"YI FEI" SP.ZO.O
UL. NADRZECZNA, NR 14, LOK. H-5/B-23, 05-552, WOLKA KOSOWSKA, POLAND

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

Net Weight	:	10mL or 15mL per consumer product
Style/Item No.	:	4/23/2016
SGS Report No.	:	HKHC1611008000HC
SGS Case No.	:	HKHC161100003496 (GZCPCH160701987)
Manufacturer	:	Guangzhou Yidingcheng Biological Technology Co., Ltd.
Region of Origin	:	China
Region of Destination	:	EU
Sample Receiving Date	:	Nov 03 – 22, 2016
Test Period	:	Nov 03 – 30, 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.

Tin-Ki LEUNG, Martin
BSc(Hons), MRSB, MSCS,
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 GEL POLISH – black color for consumer health and no other part of the product. The product is for EU market and intended for application on nail plates before being light-cured for changing appearance by adults.
The net weight of this product (The formulation under assessment) is 10mL or 15mL 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	25133-97-5	N/A	58.4000	Antistatic / binding / film forming
HEMA	868-77-9	212-782-2	35.0000	Film forming
Hydroxycyclohexyl Phenyl Ketone	947-19-3	213-426-9	3.5000	Binding
Trimethylbenzoyl Diphenylphosphine Oxide	75980-60-8	278-355-8	2.4600	Skin conditioning
Ethylene Distearamide	110-30-5	203-755-6	0.0400	Viscosity controlling
Colouring Agent (May Contain)				
CI 77266	1333-86-4	215-609-9	0.6000	Cosmetic colorant

FRAGRANCE ALLERGENS

No parfum is present in the formulation.

2 Physical/chemical characteristics and stability of the formulation

2.1 The product is a black colored gel.

2.2 The stability test result on formulation, by in house method of manufacturer Guangzhou Yidingcheng Biological Technology Co., Ltd. on product name Gel Polish, with a testing period May 20 – Sep 05, 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 : Room temperature, 0℃ and 40℃, 60% humidity conditions for 3 months
Testing parameters : Acrylic monomer, appearance, weight changing
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 and 2.6.13 by third party laboratory (SGS report no. GZCPCH160701987.1) with testing period Jul 19 – Aug 09, 2016 was submitted and reviewed based on following criteria.
Product Category of this product: 2

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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 of formulation with reference to European Pharmacopeia 8.05.1.3 by third party laboratory (SGS report no. GZCPCH160701987.4) with testing period Jul 19 – Aug 31, 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. GZCPCH160501219E) with testing period May 16 – 23, 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 formaldehyde on formulation, with reference to European Directive 90/207/EEC, by third party laboratory (SGS report no. GZCPCH160701987.1), with testing period Jul 19 – Aug 09, 2016 indicate that formaldehyde is not detected, with the method detection limit of 30 mg/kg.
Conclusion: The formaldehyde content of the formulation is acceptable.

4.3 The determination of NDELA on formulation, with reference to ISO 15819:2014, by third party laboratory (SGS report no. GZCPCH160701987.1), with testing period Jul 19 – Aug 09, 2016 indicates that NDELA is not detected, with the method detection limit of 15 mg/kg.
Conclusion: The NDELA content of the formulation is acceptable.

4.4 The determination of phthalates Dibutyl Phthalate (DBP), Di-methoxyethyl Phthalate (DMEP), Benzylbutyl Phthalate (BBP), Di-(2-ethylhexyl) Phthalate (DEHP), n-Pentyl-isopentyl Phthalate (nPiPP/iPnPP), Di-n-Pentyl Phthalate (DnPP) and Diisopentyl Phthalate (DiPP) by third party laboratory (GZCPCH160701987.1), with testing period Jul 19 – Aug 09, 2016 indicates total tested phthalates is not detected, with the method detection limit of 5 ppm for each phthalate.
Conclusion: The phthalate content of the formulation is acceptable.

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

No.	Immediate Container	Material
1.	Black plastic cap	Plastic
2.	Transparent glass bottle	Glass
3.	Pipe (Translucent plastic)	Plastic
4.	Gasket (White plastic filament)	Plastic

4.6 For packaging material, test results of lead, cadmium, mercury and chromium (VI) on immediate container by third party laboratory (SGS report no. GZCPCH160701987.1) with testing period Jul 19 – Aug 09, 2016 indicates the total amount is less than 100ppm.
Conclusion: The heavy metal content of the packaging material is acceptable.

4.7 Packaging compatibility test result on packaging material, by in house method of manufacturer, Guangzhou Yidingcheng Biological Technology Co., Ltd., on product name Gel Polish, with a testing period May 20 – Sep 05, 2016, was submitted and reviewed.
Testing conditions : Room temperature, 0℃ and 40℃, 60% humidity conditions for 3 months
Testing parameters : Package appearance
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 by adults. Application of this product to any 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: Gel polish
Physical form: Liquid
The site(s) of application: nails
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: 24 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: 16 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.

