Issued: 28 Jul 2015 Report: SZHH00956644

Cosmetic Product Safety Report

CCO NAIL GEL COLOR 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	45	100	45	72869-86-4/41137-60-4	276-957-5
HYDROXYETHYL METHACRYLATE (HEMA)	25	100	25	868-77-9	212-782-2
HYDROXYPROPYL METHACRYLATE	25	100	25	27813-02-1	248-666-3
ETHYL TRIMETHYLBENZOYL PHENYLPHOSPHINATE	2.5	100	2.5	84434-11-7	282-810-6
HYDROXYCYCLOHEXYL PHENYL KETONE	2.5	100	2.5	947-19-3	213-426-9
MAY CONTAIN (+/-)					
CI 77266	1	100	1	1333-86-4 / 7440-44-0	215-609-9 / 231-153-3
TITANIUM DIOXIDE (CI 77891)	5	100	5	13463-67-7/1317-70-0/1317-80-2	236-675-5/205-280-1/215-282-2
FD&C RED NO. 30 (CI 73360)	2	100	2	122-99-6 & 14807-96-6 & 2379-74-0 & 57-55-6 & 7732-18-5 & POLYMER	235-428-9
CI 15880 (D & C RED NO.34 / PIGMENT RED 63:1)	2	100	2	6417-83-0	229-142-3
CI 74160 (PIGMENT BLUE 15)	2	100	2	147-14-8	205-685-1
CI PIGMENT GREEN 7	1	100	1	1328-53-6	215-524-7
CI 19140 (FD&C YELLOW NO. 5)	1	100	1	1934-21-0	217-699-5
CI 60725 (FD&C VIOLET NO 2 / SOLVENT VIOLET 13)	1	100	1	81-48-1	201-353-5
CI 77007	4	100	4	1302-83-6 / 101357-30-6 / 57455-37-5/ 67053-79-6	215-111-1, 309-928-3
CI 77000 (ALUMINUM POWDER)	8	100	8	7429-90-5	231-072-3
MICA (CI 77019)	10	100	10	12001-26-2	310-127-6

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

LABELLED WARNINGS & INSTRUCTIONS OF USE

Keep away from eyes.

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, colorants, artificial nail builder and colorant is designed to be used on the surface of nail. The colorants were approved for use and at levels within the restrictions (where applicable) under European Cosmetic Directive and Regulation, supporting their 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 ingredients. They are present at typical concentrations where they are unlikely to cause irritation or allergy.

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 is an unlikely route of exposure

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.

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
7/F, Shekou Technology Main Building, Industrial 7th Road. Shekou, Nanshan District Shenzhen, China

Date: 28 Jul 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: 0.150000 No NOAEL Available NOAEL mg/kg bw day: -

SED Child mg/kg bw/day: 0.538922 No NOAEL Available

SED Baby mg/kg bw/day: 1.525423 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: 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: HYDROXYPROPYL METHACRYLATE

CAS: 27813-02-1

EINECS 248-666-3

Regulatory Summary:

EU DSD/DPD Classification> R36, R43

EU CLP Harmonised Classification>

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.083333 No NOAEL Available NOAEL mg/kg bw day: -

SED Child mg/kg bw/day: 0.299401 No NOAEL Available

SED Baby mg/kg bw/day: 0.847457 No NOAEL Available

Toxicological Summary:

This is of low oral and dermal toxicity but is seriously irritating to the eyes and has been shown to have skin sensitising properties in humans. It is recommended by the manufacturer that its use be restricted to preparations for nail extensions.

