Issued: 09 Jun 2015 Report: SHAH00956642

Cosmetic Product Safety Report

CCO NAIL GEL TOP COAT

This safety assessment relates to the formulation described below. If the information below is incorrect, please amend and resubmit for reassessment.

Guangzhou COCOME Cosmetics Co., Ltd.

Room 6008~6010, Geping Business Building, No. 685 South Baiyun Dadao, Baiyun District, Guangzhou 510405, China

Formulation Ref: N/A

Buyer/Final Retailer: N/A

Manufacturer: N/A

PRODUCT FORMULATION

The chemical names shown below refer to the raw materials used to formulate this product. The identity of the raw materials is not necessarily based on the International Nomenclature of Cosmetic Ingredients (INCI) and does not represent the INCI listing that must be shown on the product label and is for assessment purposes only. An outline INCI label can be prepared on request.

Chemical Name	Conc	% Active	Active in Product	CAS No	Einecs No
DI-HEMA TRIMETHYLHEXYL DICARBAMATE	50	100	50	72869-86-4/41137-60-4	276-957-5
HYDROXYPROPYL METHACRYLATE	20	100	20	27813-02-1	213-090-3
HYDROXYETHYL METHACRYLATE (HEMA)	25	100	25	868-77-9	212-782-2
HYDROXYCYCLOHEXYL PHENYL KETONE	2	100	2	947-19-3	213-426-9
CI 60725 (FD&C VIOLET NO 2 / SOLVENT VIOLET 13)	1	100	1	81-48-1	201-353-5
ETHYL TRIMETHYLBENZOYL PHENYLPHOSPHINATE	2	100	2	84434-11-7	282-810-6

MSDS/SDS, CoA/TDS and toxicity profile (where applicable) were listed in the Appendix 1

LABELLED WARNINGS & INSTRUCTIONS OF USE

Keep away from eyes.

Keep away from children

CONSUMER EXPOSURE

Product Class: Nail varnish
IFRA Product type: Nail Polish/Varnish, Base layers, Fillers
IFRA Category: Category 8
Targeted Population: Adult Female & Adult Males Mean value 60kg

Amount per application/g:	0.20	Number of applications per day:	2-3 times per week
Skin Surface Area of Application/cm^2:	4	Physical form:	Gel
Total Amount applied per day/g:	0.20	Part of body exposed to undiluted	Nails and cuticles

Estimated Daily Exposure mg/kg/day: -
Amount Per Unit Area of Skin per day mg/cm^2/day: 5.00
Retention factor: 0.10
Exposure Time Neat: 3360 min
Exposure Time Dilute: Not Applicable
Exposure time Solvent Inhalation: Inhalation - 5mins. Inhalation rate: 23.1 litres/min
Exposure time Aerosol Inhalation: Not Applicable

MICROBIOLOGICAL QUALITY

To comply with "Guidelines on Microbiological Quality of the Finished Cosmetic Product" under SCCS's Notes of Guidance, the following limits apply to this product:

Category 2: Other cosmetic products. TVC should not exceed 1000 cfu/g or ml in 0.1 g or ml of the product Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans must not be detectable in 0.1 g or ml of the cosmetic product

Microbiological specifications for the product have been supplied and meet the industry requirements specified therein for this type of product.

Microbiological specification test report or data was listed in the Appendix 2-1

This formulation contains raw materials which will help create an environment that is hostile to microbial growth and it may be inhibited. This product may not require preservative challenge testing. Example of these materials are listed in Guidelines for the risk assessment and identification of microbiologically low risk products, BS ISO 29621.

STABILITY OF COSMETIC PRODUCT

Stability testing report or data has been supplied and products appears to be stable under conditions of testing

Stability Test Report or Data of Cosmetic Product was listed in the Appendix 3

PACKAGING COMPATIBILITY

It is assumed that the responsible person has identified the most applicable testing required to determine the packaging stability and its interaction with the cosmetic product contained within it. Taking into consideration the information supplied to the assessor, there appears to be no immediate health concern due to the characteristics of packaging materials in direct contact with the final product.

Packaging Compatibility Test Report and/or data was listed in the Appendix 4

SERIOUS / UNDESIRABLE EFFECTS

The supplier has confirmed that no undesirable effects or serious undesirable effects of this cosmetic product have been reported or, where relevant, cosmetic products with a similar formulation.

Serious/ Undesirable Effects of Cosmetic Product Declaration was listed in Appendix 5

FRAGRANCE COMPOSITIONS

This formulation does not contain a synthetic fragrance and therefore a fragrance safety evalution as per IFRA code of practice is not applicable to this product.

According to Cosmetic Regulation (EC) No. 1223/2009, a complete cosmetic product safety report shall, at a minimum, contain cosmetic product safety information and cosmetic product safety assessment. The former includes raw materials and packaging material specifications, toxicological profile of substance (taking into account of purity of substance) contained in the cosmetic product and any known undesirable effects of the cosmetic product.

TOXICOLOGICAL & REGULATORY REVIEW

A gel formulation of film former agents, monomers, colorant, artificial nail builder and colorant is designed to be used on the surface of nail. The colorant was approved for use and at levels within the restrictions (where applicable) under European Cosmetic Directive and Regulation, supporting its safe use in this product. The NOAEL for Di-HEMA Trimethylhexyl Dicarbamate and Ethyl Trimethylbenzoyl Phenylphosphinate are not available at date of this assessment. Base on their large molecular weight, it should be considered not to be bioavailable via the oral, as well as the dermal routes. Thus, there is no safety concern on this copolymer.
The raw materials used to formulate this product are all well known cosmetic product ingredients. They are present at typical concentrations where they are unlikely to cause irritation but may cause allergy in a small percentage of the general population.

Limits of heavy metals were satisfied legal requirements and testing report was listed in the Appendix 7

No existing studies from human volunteers were provided.
If used as directed, use of this product should be uneventful.

Effects of the product as supplied on the skin

The formulation as supplied may cause slight skin irritation especially if exposure is prolonged and/or repeated. However, under normal conditions of use, the likelihood of causing skin irritancy will be very low.

Repeated exposure to the formulation as supplied is unlikely to produce allergy by skin contact.

Exposure to this product is unlikely to result in phototoxic effects.

Unlikely to cause damage to internal organs following absorption through the skin.

Effects of the product as supplied on the eye

Accidental exposure of the eye to the formulation as supplied may result in slight eye irritation.

Effects following ingestion of the product as supplied

The formulation as supplied if swallowed may cause slight, transient irritation to the mouth and upper digestive tract.

Effects of inhaling the product

Inhalation of the may cause slight irritation of the nose and upper respiratory tract.

Overall Assessment Conclusion

The ingredients are legally permitted as per Cosmetic Regulation (EC) No 1223/2009 and its amendments and the safety assessment has been carried out in accordance to this regulation. They must comply with the relevant purity standards for cosmetic ingredients. It is assumed that these ingredients do not contain any undisclosed impurities/contaminants that would affect the conclusions reached. The product must be manufactured in accordance with EU Guidance on Good Manufacturing Practice.

Keep away from eyes.

Keep away from children

Under normal or reasonably foreseeable conditions of use, product made to this formulation is unlikely to produce an abnormally high number of adverse reactions.

Cosmetic Regulations Product Safety Assessor

Zhongrui Li BSc, MSc in Toxicology, MBTS, Diplomate of Certified Toxicologist
Intertek Testing Services Shenzhen Limited
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Date: 09 Jun 2015

SUMMARY OF TOXICOLOGICAL INFORMATION OF SUBSTANCES

Chemical Substance: DI-HEMA TRIMETHYLHEXYL DICARBAMATE

EU INCI NAME:DI-HEMA TRIMETHYLHEXYL DICARBAMATE

CAS: 72869-86-4/41137-60-4 Function: Film former

EINECS 276-957-5

Log Kow: 0.598 Melting Point: <-20

Boiling Point: >250

Water Solubility: 0.003 g/l

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> R52/53

EU CLP Harmonised Classification> Chronic aquatic 3

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.166666 No NOAEL Available NOAEL mg/kg bw day: -

SED Child mg/kg bw/day: 0.598802 No NOAEL Available

SED Baby mg/kg bw/day: 1.694915 No NOAEL Available

Toxicological Summary:

Function: Polymer component. Used in nail enhancement products and undergoes rapid polymerization to form a hard material and speeds up polymerization and/or form cross-links. Di-HEMA Trimethylhexyl Dicarbamate were considered to be capable to causing hypersensitivity/allergy in humans. Dermal irritation caused by methacrylates is documented in guinea pigs and rabbits. cross-reactivity between various methacrylate esters in some sensitization tests. Not shown to have to have any endocrine disrupting activity. Non-mutagenic in bacterial test systems, but weak mutagenic responses were seen in mammalian cell test systems. CIR Expert Panel decided that these methacrylate esters should be restricted to the nail and must not be in contact with the skin. (Reference CIR Compendium 2010) Toxicological Data from MSDS from manufacturer: Acute oral toxicity: LD50 rat, > 2,000 mg/kg OECD 401, limit test, GLP; Irritant effect on the skin:not irritating rabbit, 4 h, OECD 404, GLP; Irritant effect on the eyes:not irritating rabbit, OECD 405, GLP; not mutagenic in bacteria and mammalian cells in vitro.source: literature

Chemical Substance: HYDROXYPROPYL METHACRYLATE

CAS: 27813-02-1 Function: Co-polymer component

EINECS 213-090-3

Regulatory Summary:

EU DSD/DPD Classification> R36/38, R43

EU CLP Harmonised Classification>

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.066666 MoS - Adult 60kg: 8999.9 NOAEL mg/kg bw day: 300

SED Child mg/kg bw/day: 0.239520 MoS - Child 16.7kg: 2505.3 NOAEL test method: combined repeated dose toxicity and reproductive/developmental toxicity study on rats

SED Baby mg/kg bw/day: 0.677966 MoS - Baby 5.9kg: 884.9

Toxicological Summary:

A reactive component of polymers that is irritating to skin and eyes and may cause sentitization by skin contact. The material is sensitive to heat and light and prone to polymerisation. When polymerised the irritant properties will be lost as will the potential to cause sensitization. When used as a component of a nail extender formulation, polymerisation will occur which will reduce to biological properties of the material. Use should then be uneventful.
A NOAEL of 300 mg/kg bw /day can be assigned based on a combined repeated dose toxicity and reproductive/developmental toxicity study on rats administered Methacrylic acid, monoester with propane -1, 2-diol by gavage at doses up to 1,000 mg/kg bw/day. (Section 6.5). (OECD SIDS, 2006).

Chemical Substance: HYDROXYETHYL METHACRYLATE (HEMA)

EU INCI NAME:HEMA

CAS: 868-77-9 Function: Film former

EINECS 212-782-2

Appearance: clean mobile liquid

Log Kow: 0.42 at 25 °C

Water Solubility: freely soluble (25 °C)

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> R36/38-43

EU CLP Harmonised Classification> H319 ,H317,H315

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.083333 MoS - Adult 60kg: 360.1 NOAEL mg/kg bw day: 30

SED Child mg/kg bw/day: 0.299401 MoS - Child 16.7kg: 100.2

SED Baby mg/kg bw/day: 0.847457 MoS - Baby 5.9kg: 35.3

Toxicological Summary:

Cosmetic Function :Film Forming. As supplied classified as irritating to skin and eyes along with a skin sensitiser. The extent and time of exposure to this substance must be minimised.
CIR Concludes, 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.
Whether or not this chemical induces skin sensitization in humans is equivocal; mixed results are reported in the literature on dental clients. HEMA has sensitizing properties and HEMA has potential for cross-reaction with other (meth)acrylates (OECD SIDS, 2001). The oral toxicity study performed according to OECD Guideline 422 was selected as key study, and the NOAEL was 30 mg/kg based on elevated blood urea nitrogen; the LOAEL was 100 mg/kg/day based on the increase of relative kidney weight. HEMA is not mutagenic in bacteria but might be clastogenic and induce polyploidy in mammalian cells in vitro. HEMA is not genotoxic in vivo.

Chemical Substance: HYDROXYCYCLOHEXYL PHENYL KETONE

EU INCI NAME:HYDROXYCYCLOHEXYL PHENYL KETONE

CAS: 947-19-3 Function: Binding / Artificial Nail Builder

EINECS 213-426-9

Appearance: white solid

Log Kow: 2.34 at 25 °C (QSAR); 2.81 at 25°C (pH = 5.8)

Water Solubility: 42 mg/L in water at room temperature (PH 7)

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> R36

EU CLP Harmonised Classification> unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.006666	MoS - Adult 60kg: 14999.9	NOAEL mg/kg bw day: 100
SED Child mg/kg bw/day: 0.023952	MoS - Child 16.7kg: 4175.5	NOAEL test method: 28-day repeated oral toxicity study
SED Baby mg/kg bw/day: 0.067796	MoS - Baby 5.9kg: 1475.5	

Toxicological Summary:

Cosmetic Functions : Binding / Artificial Nail Builder. This curing agent is non-irritating to the skin and eyes and is not a sensitizer. It is unlikely to have any adverse effects when incorporated into a product. From the 28-day oral repeated toxicity study, the NOAEL is 300 mg/kg. With an uncertainty factor of 3, o the NOAEL=100 mg/kg is selected to calculate MoS. A DNEL of 1.25 mg/kg bw for general long-term exposure is listed in REACH Dossier.

Chemical Substance: CI 60725 (FD&C VIOLET NO 2 / SOLVENT VIOLET 13)

EU INCI NAME:CI 60725

CAS: 81-48-1 Function: Colour

EINECS 201-353-5

Appearance: Powdered solid Melting Point: Not available.

Log Kow: Not available. Boiling Point: N/A

Chemical Structure:

Water Solubility: Not available. Vapour Pressure: Not available.

Cosmetic Regulatory Summary:

EU Cosmetics Status: Approved colour all products

Regulatory Summary:

EU DSD/DPD Classification> Unclassified

EU CLP Harmonised Classification> Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.003333	No NOAEL Available	NOAEL mg/kg bw day: -
SED Child mg/kg bw/day: 0.011976	No NOAEL Available	NOAEL test method: -
SED Baby mg/kg bw/day: 0.033898	No NOAEL Available	

Toxicological Summary:

Function: Colourant. An essentially water insoluble monoazo dye permitted for use in cosmetic products. Minimally toxic with low irritation potential. Most unlikely to cause irritancy or allergy at typical levels of use. No data was available for acute toxicity, skin and eye irritation, skin sensitization, mutagenicity, reproductive toxicity, bioaccumulation and phototoxicity. This colour has been prohibited for use as a hair dye substance due to the bladder cancer risk (COMMISSION DIRECTIVE 2008/88/EC of 23 September 2008). Included in Annex II to Directive 76/768/EEC. The United States shall adopt this provision from 14 Aug 2009. As CI 60725 (FD&C Violet No 2 / Solvent Violet 13) is permitted in Europe in cosmetics as a colorant (Regulation (EC) No. 1223/2009) and by other scientific literature, safety concerns are thus not expected.

Chemical Substance: ETHYL TRIMETHYLBENZOYL PHENYLPHOSPHINATE

EU INCI NAME:ETHYL TRIMETHYLBENZOYL PHENYLPHOSPHINATE

CAS: 84434-11-7 Function: photoinitiatior

Appearance: yellow liquid

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> Not classified

EU CLP Harmonised Classification> Not classified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.006666	No NOAEL Available	NOAEL mg/kg bw day: -
SED Child mg/kg bw/day: 0.023952	No NOAEL Available	
SED Baby mg/kg bw/day: 0.067796	No NOAEL Available	

Toxicological Summary:

Function: UV Absorber/photoinitiator. Used in the polymer manufacturing inductries for initiating photochemical reaction to form polymers. This phosphinate is not acutely toxic and non irritating to the skin and eyes. When used as a cosmetic ingredient, it will be consumed during reaction and in the process will form a hardened polymeric resin and in the case of nail varnishes, its use should be uneventful taking into account its toxicological profile. Acute toxicity LD50/oral/rat = > 5000 mg/kg LD50/skin/rbt= non irritant Sensitization: None. Eye irritation non-irritant type of value: LD50 Species: rat Value: > 2,000 mg/kg; Irritation / corrosion; Skin: Species: rabbit Result: non-irritant Method: Draize test; Eye: Species: rabbit Result: non-irritant Method: Draize test

Note: In the absence of NOAEL data, the Margin of Safety (MoS) has not been calculated.
Unless otherwise determined and in the absence of literature or other experimental data, a Dermal Absorption (DAp) of 100% is taken as the worst case scenario.
NOAEL: No Observed Adverse Effect Level; MoS: Margin of Safety; SED Systemic Exposure Dosage
Calculation of Margin of Safety: MoS = NOAEL / SED

Reference for skin surface area, exposures and application quantities are derived from:
1. RIVM Report 320104001/2006
2. References sited in Dermal Sensitization Quantitative Risk Assessment (QRA) For Fragrance Ingredients, 2006 revision
3. Exposure factors handbook 2009 Update
4. The SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 8th Revision SCCS/1501/12
5. Colipa Data SCCNFP/0321/02
6. McNamara et al, Food Chem. Tox; 2007, 45, 2086
7. Loretz et al, Food Chem. Tox; 2008, 46, 1516
N.B. Exposure times have been taken from RIVM Report 320104001/2006
8. Body weights taken from Exposure factors handbook 2009 Update and mean values have been used unless specified otherwise
9. ConsExpo database
10. New default values for the spray model, RIVM, March 2010

This formulation has been safety assessed by Intertek with reference to Articles 3 and 10 of Cosmetic Regulation (EC) No. 1223/2009. The safety assessment is based on the chemical specification and toxicological profile of the ingredients as supplied at the time of assessment.
The supplier to this safety assessment is advised to ask for a new safety evaluation if any change in formulation occurs, change in raw materials used, abnormally high number of adverse events are recorded, changes in recommended uses or other circumstances that may affect the safety of this product.

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