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9 Information on the cosmetic product

No valid GMP certificate covering the scope of gel polish product has been submitted by the time of assessment. The product has to be manufactured in GMP compliance setting in order to comply with the EU Cosmetic Regulation.

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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 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, Hydroquinone methylether (MEHQ) and Trimethylbenzoyl Diphenylphosphine Oxide (TPO), 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. Recommended labelled warnings and instructions of use

For professional use only. ***(Mandatory)***
Avoid skin contact ***(Mandatory)***
Read directions for use carefully. ***(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.
Do not use in eye and mouth area.

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. However, no valid GMP certificate on manufacturing setting covering the scope of nail gel products has been submitted by the time of assessment. The product has to be manufactured in GMP compliance setting in order to comply with the EU Cosmetics Regulation. It is recommended to submit the corresponding valid GMP certificate.
This product is a light-cured nail gel which hardens on the nail plates under the influence of UV-light. The product contains hazardous substances Hydroquinone methylether (MeHQ) (CAS No. 150-76-5), as polymerization inhibitor, at a level of 200 ppm that requires this product to be used by professional only, as the product is expected to cause sensitization by skin contact as neat. 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 the potential hazard if misused and to keep the product out of reach of children. 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.
In addition, this formulation contains Trimethylbenzoyl Diphenylphosphine Oxide (TPO) which is classified as toxic to reproduction Repr. 2 and the substance is considered to be allergenic. The European Commission's Standing Committee on Cosmetics Products has voted that TPO is permitted only for use by professionals in nail modeling products at its meeting on 22 October, 2015 based on the opinion of Commission's Scientific Committee on Consumer Safety (SCCS). The client is hence drawn attention that

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such product can only be used by professionals when used as directed once the amendment is adopted in regulation and become effective.

4. Assessor's credentials and approval of Part B
Date: Nov 30, 2016

Tin-Ki LEUNG, Martin BSc(Hons), MRSB, MSCS, Cosmetic Safety Assessor

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: 0.1600000 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. HEMA

CAS No.: 868-77-9
EINECS/ELINCS: 212-782-2
CLP Classification: H315: Skin Irrit. 2; H317: Skin Sens. 1; H319: Eye Irrit. 2
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: safe in nail enhancement products when skin contact is avoided; products containing this ingredient should be accompanied with directions to avoid skin contact because of the sensitizing potential of methacrylates
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 30 mg/kg bw/day
SED: 0.0958904 mg/kg bw/day
MOS: 156.43
HEMA is the organic compound that can be used as a monomer for synthesis of polymer that is contained in preparations such as paint, adhesive, coating, dental adhesive system and others. It can be used as film forming agent in nail enhancement products. The acute toxicity of hydroxyethylmethacrylate (HEMA) is low

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(Oral LD50 > 4000 mg/kg; Dermal LD50 > 3000 mg/kg). HEMA is not more than slightly irritating to skin, and moderately irritating to eyes. HEMA is hydrolyzed to methacrylic acid and ethylene glycol. While other acrylates and methacrylates have been shown to cause nasal lesions on inhalation after hydrolysis to Methacrylic Acid (MAA), this effect has not been observed for HEMA. Occupational and non-occupational inhalation exposures to HEMA are considered to be low based on its physicochemical properties (low vapour pressure) and use patterns. This chemical was not mutagenic in bacteria but was clastogenic and induced polyploidy in mammalian cells in vitro. It, however, did not induce micronuclei in rat bone marrow up to the maximum tolerated dose. Based on the weight of evidence, it could be concluded that the chemical was not genotoxic in vivo, as it did not induce micronuclei in bone marrow. Animal studies suggest HEMA is a weak skin sensitizer in guinea pigs giving variable (mixed) results depending on the protocol. Positive reactions were shown only with injection of Freund's adjuvant but not by topical application alone. Whether or not this chemical induces skin sensitization in humans is equivocal; mixed results are reported in the literature on dental clients. Based on human patch test results, HEMA has sensitizing properties and HEMA has potential for cross-reaction with other (meth)acrylates. On the other hand, the CIR Expert Panel concluded that this methacrylate is safe in nail enhancement products when skin contact is avoided; products containing this ingredient should be accompanied with directions to avoid skin contact because of the sensitizing potential of methacrylates.
The submitted Certificate of Analysis (COA) of the ingredient, HEMA (CAS No. 868-77-9), as supplied by MITSUBISHI RAYON CO., LTD., with the product name of 2-Hydroxyethyl Methacrylate, indicated that polymerization inhibitor, MEHQ, was added at a level of 200 ppm as inhibitors.

3. Hydroxycyclohexyl Phenyl Ketone
CAS No.: 947-19-3
EINECS/ELINCS: 213-426-9
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 300 mg/kg bw/day
SED: 0.0095890 mg/kg bw/day
MOS: 15642.92
Hydroxycyclohexyl Phenyl Ketone is the organic compound that conforms to the formula $C_{13}H_{16}O_2$. It is used as photoinitiator or binding agent in artificial nail building. This substance was found to not irritant to the skin and to the eyes when rinsed 30 seconds after application, and was found to be devoid of a skin sensitizing potential. No developmental and mutagenic toxicity was observed.

4. Trimethylbenzoyl Diphenylphosphine Oxide
CAS No.: 75980-60-8
EINECS/ELINCS: 278-355-8
CLP Classification: H361f Repr. 2
EU Cosmetic Regulation: for professional use
SCCS opinion: safe when used as a nail modelling product at a concentration of at maximum 5.0% (SCCS/1528/14).
CIR recommendation: None
Food additive recommendation: None

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Toxicological profile by chemical supplier: None
NOAEL: 50 mg/kg bw/day (Corrected with 50% bioavailability)
SED: 0.0146027 mg/kg bw/day
MOS: 1712.01
Trimethylbenzoyl Diphenylphosphine Oxide (TPO) is used as a key processing aid in form of a chemical photo-initiator for polymerisation in artificial nail systems, primarily in UV-curable one-component gel systems. TPO splits into two free radical fragments, which subsequently become incorporated into the polymer as chain ends. Therefore, TPO will be rapidly consumed during the polymerisation process. Even if minor residual amounts remain, they will be trapped in the rapidly hardened polymer matrix of the formed nail coating. The current and anticipated use concentrations in the gels are in the range between 0.5% - 5.0%. TPO has irritant potential to rabbit skin and rabbit eyes, and has been positively tested in an LLNA test in mice. An EC3 of 27% was calculated indicating a moderate sensitising potential. In several repeated dose toxicity studies in rats, TPO induced marked testicular atrophy. TPO is classified as toxic to reproduction (classification as Repr. 2; H361f according to CLP Regulation). However, TPO is not expected to cause mutagenic effects in vivo. The SCCS is of the opinion that Trimethylbenzoyl diphenylphosphine oxide (TPO) is safe when used as a nail modelling product at a concentration of at maximum 5.0%. However, TPO is considered a moderate skin sensitizer.
The European Commission's Standing Committee on Cosmetics Products has voted to approve the use of trimethylbenzoyl diphenylphosphine oxide (TPO) as an ingredient in nail modelling products, for professional use at its meeting on 22 October, 2015. TPO is classified as carcinogenic, mutagenic or reprotoxic (CMR), but was considered safe for use in such products by the Commission's Scientific Committee on Consumer Safety (SCCS). The substance is considered to be allergenic, and, therefore, permitted only for use by professionals.

5. Ethylene Distearamide
CAS No.: 110-30-5
EINECS/ELINCS: 203-755-6 / 931-299-4
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.0001096 mg/kg bw/day
MOS: --
Ethylene Distearamide is the diamide that conforms to the formula $C_{38}H_{76}N_2O_2$. It is used as viscosity controlling in cosmetics. Amides, C16-C18 (even), N,N'-ethylenebis (Ethylene Distearamide) shows no toxicity in the range of water solubility. The substance is not classified as carcinogenic, mutagenic or toxic for reproduction nor is there any evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.

6. Carbon Black (CI 77266)
CAS No.: 1333-86-4 / 7440-44-0
EINECS/ELINCS: 215-609-9 / 231-153-3 / 931-328-0 / 931-334-3
CLP Classification: N/A
EU Cosmetic Regulation: Annex VI/126 & 126a

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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.

SCCS opinion: Same as EU Cosmetic Regulation
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 1000 mg/kg bw/day
SED: 0.0016438 mg/kg bw/day
MOS: 304173.26
CI 77266 (Carbon Black) is authorized as a colourant in cosmetics under entry 126 of Annex IV to Regulation (EC) No 1223/2009. However, it should have a purity >97%, with the following impurity profile: Ash content ≤ 0,15 %, total sulphur ≤ 0,65 %, total PAH ≤ 500 ppb and benzo(a)pyrene ≤ 5 ppb, dibenz(a,h)anthracene ≤ 5 ppb, total As ≤ 3 ppm, total Pb ≤ 10 ppm, total Hg ≤ 1 ppm. The SCCS concluded that the use of Carbon Black in its nano-structured form (with a primary particle size of 20 nm or larger) at a concentration up to 10 % w/w as a colourant in cosmetic products does not pose any risk of adverse effects in humans after application on healthy, intact skin. Carbon Black (nano) (according to the SCCS's specifications) is authorized for use as a colourant in cosmetic products at a maximum concentration of 10 % w/w, except in applications that may lead to exposure of the end user's lungs by inhalation.

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

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