Chemical Substance: ETHYL TRIMETHYLBENZOYL PHENYLPHOSPHINATE

EU INCI NAME:ETHYL TRIMETHYLBENZOYL PHENYLPHOSPHINATE

CAS: 84434-11-7 Function: photoinitiatior

EINECS 282-810-6

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: 0.008333 No NOAEL Available NOAEL mg/kg bw day: -

SED Child mg/kg bw/day: 0.029940 No NOAEL Available

SED Baby mg/kg bw/day: 0.084745 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

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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: 0.008333 MoS - Adult 60kg: 12000.4 NOAEL mg/kg bw day: 100

SED Child mg/kg bw/day: 0.029940 MoS - Child 16.7kg: 3340.4 NOAEL test method: 28-day repeated oral toxicity study

SED Baby mg/kg bw/day: 0.084745 MoS - Baby 5.9kg: 1180.9

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: MAY CONTAIN (+/-)

EU DSD/DPD Classification>

EU CLP Harmonised Classification>

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: .000000 No NOAEL Available

SED Child mg/kg bw/day: .000000 No NOAEL Available

SED Baby mg/kg bw/day: .000000 No NOAEL Available

Toxicological Summary:

Chemical Substance: CI 77266

EU INCI NAME:CI 77266

CAS: 1333-86-4 / 7440-44-0
EINECS 215-609-9 / 231-153-3

Function: Colour

Appearance: Black, solid powder.

Melting Point: Not determined
Boiling Point: N/A

Water Solubility: Insoluble (< 0.1 mg/L) (ECHA, 2013).

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 MoS - Adult 60kg: 7800000.0
SED Child mg/kg bw/day: 0.011976 MoS - Child 16.7kg: 2171000.0
SED Baby mg/kg bw/day: 0.033898 MoS - Baby 5.9kg: 766999.9

NOAEL mg/kg bw day: 26000
NOAEL test method: Determined in a chronic dermal irritation study (OECD, 2005).

Toxicological Summary:

Carbon Black has minimal potential to cause irritancy or allergy. An approved cosmetic colour in the EU for all products as field of application is 1. As supplied, it has a very low acute oral toxicity (LD50: rat, > 8000 mg/kg/bw), moderate dermal
(LD50: rabbit, >500 mg/kg/bw) and low acute inhalation toxicity (LC50: rats, > 4.6 mg/m³/4hrs) (OECD, 2005). A 20% of Carbon Black applied under occlusion was not found to be irritating to skin, 100 mg instilled into rabbit eyes was not found to be irritating to eyes ECHA, 2013). It is not absorbed by the skin based on study on its lack of gastrointestinal tract absorption (OECD, 2005). Repeated dose toxicity study in rats with up to 20% (26000mg/kg.bw/day)Carbon Black produced no adverse effect (OECD, 2005). It was not found to be a toxic to reproduction nor a developmental toxicant (OECD,2005). Positive results from oxidative stress *in vitro* mammalian cell gene mutation assay and *in vivo* gene mutation assays indicated that it may cause genetic defects (ECHA, 2013). Carcinogenicity studies using 2.5 mg/m3 or up to 12.2 mg/m3 for up to 20 months provided evidence of potential carcinogenesis (OECD, 2005). A number of cases of skin cancer were identified in Carbon Black production workers in the US, whilst in a UK cohort study of Carbon Black workers no excesses of skin cancer were found. Also, a study in the rubber and tyre manufacturing industry did not reveal an increased risk of squamous cell skin cancer in workers exposed to Carbon Black contaminated materials. The OECD concluded that the relevance of Carbon Black induced lung tumours in rats to human health is uncertain. At present the potential of the chemical to induce lung tumours in humans cannot be ruled out on theoretical grounds, although the epidemiological evidence does not suggest such a causal link (OECD 2005). No relevant information was available following the literature search on the photo-Induced Toxicity of Carbon Black.

In the US under FDA regulations some impurities of carbon black are no longer authorised due to classification in the IARC Monographs Group 2B (1996). Graphite and Carbon black (manufactured by the Channel process) are no longer permitted as additives in cosmetic products in the US. DC black 2 and DC black 3 are permitted for use in cosmetic products. (In the USA., 74.2052, D&C Black No. 2, 2004 is permitted for use in: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel.) Carbon black (airborne, unbound particles of respirable size) is listed in California Proposition 65 as a carcinogen.

In accordance to the USA FDA regulation, the requirement is that the grade of the black pigment shall contain < 5 ppm total extraction level of the 12 types of polynuclear aromatic hydrocarbons (PNA) and < 20 ppb for Benzo(a)pyrene identified in black pigment as stated by the CTFA in accordance to methodology in FAP 6B3901) (Kashtok, M, 1990. *Food and color Additives Review Section, HFF-415*, FDA Department of Health and Human Services). Polynuclear aromatic hydrocarbons have carcinogenic potential and are known manufacturing low contaminants of this pigment (Kashtok, M, 1990). The PNA are known to be strongly bound to the pigment. Thus exposure to them depends on their bioavailability. Conditions under which unbound PNA's can become available are high temperature using aromatic solvents or in the presenc of certain ingredients that interact with the carbon surface to displace the PNA's from binding to it. In leave-on cosmetic products such as lipsticks, pigment intake of 0.1 mg/person/day results in an estimated intake of 0.5 and 0.002 ng/person/day of a specified the PNA's and Benzo(a)pyrene respectively. In an external cosmetic product application of approximately 10 mg/person/day of the pigment intake, the exposure is estimated to be up to 100 times higher than the ingested product such as a lipstick, that is, 50 and 0.2 ng/person/day for the specified PNA's and Benzo (a)pyrene respectively. The use of high purity of it as obtained from furnace processing is recommended a quality also suitable for food contact products (21CFR178.3297 revised April 1, 2011).

Chemical Substance: TITANIUM DIOXIDE (CI 77891)

EU INCI NAME:TITANIUM DIOXIDE

CAS: 13463-67-7/1317-70-0/1317-80-2
EINECS 236-675-5/205-280-1/215-282-2

Function: Opacifying / UV Absorber / UV Filter

Appearance: Solid
Log Kow: N/A

Melting Point: 1843
Boiling Point: 2500 - 3000 °C (Calculated value).

Water Solubility: Insoluble (<0.1mg/L)

Vapour Pressure: N/A

Cosmetic Regulatory Summary:

EU Cosmetics Status: Approved UV filter

Regulatory Summary:

EU DSD/DPD Classification> unclassified

EU CLP Harmonised Classification> Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.016666 MoS - Adult 60kg: 1439999.9
SED Child mg/kg bw/day: 0.059880 MoS - Child 16.7kg: 400799.9
SED Baby mg/kg bw/day: 0.169491 MoS - Baby 5.9kg: 141600.1

NOAEL mg/kg bw day: 24000
NOAEL test method: The no-observed effect level (NOEL) through oral gavage is >24, 000 mg/kg (REACH Dossier)

Toxicological Summary:

Titanium dioxide is unlikely to cause adverse effects at the typical concentrations used in cosmetics. Available as a micronised product which may present a respiratory irritation hazard when handled in bulk. Use of such grades is generally restricted to liquid formulations where the likelihood of the formation of respirable atmospheres is low. Can be produced in either anatase or rutile crystal form. Rutile TiO2 produces higher opacity and greater scatter than anatase since the rutile crystal has a higher index of refraction; anatase is less abrasive than rutile, but is also used with UV brighteners, since rutile reduces the efficiency of the brighteners due to UV absorption in the same wavelength range. Generally, rutile is preferred for coatings due to its higher opacity .

Titanium dioxide was found to be non toxic for both oral and dermal in rat and mice. Poor dermal penetration. Non irritating to the skin and eyes, non sensitizing in animal and human and non photo toxic. Reported as non mutagenic and practically non toxic in repeated dose toxicity studies. IARC classification: Group 2B (possibly carcinogenic to humans). All the four forms of titanium dioxide are not found to be accumulated in the tissues.
No-Observed-Adverse-Effect Level (NOAEL) and Rationale: In a repeated 28-day toxicity study in rats dosed orally through gavage with titanium dioxide suspended in water at concentration of 24,000 mg/kg showed no effects in any of the endpoint tested. The no-observed effect level (NOEL) through oral gavage is >24, 000 mg/kg (REACH Dossier)

Chemical Substance: FD&C RED NO. 30 (CI 73360)

EU INCI NAME:P-HYDROXYBENZOIC ACID & TALC & FD&C RED NO. 30 & PROPYLENE GLYCOL & AQUA & ACRYLIC 3076

CAS: 122-99-6 & 14807-96-6 & 2379-74-0 & 57-55-6 & 7732
EINECS -18-5 & polymer
235-428-9

Cosmetic Regulatory Summary:

EU Cosmetics Status: Approved colour all products

Regulatory Summary:

EU DSD/DPD Classification› Unclassified

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

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

Toxicological Summary:

The insoluble aluminium salt of tartrazine. Unlikely to cause adverse effects at the typical concentrations used in cosmetics. Widely used and well accepted in cosmetic products.
CI 73360 has been prohibited for use as a hair dye due to the bladder cancer risk (COMMISSION DIRECTIVE 2008/88/EC of 23 September 2008). Is included in Annex II to Directive 76/768/EEC. The United States shall adopt this provision from 14 Aug 2009.

Chemical Substance: CI 15880 (D & C RED NO.34 / PIGMENT RED 63:1)

EU INCI NAME:CI 15880

CAS: 6417-83-0 Function: Hair Dye
EINECS 229-142-3

Cosmetic Regulatory Summary:

EU Cosmetics Status: Approved colour all products except Prohibited as a hair dye substance

Regulatory Summary:

EU DSD/DPD Classification› Prohibited

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

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

Toxicological Summary:

An approved cosmetic colourant. A diazodye permitted in all products including toys. Will not break down to a carcinogenic amine.
Prohibited in cosmetic products in the EU when used as a substance in hair dye products-2008/88/EC. Application and withdrawal date will be 14/04/2009, when used as a substance in hair dye products , II/1349.

Chemical Substance: CI 74160 (PIGMENT BLUE 15)

EU INCI NAME:CI 74160

CAS: 147-14-8 Function: Colour
EINECS 205-685-1

Cosmetic Regulatory Summary:

EU Cosmetics Status: Approved colour all products

Regulatory Summary:

EU DSD/DPD Classification› Unclassified

EU CLP Harmonised Classification›

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.006666 MoS - Adult 60kg: 29999.9 NOAEL mg/kg bw day: 200
SED Child mg/kg bw/day: 0.023952 MoS - Child 16.7kg: 8350.1 NOAEL test method: repeated dose 28-day oral toxicity studies in rats
SED Baby mg/kg bw/day: 0.067796 MoS - Baby 5.9kg: 2950.1

Toxicological Summary:

A phthalocyanine pigment which is an approved colour in all cosmetic products. As supplied reported to lack potential to irritate the skin and minimally irritating to eyes. The acute oral LD50 is in excess of 10g/kg. If used at low concentrations unlikely to cause irritancy or sensitisation. Not based on aromatic amines.
CI 74160 has been prohibited for use as a hair dye due to the bladder cancer risk (COMMISSION DIRECTIVE 2008/88/EC of 23 September 2008). Is included in Annex II to Directive 76/768/EEC. The United States shall adopt this provision from 14 Aug 2009.

Chemical Substance: CI PIGMENT GREEN 7

EU INCI NAME:CI 74260

CAS: 1328-53-6
EINECS 215-524-7

Function: cosmetic colorants

Cosmetic Regulatory Summary:

EU Cosmetics Status: Approved colour but not close to eyes

Regulatory Summary:

EU DSD/DPD Classification> unclassified

EU CLP Harmonised Classification>

Systemic Exposure Dosage / Margin of Safety:

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

Toxicological Summary:

A green powder. In Draize test (rabbit) non irritant to the mucous membrane , eyes, and skin.
Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of the eyes. A phthalocyanine colour is unlikely to cause skin or eye irritancy at the typical levels of use in a rinse off product.
CI 74260 has been prohibited for use as a hair dye due to the bladder cancer risk (COMMISSION DIRECTIVE 2008/88/EC of 23 September 2008). Is included in Annex II to Directive 76/768/EEC. The United States shall adopt this provision from 14 Aug 2009.

Chemical Substance: CI 19140 (FD&C YELLOW NO. 5)

EU INCI NAME:CI 19140

CAS: 1934-21-0
EINECS 217-699-5

Function: Colour

Appearance: Orange / yellow powder
Log Kow: – 10.17 (calculated by QSAR)*

Melting Point: 349.8 (calculated by QSAR)*
Boiling Point: 870 (calculated by QSAR)*

Chemical Structure:

Water Solubility: Soluble in water

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 MoS - Adult 60kg: 86538461.5 NOAEL mg/kg bw day: 750
SED Child mg/kg bw/day: 0.011976 MoS - Child 16.7kg: 24086538.4 NOAEL test method: sub-chronic study, four groups of rats (15 of each sex)
SED Baby mg/kg bw/day: 0.033898 MoS - Baby 5.9kg: 8509615.3

Toxicological Summary:

Functions: Cosmetic colorant. It is also called tartrazine, CI Food Yellow 4, Acid Yellow 23 or FD&C Yellow No. 5, and approved for use in cosmetics, food and beverages. CI 19140 has low of acute toxicity with LD 50 of 12750 mg/ kg for mice and LD50 of greater than 2000 mg/k for rats. It is unlikely to cause skin irritation and eye irritation. It is not a skin sensitizer but has exhibited potential for this (SCCNFP, 2004). Skin penetration of Acid Yellow 23 is low and the maximum absorption through skin 13.2 µg/cm2 (0.26%). Two skin absorption studies of acid yellow 23 were investigated on the outer skin of porcine ears. Based on the skin absorption studies, a penetration rate of 13.2 µg/cm² (0.26 %) representing the highest value derived from the above described test will be used as a worst case scenario for the final risk assessment (SCCSNFP, 2004). Tartrazine was not mutagenic in vitro (e.g. the Ames test, in vitro studies in Salmonella typhimurium and in cultures of Escherichia coli) and in vivo (e.g. the micronucleus gut assay) (SCCNFP, 2004). In one sub-chronic study, four groups of rats (15 of each sex) were given diets with 0, 0.03, 0.3, or 1.5 % tartrazine (equivalent to 0, 15, 150, or 750 mg/kg bw/day) for 64 weeks. The dye had no effects on mortality, food intake, growth, organ weights, histopathology, blood picture or tumour incidence (Mannell et al., 1958). This study was used by JECFA to establish the ADI based on the No-Observed-Adverse-Effect Level (NOAEL) of 750 mg/kg bw/day (being the highest dose level tested) and a safety factor of 100 (EFSA, 2009). In one reproductive toxicity study, tartrazine was given to Osborne-Mendel rats (no detail on number) by gavage at dose levels of 0, 60, 100, 200, 400, 600, or 1000 mg/kg bw/day on days 0-19 of gestation. No dose-related effects were observed. The NOAEL for teratogenicity of Acid Yellow 23 was greater than 1000 mg/kg/day in this study. A 2-generation chronic toxicity/carcinogenicity study was conducted with different concentrations of Acid Yellow 23. Male and female rats were fed a basal diet (control group) or basal diet blended with commercial Acid Yellow 23 (0.1%, 1.0%, 2.0%, 5.0%) for approx. 2 months prior to mating. No treatment-related effects on fertility, gestation, parturition, lactation, pup survival through weaning or number of alive and still-born pups were observed. Slight decreases in body weight (4-5 %) and slight increases in food consumption were noted at the 5.0 % dose group. The NOAEL for reproductive and teratogenic toxicity of Acid Yellow 23 was 5 % in the diet (equivalent to 2641-3348 mg/kg bw/day, for males and females, respectively) (EFSA, 2009; SCCSNFP, 2004). Three groups of dogs were given 0, 1 or 2 % tartrazine (corresponding to 0, 250 and 500 mg/kg bw/day) in their diets for two years. No tartrazine-related effects

According to the CFR - Code of Federal Regulations Title 21 the colour "may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity." A review was conducted by the SCCNFP (SCCNFP/0786/04).

The Cosmetics Directive 2009/36/EC has amended the use of this colour to be used in non oxidative hair dyes at a maximum concentration of 0.5%. This does not effect its use in other permitted cosmetic product types.

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

EU INCI NAME:CI 60725

CAS: 81-48-1
EINECS 201-353-5

Function: Colour

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

SED Child mg/kg bw/day: 0.011976 No NOAEL Available

SED Baby mg/kg bw/day: 0.033898 No NOAEL Available

NOAEL mg/kg bw day: -

NOAEL test method: -

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: CI 77007

EU INCI NAME:CI 77007

CAS: 1302-83-6 / 101357-30-6 / 57455-37-5/ 67053-79-6
EINECS 215-111-1, 309-928-3

Function: Colour

Appearance: Not available.

Melting Point: Not available.

Log Kow: Not available.

Boiling Point: Not available.

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: 0.013333 No NOAEL Available

SED Child mg/kg bw/day: 0.047904 No NOAEL Available

SED Baby mg/kg bw/day: 0.135593 No NOAEL Available

NOAEL mg/kg bw day: -

NOAEL test method: -

Toxicological Summary:

This pigment is permitted for use in all cosmetic products and has minimal toxic properties. Unlikely to cause adverse effects at the typical concentrations used in cosmetics.

Chemical Substance: CI 77000 (ALUMINUM POWDER)

EU INCI NAME:CI 77000

CAS: 7429-90-5
EINECS 231-072-3

Function: Colour

Cosmetic Regulatory Summary:

EU Cosmetics Status: Approved colour all products

Regulatory Summary:

EU DSD/DPD Classification> R15-17

EU CLP Harmonised Classification> H228, H261

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.026666 No NOAEL Available

SED Child mg/kg bw/day: 0.095808 No NOAEL Available

SED Baby mg/kg bw/day: 0.271186 No NOAEL Available

NOAEL mg/kg bw day: -

Toxicological Summary:

Aluminium is the most abundant metal in the earth crust and not classified as toxic. Aluminium powder form is pyrophoric and can cause an explosive reaction in air. It reacts to form oxides and hydroxides which are form alkaline solutions with water. Although in powder form aluminium can react with water, this is unlikely to occur in an oil-based cosmetic formulation. Hence incorporation into an oil-based cosmetic formulation is unlikely to give rise to skin or eye irritation. Highly reflective particles which give colour by reflectance. The product is essentially inert. May cause a foreign body reaction should they enter the eye and enhance the eye irritancy potential of other components in a product. If inhaled may cause slight transient respiratory irritation.

Aluminium is an approved colour permitted for use in cosmetic products in the EU and also the US (73.26454)

Chemical Substance: MICA (CI 77019)

EU INCI NAME:MICA

CAS: 12001-26-2
EINECS 310-127-6

Function: Opacifying

Appearance: Crystalline solid

Melting Point: Not available.

Log Kow: N/A

Boiling Point: N/A

Water Solubility: Insoluble

Vapour Pressure: N/A

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> unclassified

EU CLP Harmonised Classification> unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.033333 No NOAEL Available

SED Child mg/kg bw/day: 0.119760 No NOAEL Available

SED Baby mg/kg bw/day: 0.338983 No NOAEL Available

NOAEL mg/kg bw day: -

NOAEL test method: -

Toxicological Summary:

Cosmetic function : Opacifying. A silicate mineral with a wide variety of applications. Used in the production of pearlescent pigments and as a bulking agent in cosmetic products. Not classified as irritating to the skin or eyes and not a skin sensitizer. The material is inert and of a size unlikely to be inhaled. