is inadequate evidence in humans for the carcinogenicity of titanium dioxide but sufficient evidence in experimental animals for the carcinogenicity of titanium dioxide. Both nano and non nano size Titanium dioxide was classified as a Group 2B carcinogen (Possibly carcinogenic to humans). Titanium dioxide particles have shown to lead to carcinogenic effects after inhalation. Therefore the SCCS does not recommend the use of nano titanium dioxide in applications that might lead to inhalation exposure to the nanoparticles (such as powders or sprayable products). However, due to the lack of penetration of titanium dioxide nanoparticles through human skin, systemic exposure of the titanium dioxide to reach viable cells of the epidermis, dermis, or other organs is unlikely. Therefore, the SCCS considers that the use of nano titanium dioxide in dermally applied cosmetic products should not pose any significant risk to the consumer. The EU Cosmetic Regulation currently allows the safe use of titanium dioxide as a UV-filter at a maximum concentration of 25% in cosmetic products. In light of the SCCS opinions mentioned above, titanium dioxide (nano), according to the SCCS's specifications, should be authorised for use as a UV-filter in cosmetic products at a maximum concentration of 25 % w/w, except in applications that may lead to exposure of the end-user's lungs by inhalation.
On Nov 6, 2015, the French Agency for Food, Environmental and Occupational Health and Safety (Anses) has submitted an intention to the ECHA to propose a harmonised classification for titanium dioxide as a category 1B carcinogen. If the CLH proposal is accepted, the use of titanium dioxide will be prohibited

unless it is further reviewed and found save by the SCCS for use in cosmetic products.

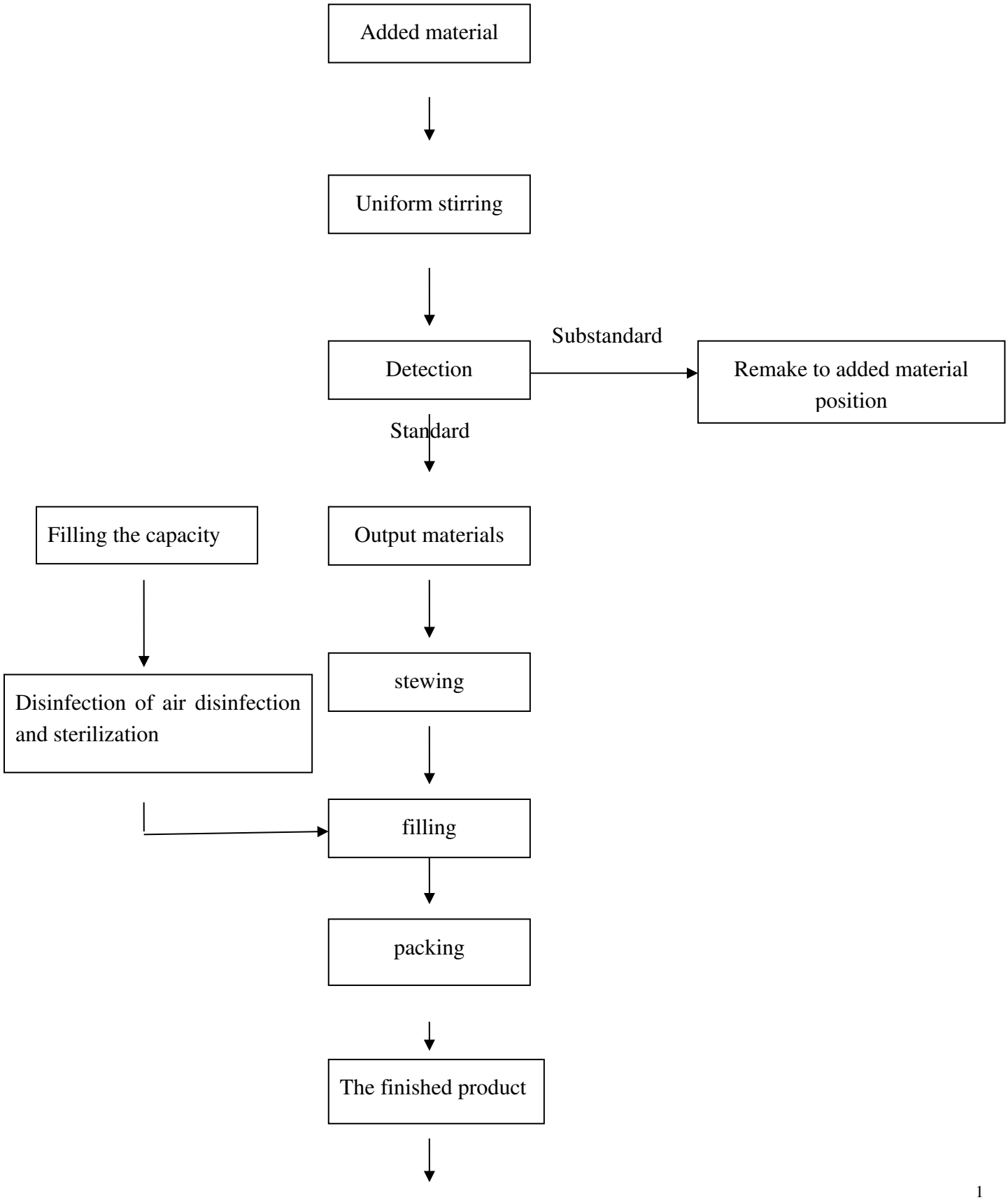
******** End of Annex ********

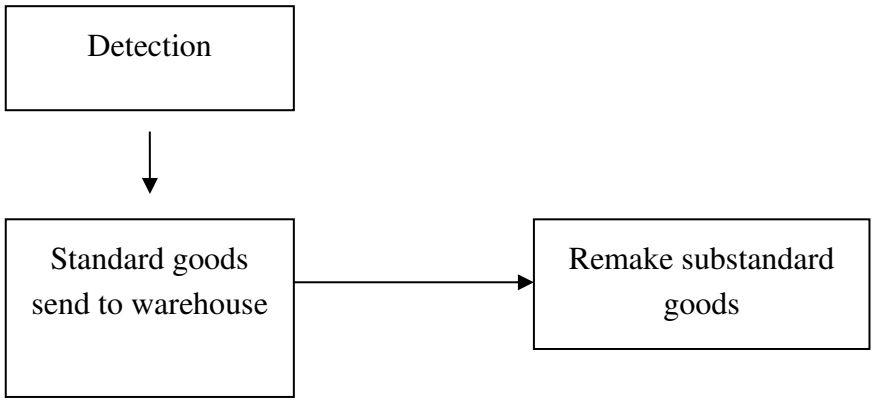
Part 8 Manufacturing process
Awesome Cosmetics, Base Gel

Manufacturing process

Status	Data received
	Limited data
Description manufacturing process	Detailed description of manufacturing process is missing. Only global information is given about the manufacturing process.
Extra info manufacturing process	

Process flow diagram




Detection
Standard goods send to warehouse
Remake substandard goods

GMP compliance

GMP status:	In compliance
GMP garanteed by	Intertek China
Adress	5/F., M-Space, Bldg A Nanhai Avenue South Shekou
City	Shenzhen
Country	China
Telephone	+86 755 2602 0547
Website	www.intertek.com
Issue date:	14-8-2018

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Heyuan MissGel New Material Co., Ltd.

2/F, Bldg. A2, Xinhuafeng Tech. Park, Hudieling Ind. Zone, Xiantang Town, Dongyuan County, Heyuan City, Guangdong Province, China

has been assessed by Intertek as conforming to the requirements of:

COSMETIC GOOD MANUFACTURING PRACTICE GUIDELINES (2008) PUBLISHED BY U.S. FOOD AND DRUG ADMINISTRATION

The scope of activities:

Manufacturing of Cosmetics for Nail Art, including Nail Gel

GMPC
Intertek

Certificate Number:
SZ1808C7

Initial Audit Date:
18-20 May, 2015

Certificate Issue Date:
14 Aug, 2018

Certificate Expiry Date:
13 Aug, 2021

Certification Administration Centre
Intertek Testing Services

1st year | 2nd year

This certificate is valid as long as it bears a proper and authentic Intertek's Laser Logo dedicated for the year of initial certification and after satisfactory annual surveillance.

Helen Xue
General Manager
Chemicals & Pharmaceuticals Division

intertek
Total Quality. Assured.

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2/F, Bldg. A2, Xinhuafeng Tech. Park, Hudieling Ind. Zone, Xiantang Town, Dongyuan County, Heyuan City, Guangdong Province, China

has been assessed by Intertek as conforming to the requirements of:

ISO22716:2007(E) COSMETICS - GUIDELINES ON GOOD MANUFACTURING PRACTICES

The scope of activities:

Manufacturing of Cosmetics for Nail Art, including Nail Gel

ISO 22716
Intertek

Certificate Number:
SZ1808C6

Initial Audit Date:
18-20 May, 2015

Certificate Issue Date:
14 Aug, 2018

Certificate Expiry Date:
13 Aug, 2021

Certification Administration Centre
Intertek Testing Services

1st year | 2nd year

This certificate is valid as long as it bears a proper and authentic Intertek's Laser Logo dedicated for the year of initial certification and after satisfactory annual surveillance.

Helen Xue
General Manager
Chemicals & Pharmaceuticals Division

Product stability

Stability test protocol:	3 month accelerated test
Test decription:	Product stability tests are used to assure stability and physical integrity of the product under storage. Products are exposed to elevated temperatures, elevated humidity's, exposure to light, mechanical tests, and cycling tests in which the temperature and/or humidity are changed at regular intervals and which, therefore, subject the pack to varying stresses, are sometimes more severe tests than continuous storage at one condition, such as freeze/thaw tests. The endpoints are: Appearance, colour, odour, taste, texture. All the parameters of product specifications should be measured (e.g. pH, viscosity). Other endpoints are active ingredient / preservatives content and activity. Emulsions should be examined after storage for droplet size of the disperse phase even if this is not included in the product specification. Accelerated testing of the product had been performed with control test at low degree and room temperature. Accelerated testing of the product has been done on elevated temperature in the temperature range of 37 – 45 degree. Protocols which are used are not strict protocols, but follow the guidelines on stability testing of cosmetic products, Cosmetic Europe. The guidelines for accelerated tests have the following protocols or are derived of those protocols: a control at 4 degrees Celsius / ambient humidity is used, combined with variable temperature conditions including 20°C (projected shelf-life), 37°C (max 3-6 months), or 45°C (max 1-3 months) at ambient humidity or 37 °C / 80% ambient humidity. The assessment of samples stored at elevated temperature may be made very approximately on the assumption of a two-fold acceleration for each 10°C rise in temperature. Optional are cycling tests, light tests and mechanical tests.
Additional information:	Stability of appearance, odour, pH value and viscosity tested at 25, 40 and -5~-15 tested for 12 weeks was acceptable for this application.

Stability tested by	SGS Hong Kong Limited
Adress	On Wui Centre, 25 Lok Yip Road
City	New Territories, Hong Kong
City	Hong Kong
Telephone	+85223344481
Website	www.sgsgroup.com.hk
Date of testing:	29-7-2016

PART A - COSMETIC PRODUCT SAFETY INFORMATION

INTRODUCTION

SGS is requested to review the safety of the product formula BASE GEL for consumer health and no other part of the product. The product is for EU market and intended for application on nail plates then light-cured for changing appearance by adults. This product is not a finished consumer product as it is indicated to be supplied to other manufacturers for re-packaging. The client and the manufacturers are drawn to the attention that the finished consumer product should be assessed individually and a separate safety report is required.

The net weight of this product (The formulation under assessment) is 1 kg or 5 kg per consumer product. Detailed formulation is submitted by the client as in Section 1.

LITERATURE SOURCES

This review was compiled by using information gathered from raw material suppliers and various online databases including the EU Scientific Committee on Consumer Safety (SCCS) opinions, Cosmetic Ingredients Review (CIR); detailed references are not reported here but are recorded in the SGS Scientific Archives.

1 Quantitative and qualitative composition of cosmetic product under assessment

INCI or Chemical Name	CAS No.	EINECS/ ELINCS	Conc. %	Intended Function
Acrylates Copolymer	25035-69-2	N/A	54.7600	Antistatic / binding / film forming
Ethyl Methacrylate	97-63-2	202-597-5	31.5100	Viscosity controlling
Ethyl Acetate	141-78-6	205-500-4	5.2000	Perfuming / solvent
Butyl Acetate	123-86-4	204-658-1	3.3000	Masking / solvent
Dimethicone	9016-00-6	N/A	2.8900	Antifoaming / emollient / skin conditioning / skin protecting
Microcrystalline Wax	63231-60-7	264-038-1	2.2400	Binding / bulking / emulsion stabilising / viscosity controlling
Colouring Agent				
CI 77891	13463-67-7	236-675-5	0.1000	Cosmetic colorant / opacifying / UV absorber / UV filter

FRAGRANCE ALLERGENS

No parfum is present in the formulation.

2 Physical/chemical characteristics and stability of the formulation

2.1 The product is a colourless liquid, with pH value 5.8 – 6.1, and viscosity 5300 – 5700 mpa/s.

2.2 The stability test result on formulation, by in house method of manufacturer Dongyuan MissGel Chemical Limited Company, on product name Base Gel (Batch no. 15111601), with a testing period Nov 17, 2015 – Feb 16, 2016, was submitted and reviewed. It is the responsibility of the manufacturer and responsible person to determine the product's minimum durability and period-after-opening (PAO), if applicable, using the available data.

Testing conditions : 25℃, 40±1℃, and -5 ~ -15℃ for 12 weeks

Testing parameters : Appearance, odour, pH value, and viscosity

Conclusion: The stability of the formulation is acceptable for this application.

Microbiological quality

Stability test protocol:	Ph. Eur
Description:	The antimicrobial activity of the preparation in its final container is investigated over the period of validity to ensure that such activity has not been impaired by storage. The test consists of challenging the preparation, wherever possible in its final container, with a prescribed inoculum of suitable micro-organisms, storing the inoculated preparation at a prescribed temperature, withdrawing samples from the container at specified intervals of time and counting the organisms in the samples so removed. Single-strain challenges are used comprising P. aeruginosa, S. aureus, C. albicans, A. Brasiliensis. A suitable sample is removed from each container, typically 1 mL or 1 g, at zero hour and at appropriate intervals according to the type of the product and the number of viable micro-organisms is determined by plate count or membrane filtration. These intervals are as follows. For parenteral/eye/intrauterine/intramammary preparations the intervals are at 0, 6, 24 h, and 7, 14, 28d. For ear/nasal/cutaneous application/inhalation preparations the intervals are at 0, 2, 7, 14, 28d. For oral/oromucosal/rectal preparations the intervals are at 0, 14, 28d. For bacteria, a log reduction of 3 should be observed after 7d; for fungi this is a log reduction up to 2 after 14d. At 28d, no increase in number of viable micro-organisms compared to the previous reading should be observed.oduct and the number of viable micro-organisms is determined by plate count or membrane filtration.
Tested by:	SGS Hong Kong Limited
Adress	On Wui Centre, 25 Lok Yip Road
City	New Territories, Hong Kong
Telephone	+85223344481
Website	www.sgsgroup.com.hk
Date of testing:	24-5-2016
Status:	In compliance

3 Microbiological quality

3.1 The microbiological test result on formulation, with reference to European Pharmacopeia 8.0 2.6.12 & 2.6.13, by third party laboratory (SGS report no. GZCPCH160501162E-1.3), with testing period May 24 – Jun 02, 2016, was submitted and reviewed based on following criteria.

Product Category of this product: 2

Micro-organisms	Total viable count and Total yeast and mold	*P.aeruginosa*, *S.aureus* and *C.albicans*
Category 1: Products specifically intended for children under 3 years, to be used in the eye area and on mucous membranes	≤ 100 cfu/g or 100 cfu/ml	not detectable in 1g or 1 ml
Category 2: Other products	≤ 1000 cfu/g or 1000 cfu/ml	not detectable in 0.1g or 0.1 ml

Conclusion: The microbiological quality of the formulation is acceptable for this application.

3.2 The preservation efficacy test result on formulation, with reference to European Pharmacopeia 8.0 5.1.3, by third party laboratory (SGS report no. GZCPCH160501162E-1.5), with testing period May 24 – Jul 11, 2016, was submitted and reviewed based on following criteria.

		Day 2	Day 7	Day 14	Day 28
Criteria A	*E.coli, P.aeruginosa, S.aureus*	2	3	/	NI
	C. albicans	/	/	2	NI
	A. brasiliensis (niger)	/	/	2	NI
Criteria B	*E.coli, P.aeruginosa, S.aureus*	/	/	3	NI
	C. albicans	/	/	1	NI
	A. brasiliensis (niger)	/	/	1	NI

NI: No increase

Conclusion: The preservative efficacy of the formulation achieved B criteria and is acceptable for this application.

4 Impurities, traces and information about the formulation and the packaging material

4.1 The heavy metal test result on formulation, by third party laboratory (SGS report no. GZCPCH160501162E-1.2), with testing period May 24 – 31, 2016, was submitted and reviewed based on following criteria.

	German Health Authority BgA (Recommendation from German Health Journal No. 28, July 1985) and The German Health Journal No. 7/1992, Session 45 from November 14, 1991					
Test items	As	Hg	Pb	Sb	Cd	Ni (soluble)
Limit (mg/kg)	≤5	≤1	≤20	≤10	≤5	≤10

Conclusion: The heavy metal content of the formulation is acceptable for this application.

4.2 The determination of phthalates Benzyl Butyl Phthalate (BBP), Bis(2-Ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Bis(2-Methoxyethyl) Phthalate (DMEP), Di-n-Pentyl Phthalate (DnPP), Diisopentylphthalate (DIPP), and N-pentyl iso-pentyl phthalate (PIPP), by third party laboratory (SGS report no.GZCPCH160501162E-1.1) with testing period May 24 – 31, 2016, indicates total tested phthalates is not detected, with a detection limit of 5 mg/kg.

Conclusion: The phthalates content of the formulation is acceptable.

4.3 The determination of hydroquinone, with reference to Hygienic Standard for Cosmetics 2007, by third party laboratory (SGS report no.GZCPCH160501162E-1.4) with testing period May 24 – Jun 03, 2016, indicates hydroquinone is not detected, with a detection limit of 7 µg/kg.

Part 12 PIF Raw materials overview

Awesome Cosmetics, Base Gel

Qualitative composition: purity grade & physical information on raw materials

Code	Raw materials	Supplier	Manufacturer	Physical state	Physical infomation	Purity grade
	Acrylates Copolymer, Acrylates Copolymer [Zhaoqing Powerdream Chemical Co., Ltd.]	Zhaoqing Powerdream Chemical Co., Ltd.	Zhaoqing Powerdream Chemical Co., Ltd.	liquid	see Annex I, MSDS section 9	unknown
	Ethyl Methacrylate, Ethyl Methacrylate [Sigma Aldrich]	Sigma-Aldrich	Sigma-Aldrich	liquid	see Annex I, MSDS section 9	unknown
	Ethyl Acetate, Ethyl Acetate [Lily Group Co., Ltd.]	Lily Group Co. Ltd.	Lily Group Co. Ltd.	liquid	see Annex I, MSDS section 9	unknown
	Butyl Acetate, Butyl Acetate [Sigma-Aldrich]	Sigma-Aldrich	Sigma-Aldrich	liquid	see Annex I, MSDS section 9	unknown
	Dimethicone, Dimethicone [Lily Group Co., Ltd.]	Lily Group Co. Ltd.	Lily Group Co. Ltd.	liquid	see Annex I, MSDS section 9	unknown
	Microcrystalline Wax, Microcrystalline Wax [Lily Group Co., Ltd.]	Lily Group Co. Ltd.	Lily Group Co. Ltd.	solid	see Annex I, MSDS section 9	unknown
	Titanium Dioxide, CI 77891 [Lily Group Co., Ltd.]	Lily Group Co. Ltd.	Lily Group Co. Ltd.	solid	see Annex I, MSDS section 9	unknown

Identification of raw materials & documentations

Identification of raw material

Code	
Name	Acrylates Copolymer, Acrylates Copolymer [Zhaoqing Powerdream Chemical Co., Ltd.]
Supplier	Zhaoqing Powerdream Chemical Co., Ltd.
Purity grade	unknown/no document
Microbiol aspects	Not specified

Address supplier

Address	Deqing industrial park, Deqing county
City	Zhaoqing city
Country	China

Composition of raw material

Ingredient or impurity	Min %	Max %	Component
Acrylates Copolymer	0	100	Ingredient

Referred documents

CoA - Certificate of Analysis	1
(e)MSDS	1

Part 13 Raw materials & documentation

Sigma-Aldrich, Ethyl Methacrylate, Ethyl Methacrylate [Sigma Aldrich]

Identification of raw materials & documentations

Identification of raw material

Code	
Name	Ethyl Methacrylate, Ethyl Methacrylate [Sigma Aldrich]
Supplier	Sigma-Aldrich
Purity grade	unknown/no document
Microbiol aspects	Not specified

Address supplier

Address	3050 Spruce Street
City	Saint Louis
Country	United States

Composition of raw material

Ingredient or impurity	Min %	Max %	Component
Ethyl Methacrylate	96,5	100	Ingredient
p-Hydroxyanisole	0	0,025	Addition

Referred documents

CoA - Certificate of Analysis	1
(e)MSDS	1

Part 13 Raw materials & documentation

Lily Group Co. Ltd., Ethyl Acetate, Ethyl Acetate [Lily Group Co., Ltd.]

Identification of raw materials & documentations

Identification of raw material

Code	
Name	Ethyl Acetate, Ethyl Acetate [Lily Group Co., Ltd.]
Supplier	Lily Group Co. Ltd.
Purity grade	unknown/no document
Microbiol aspects	Not specified

Address supplier

Address	Nongyi Chang town, Linjiang Industrial Park
City	Hangzhou City
Country	China

Composition of raw material

Ingredient or impurity	Min %	Max %	Component

Referred documents

CoA - Certificate of Analysis	1
(e)MSDS	1

Part 13 Raw materials & documentation

Sigma-Aldrich, Butyl Acetate, Butyl Acetate [Sigma-Aldrich]

Identification of raw materials & documentations

Identification of raw material

Code	
Name	Butyl Acetate, Butyl Acetate [Sigma-Aldrich]
Supplier	Sigma-Aldrich
Purity grade	unknown/no document
Microbiol aspects	Not specified

Address supplier

Address	3050 Spruce Street
City	Saint Louis
Country	United States

Composition of raw material

Ingredient or impurity	Min %	Max %	Component

Referred documents

CoA - Certificate of Analysis	1
(e)MSDS	1

Part 13 Raw materials & documentation
Lily Group Co. Ltd., Dimethicone, Dimethicone [Lily Group Co., Ltd.]

Identification of raw materials & documentations

Identification of raw material

Code	
Name	Dimethicone, Dimethicone [Lily Group Co., Ltd.]
Supplier	Lily Group Co. Ltd.
Purity grade	unknown/no document
Microbiol aspects	Not specified

Address supplier

Address	Nongyi Chang town, Linjiang Industrial Park
City	Hangzhou City
Country	China

Composition of raw material

Ingredient or impurity	Min %	Max %	Component

Referred documents

CoA - Certificate of Analysis	1
(e)MSDS	1

Identification of raw materials & documentations

Identification of raw material

Code	
Name	Microcrystalline Wax, Microcrystalline Wax [Lily Group Co., Ltd.]
Supplier	Lily Group Co. Ltd.
Purity grade	unknown/no document
Microbiol aspects	Not specified

Address supplier

Address	Nongyi Chang town, Linjiang Industrial Park
City	Hangzhou City
Country	China

Composition of raw material

Ingredient or impurity	Min %	Max %	Component
Microcrystalline Wax	99	100	Ingredient

Referred documents

CoA - Certificate of Analysis	1
(e)MSDS	1

Part 13 Raw materials & documentation

Lily Group Co. Ltd., Titanium Dioxide, CI 77891 [Lily Group Co., Ltd.]

Identification of raw materials & documentations

Identification of raw material

Code	
Name	Titanium Dioxide, CI 77891 [Lily Group Co., Ltd.]
Supplier	Lily Group Co. Ltd.
Purity grade	unknown/no document
Microbiol aspects	Not specified

Address supplier

Address	Nongyi Chang town, Linjiang Industrial Park
City	Hangzhou City
Country	China

Composition of raw material

Ingredient or impurity	Min %	Max %	Component
CI 77891	97	100	Ingredient

Referred documents

CoA - Certificate of Analysis	1
(e)MSDS	1

Part 14 Packaging material
Awesome Cosmetics, Base Gel

Packaging material

Packaging material	PE
Purity	In compliance
Volume or weight	10 ml
Interference packaging with the product	In compliance

Packager	Heyuan MissGel New Material Co., Ltd.
Adress	2/F, Bldg. A2 Xinhuafeng Tech. Park, Hudieling Ind. Zone
City	Heyuan City, Guandong Province
Telephone	[redacted]
Website	http://www.missgelish.com/

Cosmetic quality garanteed by	SGS Hong Kong Limited
Adress	On Wui Centre, 25 Lok Yip Road
City	New Territories, Hong Kong
Country	Hong Kong
Telephone	+85223344481
Website	www.sgsgroup.com.hk

3 Microbiological quality

3.1 The microbiological test result on formulation, with reference to European Pharmacopeia 8.0 2.6.12 & 2.6.13, by third party laboratory (SGS report no. GZCPCH160501162E-1.3), with testing period May 24 – Jun 02, 2016, was submitted and reviewed based on following criteria.

Product Category of this product: 2

Micro-organisms	Total viable count and Total yeast and mold	*P.aeruginosa*, *S.aureus* and *C.albicans*
Category 1: Products specifically intended for children under 3 years, to be used in the eye area and on mucous membranes	≤ 100 cfu/g or 100 cfu/ml	not detectable in 1g or 1 ml
Category 2: Other products	≤ 1000 cfu/g or 1000 cfu/ml	not detectable in 0.1g or 0.1 ml

Conclusion: The microbiological quality of the formulation is acceptable for this application.

3.2 The preservation efficacy test result on formulation, with reference to European Pharmacopeia 8.0 5.1.3, by third party laboratory (SGS report no. GZCPCH160501162E-1.5), with testing period May 24 – Jul 11, 2016, was submitted and reviewed based on following criteria.

		Day 2	Day 7	Day 14	Day 28
Criteria A	*E.coli, P.aeruginosa, S.aureus*	2	3	/	NI
	C. albicans	/	/	2	NI
	A. brasiliensis (niger)	/	/	2	NI
Criteria B	*E.coli, P.aeruginosa, S.aureus*	/	/	3	NI
	C. albicans	/	/	1	NI
	A. brasiliensis (niger)	/	/	1	NI

NI: No increase

Conclusion: The preservative efficacy of the formulation achieved B criteria and is acceptable for this application.

4 Impurities, traces and information about the formulation and the packaging material

4.1 The heavy metal test result on formulation, by third party laboratory (SGS report no. GZCPCH160501162E-1.2), with testing period May 24 – 31, 2016, was submitted and reviewed based on following criteria.

	German Health Authority BgA (Recommendation from German Health Journal No. 28, July 1985) and The German Health Journal No. 7/1992, Session 45 from November 14, 1991					
Test items	As	Hg	Pb	Sb	Cd	Ni (soluble)
Limit (mg/kg)	≤5	≤1	≤20	≤10	≤5	≤10

Conclusion: The heavy metal content of the formulation is acceptable for this application.

4.2 The determination of phthalates Benzyl Butyl Phthalate (BBP), Bis(2-Ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Bis(2-Methoxyethyl) Phthalate (DMEP), Di-n-Pentyl Phthalate (DnPP), Diisopentylphthalate (DIPP), and N-pentyl iso-pentyl phthalate (PIPP), by third party laboratory (SGS report no.GZCPCH160501162E-1.1) with testing period May 24 – 31, 2016, indicates total tested phthalates is not detected, with a detection limit of 5 mg/kg.

Conclusion: The phthalates content of the formulation is acceptable.

4.3 The determination of hydroquinone, with reference to Hygienic Standard for Cosmetics 2007, by third party laboratory (SGS report no.GZCPCH160501162E-1.4) with testing period May 24 – Jun 03, 2016, indicates hydroquinone is not detected, with a detection limit of 7 µg/kg.

Conclusion: The hydroquinone content of the formulation is acceptable.

4.4 The client has supplied the following list of packaging parts for this product as the immediate container.

No.	Immediate Container	Material
1.	Bottle & Cap	PE

4.5 For packaging material, test result of lead, cadmium, mercury and chromium (VI) on immediate container by third party laboratory (SGS report no. GZCPCH160501162E-2) with testing period May 24 – Jun 03, 2016, indicates the total amount is less than 100ppm.
Conclusion: The heavy metal content of the packaging material is acceptable.

4.6 Packaging compatibility test result on packaging material, by in house method of manufacturer Dongyuan MissGel Chemical Limited Company, on product name Base Gel (Batch no. 15111601), with a testing period Nov 17, 2015 – Feb 16, 2016, was submitted and reviewed.
Testing conditions : 25℃, 40±1℃, and -5 ~ -15℃ for 12 weeks
Testing parameters : Packing condition
Conclusion: The stability of the packaging material is acceptable.

5 Normal and reasonably foreseeable use

The normal use of this product is for application on nail plates then light-cured by adults. Application of this product to other parts of the body is unlikely. Ingestion of this product would be a misuse.

6 Exposure to the cosmetic product

Product type: Makeup cosmetics
Use category: Nail gel
Physical form: Liquid
The site(s) of application: Nail plates
The surface area(s) of application: 4 square centimeter
The amount per application: 0.25 g
The duration of exposure: 3360 minutes
The frequency of use: 52 times per year
The normal and reasonably foreseeable exposure route(s): Primarily via dermal contact
The targeted (or exposed) population(s): Adults
The body weight: 60 kg
Estimated daily amount applied: 36 mg/day

7 Exposure and toxicological profile of the substances

There are no nanoparticles indicated to be used in this formulation.
For toxicological profile of ingredients, refer to Annex 1.
All the ingredients were found to be present at levels that were permitted by the Cosmetic Regulation. Margins of safety (MOS) have been calculated, where applicable, based on systemic NOAEL when data is in the present stage of knowledge.

8 Undesirable effects and serious undesirable effects

No data on any undesirable effects associated with this product has been supplied.

Material Safety Data Sheet (MSDS)

1 Identification of the substance/preparation and of the company/undertaking

.Product name: Nail Polish Glass Bottle

.End uses: Cosmetics containers

.Manufacturer/Supplier: Shandong Dingxin Electronic Glass Group Co.,Ltd

.Address: No.575 Shanghai Road, Rizhao City, Shandong Province, China

.Tel: +086-633-8359 602

.Fax: +086-633-8359 603

.E-Mail: wangxiaoqianglike@163.com

.Further information obtainable from: Shandong Dingxin Electronic Glass Group Co.,Ltd

.Emergency Telephone Number: +086-157 6333 8397

.Contact: Wang Xiaoqiang

2 Hazards identification

.NFPA ratings (scale 0 - 4)

Health = 0; Fire = 0; Reactivity = 0

.Classification according to Regulation (EC) No 1272/2008: The product is not classified according to the CLP regulation.

.Classification according to Directive GHS: Not applicable.

.Labelling according to Regulation (EC) No 1272/2008: Not applicable.

.Hazard pictograms: Not applicable.

.Potential Health Effects:

.Primary Entry Routes: Swallowed, Inhalation, Skin, and eye contact

.Inhalation: Product does not present an inhalation hazard under normal circumstances, If dust is generated in the production or processing ,short term exposure to high dust levels could cause respiratory tract irritation,Long term exposure to high Concentrations of dust should be avoided it will cause respiratory tract irritation and lung damage.

.Eyes: Dust may cause eye irritation inflammation,Direct contact should be avoided to prevent physical damage.

.Skin: No known acute effects of this product resulting from skin contact ,but contact the edge of the broken glass easier to cut through the skin. ,in light of good industrial hygiene exposure to any chemical should be kept to a minimum.

.Swallowed: The product is not toxic, but swallowed should be avoided to prevent physical damage.

.CARCINOGENIC EFFECTS: This material is not a known carcinogen. Classified NONE by NTP, NONE by OSHA, 3 (Not classifiable for humans) by IARC.

.MUTAGENIC EFFECTS: *Not available.*

.TERATOGENIC EFFECTS: *Not available.*

3 Composition/information on ingredients

.Description: Mixture of substances listed below with additions.

Components Name	***CAS Number***	***Approximate(%) by Wt.***	***Air Exposure Limits (mg/m3)***	
			ACGIH TLV (mg/m3)	***OSHA PEL (mg/m3)***
Silicon dioxide (SiO2)	*14808-60-7*	*73.5*	*0.1 Respirable dust*	*20 Total dust*
Aluminum oxide (AL2O3)	*1344-28-1*	*1.85*	*10 Total dust*	*15 Total dust*
Calcium oxide (CaO)	*1305-78-8*	*8.5*	*2 Calcium oxide*	*5 Calcium oxide*
Sodium dioxide (Na2O)	*1313-59-3*	*14.5*	*Not available*	*Not available*

4 First aid measures

.Inhalation: *Where have dust, move to fresh air immediately. If breathing is difficult, give oxygen. Get medical aid.*

.Eye: *Flush eyes with plenty of water for a few minutes, if uncomfortable develops or persists, Get medical aid.*

.Skin: *If there is damage ,Get medical aid*

.Ingestion: *Never give anything by mouth , Get medical aid.*

5 Fire-fighting measures

.General Information: *As in any fire,wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. Non-combustible, substance itself does not burn.*

.Flammable class: *0*

.Suitable extinguishing media: *Water, CO2, Dry Chemicals, Foam-Fog*

.Fire/Explosion Hazards: *Negligible fire hazard when exposed to heat or flame.*

.Fire Fighting Procedure: *Wear self contained breathing apparatus meeting NIOSH standards.*

6 Accidental release measures

.Small Spill: *Use appropriate tools to put the spilled solid in a convenient waste disposal container.*

.Large Spill: *No damaged products for repackaging ,Use a shovel to put the damaged products into a convenient waste disposal container. Be careful that the product is not present at a concentration level above TLV. Check TLV on the MSDS and with local authorities.*

7 Handling and storage

The regulations relating to storage remises apply to workshop where the product is handled :

.Handling: *Removal of mobile products need to wear protective gloves when products for the brittle materials, handled with care when handlingApply good manufacturing practice & industrial hygiene practices. Observe good personal hygiene, and do not eat, drink or smoke whilst handling. Wear protective goggles and gloves when handling material. Clean cloths、must be worn. Observe all warnings and precautions listed for the product.*

.Storage: *Store in a cool & dry area away from heat sources & protected from light. stored in relatively stable areas, to avoid collision occurred on a hard object Avoid dust formation .*

.Further information about storage condition: *None.*

8 Exposure controls/personal protection

.Exposure Limits: *See Section 3*

.Engineering Controls: *Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.*

.Personal Protection: *Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.*

.Protective Gloves:*Protective Gloves*

.Eye Protection: *Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.*

.Respirators: *Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.*

.Health measures: *Local exhaust ventilations may be necessary for some operation*

9 Physical and chemical properties

.General Information	
Form:	*Solid*
Color:	*Transparent*
Odor:	*Odorless*
.Change in condition	
Melting point/Melting range:	*>1600℃*
Boiling point/Boiling range:	*>2300℃*
.Self-igniting:	*Product is not self-igniting*
.Danger of explosion:	*Not available*
.Density:	
.Relative density:	*2.5083(Water=1)*
.Vapor density:	*Not available*
.Evaporation rate	*Not available*
.Solubility in/Miscibility with	
Water:	*Insoluble*
.PH-Value:	*Not available*

10 Stability and reactivity

.Chemical Stability: *Stable under normal temperatures and pressures.*

.Decomposition Products: *The following combustion products may be generated: Metal oxide.*

.Materials with which substance is incompatible: *Products can chemical reactions halides, strong oxidizers, strong acids.*

.Hazardous Polymerizations: *Will not occur.*

.Special Remarks on Reactivity: *Not available.*

.Special Remarks on Corrosively: *Not available.*

11 Toxicological information

.Chronic Effects on Humans: Causes damage to the following organs: *Not available.*

.Other Toxic Effects on Humans: *Not available.*

.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.*

.Products of Biodegradation: *None hazardous short term degradation products are not likely.*

.Water Danger/Protection: *Water hazard class 0 (German Regulation) (Self-assessment): No hazardous for water.*

13 Disposal considerations

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.

.Waste Disposal Methods: *Disposal must be done as territory and /or local government regulations..Waste management information will help to receive the best results.*

.Disposal of packaging: *Dispose of according to local regulations. Avoid disposing into drainage systems and into the environment.*

14 Transport information

.DOT Classification: *Not a DOT controlled material (United States).*

.UN Number: *Not available.*

.Packing Group: *Not available.*

.Special Provisions for Transport: *Not applicable.*

.Marine Pollutant: *Not*

.TDG Classification: *Not controlled under TDG (Canada).*

.ADR/RID Classification: *Not controlled under ADR(Europe)*

.IMO/IMDG Classification: *Not Controlled under IMDG.*

.ICAO/IATA Classification: *Not controlled under IATA.*

15 Regulatory information

US FEDERAL

TSCA: *Not listed on the TSCA inventory. It is for research and development use only.*

Health & Safety Reporting List: *None of the chemicals are on the Health & Safety Reporting List.*

CERCLA Hazardous Substances and corresponding RQs: *None of the chemicals in this material have an RQ.*

Chemical Test Rules: *None of the chemicals in this product are under a Chemical Test Rule.*

Section 12b: *None of the chemicals are listed under TSCA Section 12b.*

TSCA Significant New Use Rule: *None of the chemicals in this material have a SNUR under TSCA.*

SARA Section 302 Extremely Hazardous Substances: *None of the chemicals in this product have a TPQ.*

Section 313: *No chemicals are reportable under Section 313.*

OSHA: *None of the chemicals in this product are considered highly hazardous by OSHA.*

California Prop 65-California No Significant Risk Level: *None of the chemicals in this product are listed.*

European/International Regulations

European Labeling in Accordance with EC Directives

REACH Regulation List of Substances of very high concern (SVHC) :*None of the ingredients is listed.*

16 Other information

The contents and format of this MSDS are in accordance with ISO Commission Directive ISO11014-2009.

****

DISCLAIMER OF LIABILITY

The information in this MSDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handing, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This MSDS was prepared and is to be used only for this product. If the product is used as a component in another product, this MSDS information may not be applicable.

· ***Abbreviations and acronyms:***

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning theInternational Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

**********The End**********

Test Report **No: GZCPCH160902754E-c** **Date: 2016-09-23**

Client name:	Guangzhou Kailai Packaging Technology Co., ltd
Client address:	B building Dalang, 5block Industrial dalang south road, shijing street baiyun district Guangzhou city
Sample name:	Nail brush
Batch No./Date:	2016-9-9
Manufacturer:	Guangzhou Kailai Packaging Technology Co., ltd

Above sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

SGS job No.:	GZCPCH160902754-4
SGS reference No.:	CANCPCH1618375801
Date of receipt:	2016-09-18
Testing period:	2016-09-18~2016-09-23

TEST(S) REQUESTED:
Selected test(s) as requested by applicant:
To determine Lead, Cadmium, Mercury and Hexavalent Chromium content in the submitted packaging sample as specified in 94/62/EC and its amendments.

TEST METHOD(S):
SGS in house method, analysis of Lead, Cadmium and Mercury was performed by ICP-OES.
Analysis of Hexavalent Chromium (Cr(VI)) was performed by UV-Vis

TEST RESULT(S): Please refer to next page(s).

CONCLUSION:
The sum of Lead, Cadmium, Mercury and Hexavalent Chromium content in the submitted packaging sample complies with the Limit Stated in European Council Directive 94/62/EC-Article 11 that effective from June 2001 and its amendments.

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, and this document cannot be used for publicity without approval of the Company.
Signed for and on behalf of SGS

SGS-CSTC CONSUMER TESTING SERVICES SGS GUANGZHOU

.....
Authorized Signature
Harriet Zhong

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中国·广州·经济技术开发区科学城科珠路198号 邮编: 510663 t (86-20) 8215 5273 f (86-20) 8207 5198 e sgs.china@sgs.com

Test Report **No: GZCPCH160902754E-c** **Date: 2016-09-23**

TEST RESULT(S):

#1

Test item(s)	Unit	Test method(s) (Reference to)	Limit(s)*	Test result(s)	MDL
Lead (Pb)	mg/kg	SGS in house method, analysis was performed by ICP-OES.	/	ND	5
Cadmium (Cd)	mg/kg		/	ND	5
Mercury (Hg)	mg/kg		/	ND	5
Hexavalent Chromium (CrVI)	mg/kg	SGS in house method, analysis was performed by UV-Vis.	/	ND	5
Total (Pb + Cd + Cr VI + Hg)	mg/kg	/	100	ND	/

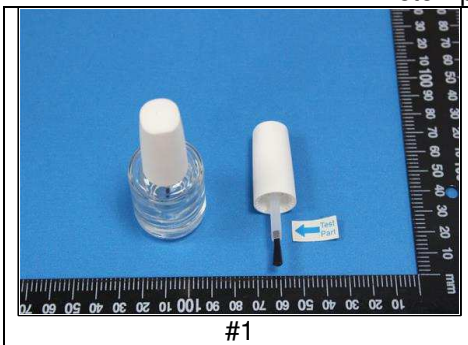
#2

Test item(s)	Unit	Test method(s) (Reference to)	Limit(s)*	Test result(s)	MDL
Lead (Pb)	mg/kg	SGS in house method, analysis was performed by ICP-OES.	/	ND	5
Cadmium (Cd)	mg/kg		/	ND	5
Mercury (Hg)	mg/kg		/	ND	5
Hexavalent Chromium (CrVI)	mg/kg	SGS in house method, analysis was performed by UV-Vis.	/	ND	5
Total (Pb + Cd + Cr VI + Hg)	mg/kg	/	100	ND	/

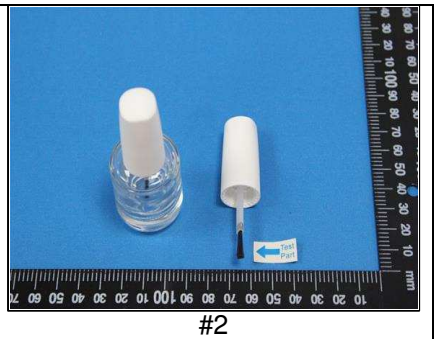
Remark:
(1) 1 mg/kg = 0.0001%
(2) MDL = Method Detection Limit
(3) ND = Not Detected (< MDL)
(4) * =The limit is quoted from European Directive 94/62/EC and its amendments.

SAMPLE DESCRIPTION: #1: subtransparent plastic
#2: black brush hair

Photo Appendix



#1



#2

*** End of Report***

SGS-CSTC Standards Technical Services Co., Ltd.
Guangzhou Branch Testing Center Cosmetics, Personal Care & Household
198 Kezhu Road, Scientech Park Guangzhou Economic & Technology Development District, Guangzhou, China 510663 t (86-20) 8215 5273 f (86-20) 8207 5198 www.sgsgroup.com.cn
中国·广州·经济技术开发区科学城科珠路198号 邮编: 510663 t (86-20) 8215 5273 f (86-20) 8207 5198 e sgs.china@sgs.com

FORMOSA POLYPROPYLENE(NINGBO) CO.,LTD
FPG NINGBO INDUSTRIAL PARK BEILUN NINGBO,CHINA

The following sample(s) was/were submitted and identified on behalf of the clients as : POLYPROPYLENE HOMOPOLYMER

SGS Job No. :	NBIN1603002320PC - NB
Material and Mark :	1120
Manufacturer :	FORMOSA POLYPROPYLENE(NINGBO) CO.,LTD
Client Ref. Information :	1040、1040F、1080、1124、1124H、1250、1250F、1352F、1450T、2100、2100M、2020S、2020H、2000MF
Date of Sample Received :	15 Mar 2016
Testing Period :	15 Mar 2016 - 22 Mar 2016
Test Requested :	Selected test(s) as requested by client.
Test Method :	Please refer to next page(s).
Test Results :	Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
FDA 21 CFR 177.1520- Soluble fraction	PASS
FDA 21 CFR 177.1520- Extractable fraction	PASS
FDA 21 CFR 177.1520-Density at 23°C	PASS
FDA 21 CFR 177.1520- Melting Point	PASS

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Ningbo Branch

Iris Xiao
Approved Signatory

1-5/F West of Building 4, Lingyun Industry Park, No.1177 Lingyun Road, Ningbo National Hi-Tech Zone, Ningbo, Zhejiang, China 315040 t E&E (86-574)89070249 t ML (86-574)89070242 www.sgsgroup.com.cn
中国·浙江·宁波市国家高新区凌云路1177号凌云产业园4号楼西1-5层 邮编: 315040 t HL (86-574)89070271 t TY (86-574)89070211 e sgs.china@sgs.com

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	NGB16-008521.001	SUBTRANSPARENT SOLID PELLET	PP

FDA 21 CFR 177.1520- Soluble fraction

Test Requested : As specified for client, to determine maximum soluble fraction in xylene for compliance with the Food and Drug Administration Regulations for polypropylene used in contact with food.

Test Method : With reference to FDA 21 CFR 177.1520 (d) (4) (i).

Simulant Used	Time	Temp	Max. Permissible Limit	Result of 001 Soluble fraction
Soluble fraction in xylene at 25ºC	2hr(s)	25℃	9.8% (w/w)	4.2% (w/w)

FDA 21 CFR 177.1520- Extractable fraction

Test Requested : As specified for client, to determine maximum extractable fraction in n-hexane for compliance with the Food and Drug Administration Regulations for polypropylene used in contact with food.

Test Method : With reference to FDA 21 CFR 177.1520(d) (3) (i).

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 001 Extractable fraction
Extractable fraction in n-hexane at reflux temperature	2hr(s)	reflux temperature	6.4% (w/w)	0.7% (w/w)

FDA 21 CFR 177.1520-Density at 23°C

Test Requested : As specified for client, to determine density at 23ºC for compliance with the Food and Drug Administration Regulations for polypropylene used in contact with food.

Test Method : With reference to FDA 21 CFR 177.1520 (d) (1).

SGS-CSTC Standards Technical Services Co., Ltd. Ningbo Branch
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Test Item(s)	Limit	*001*
Density at 23℃, g/ cm³	0.880-0.913	0.894

FDA 21 CFR 177.1520- Melting Point

Test Requested : As specified for client, to determine melting point for compliance with the Food and Drug Administration Regulations for polypropylene used in contact with food.

Test Method : With reference to FDA 21 CFR 177.1520 (d) (2).

Test Item(s)	Limit	*001*
Melting point,℃	160-180	167

Remark:
(1) g/cm³ = gram per cubic centimeter
(2) %(w/w) = percentage of weight by weight
(3) ℃ = degree Celsius
(4) hr = hour

SGS-CSTC Standards Technical Services Co., Ltd. Ningbo Branch
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中国·浙江·宁波市国家高新区凌云路1177号凌云产业园4号楼西1-5层 邮编: 315040 t HL (86-574)89070271 t TY (86-574)89070211 e sgs.china@sgs.com

Sample photo:

NGB16-008521.001

SGS authenticate the photo on original report only

*** End of Report ***

Part 15 Packaging compatibility
Awesome Cosmetics, Base Gel

Packaging compatibility

Packaging material	PE
Purity	Awesome Cosmetics, Base Gel
Volume or weight	10 ml
Interference packaging with the product	In compliance

Product compatibility tested by	Heyuan MissGel New Material Co., Ltd.
Adress	2/F, Bldg. A2 Xinhuafeng Tech. Park, Hudieling Ind. Zone
City	Heyuan City, Guandong Province
Country	China
Telephone	
Website	http://www.missgelish.com/

3 Microbiological quality

3.1 The microbiological test result on formulation, with reference to European Pharmacopeia 8.0 2.6.12 & 2.6.13, by third party laboratory (SGS report no. GZCPCH160501162E-1.3), with testing period May 24 – Jun 02, 2016, was submitted and reviewed based on following criteria.

Product Category of this product: 2

Micro-organisms	Total viable count and Total yeast and mold	*P.aeruginosa*, *S.aureus* and *C.albicans*
Category 1: Products specifically intended for children under 3 years, to be used in the eye area and on mucous membranes	≤ 100 cfu/g or 100 cfu/ml	not detectable in 1g or 1 ml
Category 2: Other products	≤ 1000 cfu/g or 1000 cfu/ml	not detectable in 0.1g or 0.1 ml

Conclusion: The microbiological quality of the formulation is acceptable for this application.

3.2 The preservation efficacy test result on formulation, with reference to European Pharmacopeia 8.0 5.1.3, by third party laboratory (SGS report no. GZCPCH160501162E-1.5), with testing period May 24 – Jul 11, 2016, was submitted and reviewed based on following criteria.

		Day 2	Day 7	Day 14	Day 28
Criteria A	*E.coli, P.aeruginosa, S.aureus*	2	3	/	NI
	C. albicans	/	/	2	NI
	A. brasiliensis (niger)	/	/	2	NI
Criteria B	*E.coli, P.aeruginosa, S.aureus*	/	/	3	NI
	C. albicans	/	/	1	NI
	A. brasiliensis (niger)	/	/	1	NI

NI: No increase

Conclusion: The preservative efficacy of the formulation achieved B criteria and is acceptable for this application.

4 Impurities, traces and information about the formulation and the packaging material

4.1 The heavy metal test result on formulation, by third party laboratory (SGS report no. GZCPCH160501162E-1.2), with testing period May 24 – 31, 2016, was submitted and reviewed based on following criteria.

	German Health Authority BgA (Recommendation from German Health Journal No. 28, July 1985) and The German Health Journal No. 7/1992, Session 45 from November 14, 1991					
Test items	As	Hg	Pb	Sb	Cd	Ni (soluble)
Limit (mg/kg)	≤5	≤1	≤20	≤10	≤5	≤10

Conclusion: The heavy metal content of the formulation is acceptable for this application.

4.2 The determination of phthalates Benzyl Butyl Phthalate (BBP), Bis(2-Ethylhexyl) Phthalate (DEHP), Dibutyl Phthalate (DBP), Bis(2-Methoxyethyl) Phthalate (DMEP), Di-n-Pentyl Phthalate (DnPP), Diisopentylphthalate (DIPP), and N-pentyl iso-pentyl phthalate (PIPP), by third party laboratory (SGS report no.GZCPCH160501162E-1.1) with testing period May 24 – 31, 2016, indicates total tested phthalates is not detected, with a detection limit of 5 mg/kg.

Conclusion: The phthalates content of the formulation is acceptable.

4.3 The determination of hydroquinone, with reference to Hygienic Standard for Cosmetics 2007, by third party laboratory (SGS report no.GZCPCH160501162E-1.4) with testing period May 24 – Jun 03, 2016, indicates hydroquinone is not detected, with a detection limit of 7 µg/kg.

Conclusion: The hydroquinone content of the formulation is acceptable.

4.4 The client has supplied the following list of packaging parts for this product as the immediate container.

No.	Immediate Container	Material
1.	Bottle & Cap	PE

4.5 For packaging material, test result of lead, cadmium, mercury and chromium (VI) on immediate container by third party laboratory (SGS report no. GZCPCH160501162E-2) with testing period May 24 – Jun 03, 2016, indicates the total amount is less than 100ppm.
Conclusion: The heavy metal content of the packaging material is acceptable.

4.6 Packaging compatibility test result on packaging material, by in house method of manufacturer Dongyuan MissGel Chemical Limited Company, on product name Base Gel (Batch no. 15111601), with a testing period Nov 17, 2015 – Feb 16, 2016, was submitted and reviewed.
Testing conditions : 25℃, 40±1℃, and -5 ~ -15℃ for 12 weeks
Testing parameters : Packing condition
Conclusion: The stability of the packaging material is acceptable.

5 Normal and reasonably foreseeable use

The normal use of this product is for application on nail plates then light-cured by adults. Application of this product to other parts of the body is unlikely. Ingestion of this product would be a misuse.

6 Exposure to the cosmetic product

Product type: Makeup cosmetics
Use category: Nail gel
Physical form: Liquid
The site(s) of application: Nail plates
The surface area(s) of application: 4 square centimeter
The amount per application: 0.25 g
The duration of exposure: 3360 minutes
The frequency of use: 52 times per year
The normal and reasonably foreseeable exposure route(s): Primarily via dermal contact
The targeted (or exposed) population(s): Adults
The body weight: 60 kg
Estimated daily amount applied: 36 mg/day

7 Exposure and toxicological profile of the substances

There are no nanoparticles indicated to be used in this formulation.
For toxicological profile of ingredients, refer to Annex 1.
All the ingredients were found to be present at levels that were permitted by the Cosmetic Regulation. Margins of safety (MOS) have been calculated, where applicable, based on systemic NOAEL when data is in the present stage of knowledge.

8 Undesirable effects and serious undesirable effects

No data on any undesirable effects associated with this product has been supplied.

Part 16 Product label
Awesome Cosmetics, Base Gel

Product label

Product name	Base Gel
Formula code	no formula code
Date	23-7-2019

Product responsible	Awesome Cosmetics
Address	Langehof 3
City	Schagen
Country	The Netherlands

Different company on label:	No
Expiration symbol:	PAO
Expiration date:	24 month(s) after opening
Label warnings:	yes
Label warnings specific:	Only for professional use, keep away from children.

Ingredient check on label:	All ingredients are declared

INCI declaration on label:	Acrylates Copolymer Ethyl Methacrylate Ethyl Acetate Butyl Acetate Dimethicone Microcrystalline Wax CI 77891

Ingredients:
Acrylates Copolymer, Ethyl Methacrylate, Ethyl Acetate, Butyl Acetate, Dimethicone, Microcrystalline Wax, CI 77891

WARNING:
Only for profesional use, keep away from children.

10ml Made in PRC

Manufactured by Miss Gel
Awesome Cosmetics
Langehof 3 - 1741 HZ Schagen

AWESOME
COSMETICS

SOAK-OFF
RUBBER COAT
UV/LED

Ingredients:
Ethyl Methacrylate, Acrylates Copolymer, Trimethylolpropane Triacrylate, Isopropyl Alcohol, Microcrystalline Wax, Butyl Acetate, CI 77000

WARNING:
Only for profesional use, keep away from children.

10ml Made in PRC

Manufactured by Miss Gel
Awesome Cosmetics
Langehof 3 - 1741 HZ Schagen

AW
C O S
M

Ingredients:
Acrylates Copolymer, Ethyl Methacrylate, Ethyl Acetate, Butyl Acetate, Dimethicone, Microcrystalline Wax, CI 77891

WARNING:
Only for profesional use, keep away from children.

10ml Made in PRC

Manufactured by Miss Gel
Awesome Cosmetics
Langehof 3 - 1741 HZ Schagen

AWESOME
COSMETICS

SOAK-OFF
BASE COAT
UV/LED

Ingredients:
Ethyl Methacrylate, Acrylates Copolymer, Trimethylolpropane Triacrylate, Isopropyl Alcohol, Microcrystalline Wax, Butyl Acetate, CI 77000

WARNING:
Only for profesional use, keep away from children.

10ml Made in PRC

Manufactured by Miss Gel
Awesome Cosmetics
Langehof 3 - 1741 HZ Schagen

AW
C O S

Ingredients:
Acrylates Copolymer, Trimethylolpropane Triacrylate, Ethyl Methacrylate, Ethyl Acetate, Dimethicone, Microcrystalline Wax, Mica, CI 77000, CI 77499, CI 19140, CI 77491, CI 77891, CI 77510, CI 77163, CI 77266

WARNING:
Only for profesional use, keep away from children.

10ml Made in PRC

Manufactured by Miss Gel
Awesome Cosmetics
Langehof 3 - 1741 HZ Schagen

AWESOME
COSMETICS

SOAK-OFF
GELPOLISH
UV/LED

83*28MM

出血3MM

Product claims & claim support

Product name	Base Gel
Formula code	no formula code
Date	23-7-2019

Status product claims:	In compliance
Claims made:	No claims made
Substantiated:	No claims made
Claim:	No claims made
Description:	There are no claims made and no substantiation necessary.
Additional info about claim:	no additional information

Product beneficial effects & clinical information

Product name	Base Gel
Formula code	no formula code
Date	23-7-2019
Beneficial effects status:	No beneficial effects
Beneficial effects:	There is no (scientific) information on beneficial effect of the product. There are no clinical studies on the product. Further information about claims on this product are described at Part 17 - Product claims & claim support.
Additional information:	no additional information

Product undesirable health effects

Demands of European legislation (EC No 1223-2009)	Status
Information on undesirable health effects	**In compliance**

The status "In compliance" implies that the primary responsible person has a quality system in place for handling of adverse or undesirable health effects. In case of a serious undesirable health effects the competent authorities of the European Union will be notified as well as the safety assessor.
The status "In compliance" also implies that the product is not known to have had a history of (serious) undesirable health effects which are related to the intrinsic safety of this product.

To whom it may concern

Awesome Cosmetics declares that we have a system in place for registering (serious) undesirable health effects of our cosmetic products. We will notify the appropriate authorities of the European member state or states where a serious undesirable health effect has occurred.

Up to this date, we have not had any reports of any serious undesirable health effects for our cosmetic products.

Sincerely,

Anet Poland
Awesome Cosmetics

A. Poland

Part 20 Animal testing product overview

Awesome Cosmetics, Base Gel

Declaration of no animal testing on the product

Formula name	Base Gel
Formula code	no formula code
Date	23-7-2019

Declaration of animal testing on product: In compliance

Miss Gel

广州市魅思美甲有限公司
Guangzhou Miss Gel Limited Company

July 12, 2016

To Whom It May Concern:

Missgel is committed to ensuring the safety and performance of the products we produce, and to fulfilling legal requirements on classification, packaging and labeling. At the same time, we are committed to acting ethically with respect to the use of animals in product testing. To this end, the company operates in accordance with the following principles:

1. Brands represented under Missgel are not tested on animals, either by the company or on its behalf by third parties. New products are assessed for safety by using all data available on the raw materials and other information on product use available internally or from the published literature.

2. Missgel does not request its suppliers to test their raw materialson animals. We have implemented an internal check to ensure none of our raw materials have been tested on animals after June 11, 2015. Furthermore, checks and balances are in place to ensure continuing compliance with our standards.

Should you have any additional concerns or questions please do not hesitate to contact me.

Sincerely,

Miranda Li
Regulatory Manager

Guangzhou Missgel Limited Company

Declaration(s) of no animal testing on individual ingredients of the product

Formula name	Base Gel
Formula code	no formula code
Date	23-7-2019

Animal testing on ingredients: Not received

Tradename	Available
Acrylates Copolymer, Acrylates Copolymer [Zhaoqing Powerdream Chemical	unknown
Ethyl Methacrylate, Ethyl Methacrylate [Sigma Aldrich]	unknown
Ethyl Acetate, Ethyl Acetate [Lily Group Co., Ltd.]	unknown
Butyl Acetate, Butyl Acetate [Sigma-Aldrich]	unknown
Dimethicone, Dimethicone [Lily Group Co., Ltd.]	unknown
Microcrystalline Wax, Microcrystalline Wax [Lily Group Co., Ltd.]	unknown
Titanium Dioxide, CI 77891 [Lily Group Co., Ltd.]	unknown

Part 22 Product changes & product history

Awesome Cosmetics, Base Gel

Product changes & product history

Status product changes:	new product
Product changes:	
Product history:	no additional information

Part 23 Registration documents

Awesome Cosmetics, Base Gel

Registration documents

Status registration documents:

CPNP registration number:

Registration date:

Description:

Information for public access

Status information: standard

Description:

Additional information public access: