COSMETIC PRODUCT SAFETY REPORT

Company Name:	Shandong Changhong Chemical Co., Ltd.
Company Address:	2411, Building 3, Aosheng Building, High-tech Zone, Jinan City, Shandong Province.
Product Name:	Gel polish (1 formulation)
Net Weight:	9g per consumer product
Region of Origin:	China
Region of Destination:	EU
Version:	1.0
Date:	2025-09-23
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

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Table of Contents

PART A – Cosmetic product safety information

A.1 Quantitative and qualitative composition of the cosmetic product

A.1.1 Nominal Composition

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

INCI Name	CAS No.	EC No.	Conc. (%, w/w)	Function
PEG-4 TRIMETHYLOLPROPANE TRIACRYLATE	28961-43-5	/	38.00	Film forming
ISOBORNYL ACRYLATE	5888-33-5	227-561-6	34.00	Nail sculpting
ACRYLOYL MORPHOLINE	5117-12-4	/	18.90	Plasticiser
ACRYLATES COPOLYMER	25035-69-2	/	6.00	Film forming
TRIMETHYLBENZOYL DITOLYLPHOSPHINE OXIDE	270586-78-2	433-490-9	2.00	Nail sculpting
HYDROXYCYCLOHEXYL PHENYL KETONE	947-19-3	213-426-9	1.00	Binding
CI 77266	1333-86-4	215-609-9	0.02	Colorant

FRAGRANCE ALLERGENS

No parfum is present in the formulation.

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

A.2.1 Physical/chemical characteristics of Raw Materials

The raw materials specifications are available upon request.

A.2.2 Physical chemical specifications of the end product

The finished product is black liquid without odour.

A.2.3 End product stability

The stability evaluation of the above formula was conducted under different operating conditions in an appropriate packaging at -5±1°C, 25±1°C, and 45±2°C for 3 months. The organoleptic, physico-chemical and microbiological examinations (including appearance, odour, pH value change, TVC bacteria, appearance of package) were carried out.

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

A.2.4 Durability (PAO)

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

A.3 Microbiological quality

A.3.1 The microbiological specifications of the substance or mixture

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

A.3.2 The microbiological testing results of end product

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

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

Conclusion: According to Appendix 9 of the 12th Revision of the NoG (SCCS/1647/22) and ISO 17516:2014, the microbiological quality of this product was considered as **acceptable** for **Category 2 products**.

A.3.3 Results of preservation challenge test

Considering the low water activity of this product, it can be judged according to ISO 29621:2017 as the microbiologically low-risk product. And therefore preservation challenge test for this product would not be necessary.

A.4 Impurities, traces and information about the packaging material

A.4.1 Impurities and Traces of prohibited substances

The potential impurities and traces relevant for the raw materials were controlled via the raw material specifications. And the raw material specifications are available upon request. This product does not contain any relevant impurity at significant levels, and the analytical testing results of heavy metals (below table) indicated the content of As, Hg, Pb, Sb, Cd and Ni (soluble) in this product were undetected and considered to be **acceptable** according to Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) (published online: 06 Oct 2016) and German Health Journal No.7/1992, Session 45 from November 14,1991. Furthermore, in conformity with the article 3 of the regulation, the safety evaluation of this impurity and trace of prohibited substances is part of the safety evaluation of the cosmetic product.

Items	Testing Results	BVL (published online: 06 Oct 2016)	German Health Journal No.7/1992, Session 45 from November 14,1991
Pb, mg/kg	<0.01	≤2.0/5.0[a]	-
Hg, mg/kg	<0.001	≤0.1	-
As, mg/kg	<0.005	≤0.5/2.5[b]	-
Sb, mg/kg	<0.005	≤0.5	-
Cd, mg/kg	<0.01	≤0.1	-
Ni (soluble), mg/kg	<2	-	≤10

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

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

Conclusion: The heavy metal content of the formulation is **acceptable**.

A.4.2 Information about the Packaging Material

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

No.	Part	Material
1	Bottle body	Glass
2	Bottle cap	PP

A.4.3 Chemical purity of the packaging materials

The analytical testing results of immediate container indicated Pb, Cd, Hg and Cr (VI) were undetected with total amount less than 100 ppm.

Conclusion: The chemical purity of the packaging material is acceptable.

A.4.4 Compatibility of package

The compatibility evaluation of the above formula was conducted under different operating conditions in an appropriate packaging at -5±1°C, 25±1°C, and 45±2°C for 3 months. The organoleptic, physico-chemical and microbiological examinations (including appearance, odour, pH value change, TVC bacteria, appearance of package) were carried out.

Conclusion: The overall results of these examinations allow it to be stated that the compatibility tests are **acceptable**.

A.5 Normal and reasonably foreseeable use

The normal use and reasonably foreseeable uses of the product are described for the product type and determine

the exposure and hazards used in the safety assessment. Product misuse is not considered.

A.5.1 Normal use and reasonably foreseeable use conditions:

The normal use of this product is intended to be applied as gel polish by the adult. Other usage is not foreseeable.

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

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

A.6 Exposure to the cosmetic product

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

A.6.1 Product Type

This cosmetic product is applied as gel polish

Product Type: Leave-on

A.6.2 Target Group

The target users for this product are: Adult, And the default body weight use for margin of safety calculation is 60kg.

A.6.3 Area of application

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

Area of application: nail plates

Application Surface area: 4 cm^2

A.6.4 Routes of Exposure

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

Routes of Exposure: Dermal

A.6.5 Amount per daily application

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

Product Exposure: 0.05 g

A.6.6 Duration and Frequency

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

Frequency of use: 52 times per year

Exposure duration: Leave-on

A.7 Exposure to the substances

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

A.7.1 Exposure to the substance

INCI Name	Inclusion level (%, w/w)	Total Systemic (SED) mg/kg bw/day	Local Dermal (CEL) μg/cm²
PEG-4 TRIMETHYLOLPROPANE TRIACRYLATE	38.00	0.3154	4750
ISOBORNYL ACRYLATE	34.00	0.2822	4250
ACRYLOYL MORPHOLINE	18.90	0.15687	2362.5
ACRYLATES COPOLYMER	6.00	0.0498	750
TRIMETHYLBENZOYL DITOLYLPHOSPHINE OXIDE	2.00	0.0166	250
HYDROXYCYCLOHEXYL PHENYL KETONE	1.00	0.0083	125
CI 77266	0.02	0.000166	2.5

A.7.2 Exposure to impurities

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

A.8 Toxicological profile of the substances

Toxicological Profiles are provided for all substances apart from those that are fragrances, regulated ingredients, aqua or substances present at levels below a threshold of toxicological concern.

Accordingly, toxicological profiles of PEG-4 TRIMETHYLOLPROPANE TRIACRYLATE, ISOBORNYL ACRYLATE, ACRYLOYL MORPHOLINE, ACRYLATES COPOLYMER, TRIMETHYLBENZOYL DITOLYLPHOSPHINE OXIDE and HYDROXYCYCLOHEXYL PHENYL KETONE are included here.

Toxicological profile of PEG-4 TRIMETHYLOLPROPANE TRIACRYLATE (CAS# 28961-43-5)

Toxicological endpoints:

Acute toxicity: Its acute toxicity was considered to be very low with oral LD_{50} > 2000 mg/kg bw in rats and dermal LD_{50} > 13200 mg/kg bw in rabbits [1].

Skin irritation: It was considered to be not irritating to skin in one primary skin irritation test in rabbits according to OECD TG 404 [1].

Eye irritation: It was considered to be irritating to eyes in one acute eye irritation test in rabbits according to OECD TG 405 [1].

Skin sensitization: Based on the results of this study and applying the evaluation criteria (at least 15% of the test animals exhibit skin reactions) it was concluded that the test substance has a sensitizing effect on the skin of the guinea pig in the BUEHLER Test under the test conditions chosen. Therefore, in accordance to classification criteria when ⩾ 15 % responding at > 20 % topical induction dose, then a subcategorisation of Skin Sens1B is considered appropriate for the test substance.

Phototoxicity: No data. But it was considered acceptable as it was demonstrated not to have significant UV absorption capacity.

Repeated dose toxicity: In one Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test according to OECD TG 422, it was administered to rats by daily oral gavage at dose levels of 100, 300 and 1000 mg/kg bw/d. Based on the results, the NOAEL for Parental systemic effects was 1000 mg/kg bw/d.

Mutagenicity/Genotoxicity: Based on the available information, it can be concluded that there is no concern with respect to genotoxicity [1].

Carcinogenicity: Weight of evidence indicated it's unlikely to be carcinogenic [1].

Reproductive toxicity: Weigt of evidence indicated it will not be classified as a reproductive or developmental toxicant [1, 2]. In one Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test according to OECD TG 422, no treatment-related changes were noted in any of the reproductive parameters investigated in this study. No developmental toxicity was observed up to the highest dose level tested (1000 mg/kg bw/d). No toxicologically significant changes were noted in any of the developmental parameters investigated in this study. Based on the results of this study, the NOAEL for reproduction and developmental toxicity was considered to be 1000 mg/kg bw/d.

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	1000 mg/kg bw/d
Exposure Estimate	0.3154 mg/kg bw/d
Margin of Safety (MoS)	3171

Regulatory Status: Not Regulated in Regulation (EC) No 1223/2009 without the assessment opinion from CIR or SCCS.

Conclusion

Hence it is concluded that the currently available data is sufficient to consider it safe to be used as intended in this product.

Reference list:

[1] ECHA. Registration dossier of PEG-4 TRIMETHYLOLPROPANE TRIACRYLATE (CAS No. 28961-43-5). Last accessed on 2024-09-12@ https://echa.europa.eu/registration-dossier/-/registered-dossier/15287.

Toxicological profile of ISOBORNYL ACRYLATE (CAS# 5888-33-5)

Toxicological endpoints:

Acute toxicity: Its acute toxicity was low with oral LD_{50} of 4350 mg/kg bw in rats and dermal LD_{50} over 3000 mg/kg bw in rabbits [1].

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

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

Skin sensitization: It was found to be skin sensitizing in one mouse local lymph node assay with EC_3 estimated to be below 5% [1].

Phototoxicity: No data. But it was considered acceptable for its current usage as it was unlikely to contact skin under normal condition of use.

Repeated dose toxicity: In one Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test in rats, Isobornyl acrylate was administered orally, by gavage, at the dosages of 25, 100 and 500 mg/kg bw/d. The treatment schedule included 2 weeks before pairing, during pairing, post coitum and post partum periods up to Day 3 post partum. Animals were administered for approximately 5 and 6 weeks for males and females, respectively. On the basis of the results obtained in the study, the NOAEL (No

Observed Adverse Effect Level) for both general toxicity and reproduction / developmental toxicity was determined to be 100 mg/kg bw/day for males and females [1].

Mutagenicity/Genotoxicity: It was tested as negative in a bacterial reverse mutation test and in one HPRT locus mutation test (OECD 476, GLP) in Chinese hamster lung fibroblasts (V79). No clastogenic potential was found in one *in vitro* micronucleus test performed in human lymphocytes. Hence, it was considered to lack genotoxicity potential [1].

Carcinogenicity: No data. But it was considered acceptable as it lacked genotoxicity potential and additionally, there is no evidence from the repeated dose studies that the substance is able to induce hyperplasia and/or pre-neoplastic lesions [1].

Reproductive toxicity: In one Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test in rats, no relevant differences were found in terms of mating performance including the pre-coital interval (number of days paired up to sperm positive day), the copulatory index (calculated as the percentage of animals mated respect to those paired) and the fertility index, these last two parameters with percentages of 100% in all groups. All pregnant females in the groups, including controls, had comparable length of gestation period and gave births. Furthermore, sex ratio calculated as the percentage of males in the litter did not differ between the groups. However, significant differences were found in terms of total litter size and litter weight in the high dose group compared to controls, from birth to Day 4 post partum. On the basis of the results obtained in the study, the NOAEL for reproduction / developmental toxicity was determined to be 100 mg/kg bw/d [1].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	100 mg/kg bw/d
Exposure Estimate	0.2822 mg/kg bw/d
Margin of Safety (MoS)	354

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

Conclusion

And it is concluded that the currently available data is sufficient to consider it safe to be used as intended in this product.

Reference list:

[1] ECHA. Registration dossier of Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate (CAS No. 5888-33-5). Last accessed on 2022-09-02@ https://echa.europa.eu/registration-dossier/-/registered-dossier/14494.

Toxicological profile of ACRYLOYL MORPHOLINE (CAS# 5117-12-4)

Toxicological endpoints:

Acute toxicity: Its acute oral toxicity was assumed to be high with oral LD_{50} of 588 mg/kg bw in rats and acute oral toxicity was assumed to be low with dermal LD_{50} > 2000 mg/kg bw in rats [1].

Skin irritation: It is not considered as a dermal irritant [1].

Eye irritation: It was considered to be corrosive to rabbit eyes [1].

Skin sensitization: It was found to be skin sensitizing in one guinea pig maximization test, but was tested as negative in one mouse local lymph node assay at the concentration up to 25% [1].

Phototoxicity: No data. But it was considered acceptable for its current usage as it was unlikely to contact skin under normal condition of use.

Repeated dose toxicity: In one 28-day repeated dose oral toxicity study in rats, the NOAEL was deemed to be 50 mg/kg bw/d [1].

Mutagenicity/Genotoxicity: Weight of evidence indicated it lacked genotoxicity potential [1].

Carcinogenicity: No data was available. But it was considered to be acceptable as was based upon an absence of mutagenic potential in vitro and clastogenic activity in vivo and no evidence of hyperplasia and/or pre-neoplastic lesions following repeated dose toxicity study [1].

Reproductive toxicity: It was found to lack reproductive or developmental toxicity potential in one reproductive / developmental toxicity screening test in rats with NOAEL of 75 mg/kg bw/d for reproductive and developmental toxicity [1].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	50 mg/kg bw/d
Exposure Estimate	0.15687 mg/kg bw/d
Margin of Safety (MoS)	319

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

Conclusion

Due to the adequate margin of safety, hence it can be concluded it is safe to be used as intended in this product.

Reference list:

[1] ECHA. Registration dossier of 4-(1-oxo-2-propenyl)-morpholine (CAS # 5117-12-4). Last accessed on 2022-04-24@ https://echa.europa.eu/registration-dossier/-/registered-dossier/16358.

Toxicological profile of ACRYLATES COPOLYMER (CAS No. 25133-97-5 / 25035-69-2 / 25212-88-8)

Toxicological endpoints:

Acute toxicity: Its acute toxicity was considered to be very low with reported LD_{50} values of 16 g/kg bw (dermal, rabbits), and > 25.2 g/kg bw in rats [1, 2].

Skin irritation: It was found to be not irritating in one primary skin irritation test in rabbits [1, 2].

Eye irritation: Acrylates Copolymer was not an ocular irritant in one study, and was slightly irritating in another when tested in rabbits according to OECD TG 405 [1, 2].

Skin sensitization: Acrylates Copolymer was not classified as a sensitizer in a local lymph node assay (LLNA), or in a Buehler test using guinea pigs [1].

Phototoxicity: No photosensitization data on this polymer were available for review, but the UV absorption characteristics suggest that phototoxicity is unlikely [1].

Repeated dose toxicity: In one 26 weeks oral toxicity study in rats, no treatment-related findings were observed. The NOAEL was reported to be over 2000 mg dry copolymer/ kg bw/d [1].

Mutagenicity/Genotoxicity: Weight of evidence indicated it lacked genotoxicity potential [1].

Carcinogenicity: No data. But it was considered to lack carcinogenicity potential because a stable high molecular weight polymer is biologically inert as its large size precludes any significant bioavailability.

Reproductive toxicity: It was considered to lack reproductive toxicity potential [1].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	2000 mg/kg bw/d
Exposure Estimate	0.0498 mg/kg bw/d
Margin of Safety (MoS)	40161

Regulatory Status: Not regulated in Regulation (EC) No 1223/2009 and with the assessment opinion from CIR that it can be safely used in leave-on and rinse-off cosmetics at the concentration up to 98.6% and 4.2% respectively [1].

Conclusion

Acrylates Copolymer, as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate, with a quantitative composition described as poly(ethyl acrylate-co-methyl methacrylate) 2:1, is produced by emulsion polymerization. As a stable high molecular weight polymer, it is generally biologically inert because its large size precludes any significant bioavailability. It was identified as Low concern polymer under the NICNAS targeted tier I approach and was recognized to pose no unreasonable risk to human health based on Tier I assessment under the NICNAS IMAP assessment framework. Hence, taking the above into account, it is concluded that it is sufficient to consider it safe to be used as intended in this product.

Reference list:

[1] CIR Expert Panel. 2018. Amended Safety Assessment of Acrylates Copolymers as Used in Cosmetics.

[2] CIR Expert Panel. Final Report on the Safety Assessment of Acrylates Copolymer and 33 Related Cosmetic Ingredients. IJT 21(Suppl. 3):1-50, 2002.

Toxicological profile of TRIMETHYLBENZOYL DITOLYLPHOSPHINE OXIDE (CAS# 270586-78-2)

Toxicological endpoints:

Acute toxicity: Its acute toxicity was considered to be very low [1, 2].

Skin irritation: It was considered to be not irritating to skin [1, 2].

Eye irritation: It was considered to be not irritating to eyes under current condition of use [1, 2].

Skin sensitization: Weight of evidence indicated it was not skin sensitizing [1, 2].

Phototoxicity: No data. But it was considered acceptable as it was demonstrated not to have significant UV absorption capacity.

Repeated dose toxicity: No repeated dose oral toxicity data was available. And in one subchronic oral toxicity test of Trimethylbenzoyl Diphenylphosphine Oxide (CAS No. 75980-60-8) in rats, NOAEL was considered as 100 mg/kg bw/d.

Mutagenicity/Genotoxicity: Based on the available information, it can be concluded that there is no concern with respect to genotoxicity [1, 2].

Carcinogenicity: Weight of evidence indicated it's unlikely to be carcinogenic under current condition of use [1, 2].

Reproductive toxicity: Weigt of evidence indicated it will not be classified as a reproductive or developmental toxicant [1, 2].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	100 mg/kg bw/d
Exposure Estimate	0.0166 mg/kg bw/d
Margin of Safety (MoS)	6024

Regulatory Status: Not Regulated in Regulation (EC) No 1223/2009 without the assessment opinion from CIR or SCCS.

Conclusion

Hence it is concluded that the currently available data is sufficient to consider it safe to be used as intended in this product.

Reference list:

[1] ECHA. Registration dossier of TRIMETHYLBENZOYL DITOLYLPHOSPHINE OXIDE (CAS No. 270586-78-2). Last accessed on 2024-09-12@ https://echa.europa.eu/registration-dossier/-/registered-dossier/34714.

[2] SCCS. OPINION ON Trimethylbenzoyl diphenylphosphine oxide (TPO). SCCS/1528/14.

Toxicological profile of Hydroxycyclohexyl Phenyl Ketone (CAS# 947-19-3)

Toxicological endpoints:

Acute toxicity: Its acute toxicity was low with oral LD_{50} of 2500 mg/kg bw and dermal LD_{50} over 5000 mg/kg bw in rats [1].

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

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

Skin sensitization: It was found to be non-sensitizing in one guinea pig maximization test with intradermal and epidermal induction level of 1% and 30% respectively.

Phototoxicity: No data. But it was considered acceptable for its current usage as it was unlikely to contact skin under normal condition of use.

Repeated dose toxicity: In one subchronic oral toxicity study in rats, NOAEL was decided to be 300 mg/kg bw/d [1].

Mutagenicity/Genotoxicity: It was tested as negative in a bacterial reverse mutation test and in one HPRT locus mutation test (OECD 476, GLP) in mammalian cells. No clastogenic potential was found in one *in-vivo* micronucleus test performed in Chinese hamsters with a single gavage dose of 5000 mg/kg bw. Hence, it was considered to lack genotoxicity potential [1].

Carcinogenicity: No data. But it was considered acceptable as it lacked genotoxicity potential and additionally, there is no evidence from the repeated dose studies that the substance is able to induce hyperplasia and/or pre-neoplastic lesions [1].

Reproductive toxicity: Weight of evidence indicated it lacked reproductive toxicity potential [1].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	300 mg/kg bw/d
Exposure Estimate	0.0083 mg/kg bw/d
Margin of Safety (MoS)	36145

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

Conclusion

And it is concluded that the currently available data is sufficient to consider it safe to be used as intended in this product.

Reference list:

[1] ECHA. Registration dossier of Hydroxycyclohexyl phenyl ketone (CAS No. 947-19-3). Last accessed on 2022-09-02@ https://echa.europa.eu/registration-dossier/-/registered-dossier/1936.

A.9 Undesirable effects and serious undesirable effects

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

No relevant data on other cosmetic product are available.

A.10 Information on the cosmetic product

No other relevant information was submitted.

PART B – Cosmetic product safety assessment

B.1 Assessment conclusion

The formulation does not contain forbidden or banned ingredients per European Cosmetics Regulation (EC) No 1223/2009 and its amendments, and the safety assessment has been carried out in accordance with this regulation and its subsequent amendments.

After overall evaluation, this product can be considered as safe to be placed on the market without posing a foreseeable risk to the health of consumers under normal condition of use WHEN SKIN CONTACT IS AVOIDED.

B.2 Labelled warnings and instructions of use

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

B.3 Reasoning

B.3.1 Safety Evaluation of the Substances

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

Substance Name	Conc. (%, w/w)	Max. allowed conc. (%)	Margin of Safety	Assessment Conclusion
PEG-4 TRIMETHYLOLPROPANE TRIACRYLATE	38.00	NA	3171	Safe for human health under normal and reasonably foreseeable conditions of use.
ISOBORNYL ACRYLATE	34.00	NA	354	Safe for human health under normal and reasonably foreseeable conditions of use.
ACRYLOYL MORPHOLINE	18.90	NA	319	Safe for human health under normal and reasonably foreseeable conditions of use.
ACRYLATES COPOLYMER	6.00	NA	40161	Safe for human health under normal and reasonably foreseeable conditions of use.
TRIMETHYLBENZOYL DITOLYLPHOSPHINE OXIDE	2.00	NA	6024	Safe for human health under normal and reasonably foreseeable conditions of use.

HYDROXYCYCLOHEXYL PHENYL KETONE	1.00	NA	36145	Safe for human health under normal and reasonably foreseeable conditions of use.
CI 77266	0.02	NA	NA	Conforms to regulated usage.

B.3.2 Safety Evaluation of the Product

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

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

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

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

Dr. Raul Xin, EUROTOX Registered Toxicologist (ERT), UKRT

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