Dreamy Gels.

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

Net Weight	:	12ml,10ml,8ml,6ml, 5ml, 1kg or 5kg per consumer product
SGS Report No.	:	HKHC1910008670HC
SGS Case No.	:	HKHC190700002470 – 102 (GZCPCH190702973)
Region of Origin	:	China
Region of Destination	:	EU
Sample Receiving Date	:	Jul 19 – Oct 17, 2019
Test Period	:	Jul 19 – Oct 24, 2019

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 to use under normal or reasonably foreseeable conditions of use.
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.

Cc

Shuping Yu, Cecilia
MSc (Food safety and Toxicology), MSc (Bioscience), MRSB
Cosmetic Safety Assessor

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PART A - COSMETIC PRODUCT SAFETY INFORMATION

INTRODUCTION

SGS is requested to review the safety of the product formula UV/LED 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 of adults then light-cured for changing appearance by professional.
The net weight of this product (The formulation under assessment) is 12ml,10ml,8ml,6ml, 5ml, 1kg or 5kg 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	45.7800	Binding
Trimethylolpropane Triacrylate	15625-89-5	239-701-3	23.8400	Film forming
Dimethicone	9016-00-6	N/A	20.8400	Antifoaming
Polymethyl Methacrylate	9011-14-7	N/A	3.8000	Film forming
Trimethylolpropane Triacrylate	15625-89-5	239-701-3	3.6100	Film forming
Microcrystalline Wax	63231-60-7	264-038-1	2.1300	Bulking / emulsion stabilising

FRAGRANCE ALLERGENS

No parfum is present in the formulation.

2 Physical/chemical characteristics and stability of the formulation

2.1 The product is liquid, with the pH value of 2.5 and the viscosity of 1800-2500 mpa.s.

2.2 The stability test results on formulation,
on sample name BASE GEL, with test date of May 31, 2019 for 12 weeks, 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 : Control experiment at room temperature (Room temperature 25°C), heat experiment (at 40±1°C), cold experiment (at -5°C to -15°C) for 12 weeks
Testing parameters : Appearance, odor, 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 Pharmacopoeia 9.0 2.6.12 and 2.6.13, by third party laboratory (SGS report no. GZCPCH190702973-3.1), with testing period Jul 08 – 17, 2019, was submitted and reviewed based on following criteria as required by the SCCS Notes of Guidance.
Product Category of this product: 2

Micro-organisms	Total viable count and Total yeast and mold	*E. Coli, 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

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Category 2: Other products	≤ 1000 cfu/g or 1000 cfu/ml	not detectable in 1g or 1 ml

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

3.2 The preservation efficacy test result of formulation is not required because the product is a low risk product.

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

4.1 The heavy metal test results on formulation, by third party laboratory (SGS report no. GZCPCH190702973-3.2), with a testing period of Jul 08 – 25, 2019, 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 Dibutyl Phthalate (DBP), Benzyl Butyl Phthalate (BBP), Bis(2-Ethylhexyl) Phthalate (DEHP), Dissobutyl phthalate (DIBP), Bis(2-Methoxyethyl) Phthalate (DMEP), Di-n-Pentyl Phthalate (DnPP), Diisopentylphthalate (DIPP), N-pentyl iso-pentyl phthalate (iPnPP) and di-n-hexyl phthalate (DnHP/DHXP), by third party laboratory (SGS report no. GZCPCH190702973-3.3), with a testing period of Jul 08 – 25, 2019, indicate none of the tested phthalates is detected, with a detection limit of 5 mg/kg for each phthalate.
Conclusion: The phthalates content of the formulation is acceptable.

4.3 The determination of hydroquinone on sample name uv/led base gel, by third party laboratory (SGS report no. GZCPCH190702973-3.4), with a testing period of Jul 08 – 25, 2019, indicate hydroquinone is not detected, with a detection limit of 7 µg/g.
Conclusion: The hydroquinone content of the formulation is acceptable.

4.4 The determination of hydroquinone on sample name uv/led base gel, by third party laboratory (SGS report no. GZCPCH190804068-2), with a testing period of Aug 29 – Sep 12, 2019, indicate 4-Methoxyphenol (MeHQ CAS no.150-76-5) is not detected, with a detection limit of 0.5 mg/kg.
Conclusion: The 4-Methoxyphenol content of the formulation is acceptable.

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

No.	Immediate Container	Material
1.	Bottle	Glass
2.	Lid	PP
3.	Brush	PP

4.6 For packaging material, test results of lead, cadmium, mercury and chromium (VI) of immediate container, by third party laboratory (SGS report no. GZCPCH190702973-9), with a testing period of Jul 08 – 25, 2019, indicate the total amount are less than 100ppm.
Conclusion: The heavy metal content of the packaging material is acceptable.

4.7 Packaging compatibility test result on packaging materials tested together with the formulation, by in house method of HEYUAN MISSGEL NEW MATERIAL LIMITED COMPANY, on sample name BASE GEL, with test date of May 31, 2019 for 12 weeks, was submitted and reviewed.

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Testing conditions : Control experiment at room temperature (Room temperature 25°C), heat experiment (at 40±1°C), cold experiment (at -5°C to -15°C) for 12 weeks
Testing parameters : Appearance and 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 of adults by professional. Application of this product to other parts of the body is unlikely. Ingestion of this product would be a misuse. Accidental exposure of hands of the professional is possible.

6 Exposure to the cosmetic product

Product type: Makeup cosmetics
Use category: Base gel
Physical form: Liquid
The site(s) of application: Nail plate
The surface area(s) of application: 4 square centimeter
The amount per application: 0.3 g
The duration of exposure: 3360 minutes
The frequency of use: 156 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: 128 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.
Systemic Exposure Dose (SED) is derived for each substance, taking into account of 50% bioavailability as a default value for oral and dermal absorption, and 100% bioavailability for inhalation, unless otherwise specified. Margins of safety (MoS) is calculated by dividing systemic NO(A)ELsys by the SED, when NO(A)EL or relevant Point of Departure (POD) is available 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 Heyuan MissGel New Material Co., Ltd., 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 SZ1808C6 which is valid until Aug 13, 2021).

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PART B - COSMETIC PRODUCT SAFETY ASSESSMENT

1. Assessment conclusion

The product complies with the Regulation (EC) No. 1223/2009 and its subsequent amendments.
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 substances, especially p-Hydroxyanisole (MEHQ), the product must be labelled for professional use, 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. Recommended 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.
May cause sensitization by skin contact. 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.
Stop using the product if redness and itching develop. If symptom persists, consult a doctor.

3. Reasoning

All the ingredients in the formulation are either reported to be used in cosmetic or within the recommended limit as suggested by SCCS and Cosmetic Ingredient Review (CIR). No CMR substance is indicated to be intentionally added to the formulation.
Margin of Safety (MoS) was derived for all ingredients except those which No Observed (Adverse) Effect Levels (NO(A)ELs) or other Point of Departure (POD) were not available. For ingredients that MoS cannot be derived, their safety is substantiated by history of safe use at similar levels in related cosmetic products, reference doses, TTC approach, etc. Detailed explanation is given in the individual ingredient toxicological summary in annex 1.
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 and microbiological quality while the product was manufactured in accordance with ISO 22716:2007 Cosmetic GMP. The preservative efficacy test is not required because it is a low microbiological risk product.
The formulation is not expected to be phototoxic and is unlikely to cause damage to internal organs through skin in the majority of consumers and professionals under normal and reasonably foreseeable conditions of use.
This product is a LED-cured nail gel which hardens on the nail plates under the influence of LED. It is expected to cause irritation if contact with skin and eyes, and cause sensitization by skin contact as supplied.
The product contains hazardous substance p-Hydroxyanisole (MEHQ) (CAS No. 150-76-5), as polymerization inhibitor, at a non-detectable level with detection limit 0.5 mg/kg, that requires this product to be used by professional only, even 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 must be labelled to provide clear instruction of use as well as warnings and cautionary statements to alert the consumers and professional the potential hazard if misused and to keep the product out of reach of children and avoid skin contact.

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As the product will be cured under LED in a few minutes, the dermal and inhalation exposure of individual ingredients will be limited. Although the professionals have high frequency in handling or using the product, dermal contact to the professionals is unlikely. Even if the product is dermally exposed to the professionals, it will be rinsed away shortly where systemic exposure is not expected to be significant via dermal penetration. Moreover, inhalation exposures to individual ingredients are considered to be low based on their physicochemical properties (low vapour pressure). Therefore, although MOS of ingredients are not derived for the professionals, the ingredients are not expected to cause significant systemic exposure, and hence risk, to the professionals via dermal and inhalation route under normal and reasonably foreseeable conditions of use.

4. Assessor's credentials and approval of Part B
Date: Oct 24, 2019

Shuping Yu, Cecilia MSc (Food safety and Toxicology), MSc (Bioscience), MRSB

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.

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

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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: 0.4891562 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. Acrylate copolymers is an eye irritant but not corrosive. 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.

The certificate of analysis of this ingredient provided by Fine chemical zone indicates the content of the residual solvent ethyl acetate is 3 ppm. It is the responsibility of the manufacturer to ensure the ingredient used is of acceptable chemical purity and does not contain hazardous amounts of residue and contaminants conforming to the recommendation of Cosmetic Europe to substantiate the safety of the product and complies with the EU Cosmetic Regulation. If it is not the case, it will void the assessment.

2. Trimethylolpropane Triacrylate

CAS No.: 15625-89-5
EINECS/ELINCS: 239-701-3
CLP Classification: H315 Skin Irrit. 2; H317 Skin sens. 1; H319 Eye Irrit. 2
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: >500 mg/kg bw/day
SED: 0.2547288 mg/kg bw/day
MOS: 981

Trimethylolpropane Triacrylate is a multifunctional monomer with a wide range of industrial applications. It can be used in the production of ultraviolet-curable nail enhancement product. It is classified as skin and eye irritant, and skin sensitizer. Trimethylolpropane Triacrylate is absorbed dermal inversely related to

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dose. Large amounts of the dose can be found unabsorpted or in skin. Main route of excretion is via inhalation, urine and faeces. Only small amount were distributed to the tissue and carcass. No accumulation in tissue was observed. A large part of the applied dose is excreted after 72h. No systemic substance related effects were observed the systemic NOAEL of trimethylolpropane Triacrylate was considered to be > 500 mg/kg bw.

3. Dimethicone

CAS No.: 63148-62-9 / 9006-65-9 / 9016-00-6 / 107-52-8 / 141-62-8 / 141-63-9
EINECS/ELINCS: - / - / - / - / 205-491-7 / 205-492-2
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 80% in hair preparation; up to 24% in make up
Food additive recommendation: Yes, the ADI is 0-1.5 mg/kg bw (applied only to compounds with a relative molecular mass in the range of 200-300
Toxicological profile by chemical supplier: None
NOAEL: 1500 mg/kg bw/day
SED: 0.2226740 mg/kg bw/day
MOS: 3368
Dimethicone is a fluid mixture of fully methylated linear siloxane polymers end-blocked with trimethylsiloxy units. It is used as conditioning agents in cosmetic formulations at concentrations of use of 80% in hair preparation and up to 24% in make-up products, Clinical and animal absorption studies reported that dimethicone was not absorbed following oral or dermal exposure due to their large molecular weight. No adverse reactions were found in rabbits following short-term dermal dosing with 6 to 79% Dimethicone. Mice and rats were dosed for 90 days with up to 10% dimethicone without adverse effect. It also did not produce adverse effects in acute and short-term inhalation-route studies. The dermal LD50 for dimethicone was greater than 2 g/kg in rats and rabbits. Most dermal irritation studies using rabbits classified dimethicone as a minimal irritant. Dimethicone was not a sensitizer in four assays using mice and guinea pigs. It was not a sensitizer at 5% in a clinical repeated insult patch test using 83 panelists. Most ocular irritation studies using rabbits classified dimethicone as a mild to minimal irritant. Dimethicone was negative in all mutagenicity assays. It was negative in both an oral and dermal dose carcinogenicity assay using mice. Dimethicone was found to cause no treatment-related adverse effects in numerous oral-dose (using rats) and dermal-dose (using rats, rabbits and monkeys) reproductive and developmental toxicity studies. Adverse effects were noted in one inhalation study with small aerosol particles. Although there were only limited inhalation toxicity findings, dimethicone is only used in aerosol formulations at a very low concentration. The CIR Panel indicated that particles from cosmetic formulation containing dimethicone would not likely be inhaled. In particular, it was stated that expected particle sizes would primarily be in the range of 60-80 µm, and less than 1% would be under 10 µm, which is an upper limit for respirable particles. The CIR Panel expects that the manufacture process for cosmetic formulations in which dimethicone is found and which may be inhaled would continue to produce particle size distribution that are not significantly respirable. The CIR Expert Panel concluded that Dimethicone is safe as used in cosmetic formulations at concentrated known to be used.

4. Polymethyl Methacrylate

CAS No.: 9011-14-7
EINECS/ELINCS: N/A
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None

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CIR recommendation: Safe to be used up to 30%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.0406027 mg/kg bw/day
MOS: --
Polymethyl Methacrylate (PMMA) (2-Propenoic acid, 2-methyl-, methyl ester, homopolymer) is the polymer of methyl methacrylate that conforms to the formula (C5H8O2)x. It is used as film formers, viscosity-increasing agents, binders and emulsion stabilizers in cosmetic ranges from 0.01 to 30%. It has been approved for use in medical device e.g. intraocular lenses, bone cement, dental fillers and dermal fillers by US FDA. Based on the chemical similarity, its safety is extrapolated to support the safety as a cosmetic ingredient whose exposure is expected to be less. Therefore, no systemic toxicity data is reviewed. It is a slight ocular irritant in New Zealand rabbits but non-irritant in primary irritation studies with rabbits. 6.8% of PMMA was not a cumulative skin irritant or sensitize in HRIPT studies. However, the unreacted monomer methy methacrylate (MMA) was found to be a sensitizing at 25% in guinea pigs. The CIR concluded that it is safe as cosmetic ingredients in the practices of use and concentration.

5. Trimethylolpropane Triacrylate
CAS No.: 15625-89-5
EINECS/ELINCS: 239-701-3
CLP Classification: H315 Skin Irrit. 2; H317 Skin sens. 1; H319 Eye Irrit. 2
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: >500 mg/kg bw/day
SED: 0.0385726 mg/kg bw/day
MOS: 6481
Trimethylolpropane Triacrylate is a multifunctional monomer with a wide range of industrial applications. It can be used in the production of ultraviolet-curable nail enhancement product. It is classified as skin and eye irritant, and skin sensitizer. Trimethylolpropane Triacrylate is absorbed dermal inversely related to dose. Large amounts of the dose can be found unabsorpted or in skin. Main route of excretion is via inhalation, urine and faeces. Only small amount were distributed to the tissue and carcass. No accumulation in tissue was observed. A large part of the applied dose is excreted after 72h. No systemic substance related effects were observed the systemic NOAEL of trimethylolpropane Triacrylate was considered to be > 500 mg/kg bw.

6. Microcrystalline Wax
CAS No.: 63231-60-7 / 64742-42-3
EINECS/ELINCS: 264-038-1 / 265-144-0
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

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Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

SED: 0.0227589 mg/kg bw/day
MOS: 24166
Microcrystalline Wax is a complex combination of long, branched chain hydrocarbons obtained from residual oils by solvent crystallization. It consists predominantly of saturated straight and branched chain hydrocarbons predominantly greater than C35. It is used as binders, emulsion stabilizers, opacifying agents, viscosity increasing agents in cosmetic. 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.
It is the responsibility of the manufacturer to ensure the ingredient used is of acceptable chemical purity and does not contain hazardous amounts of residue and contaminants as well as the physicochemical properties conforming to the recommendation of Cosmetic Europe to substantiate the safety of the product and complies with the EU Cosmetic Regulation. If it is not the case, it will void the assessment.

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

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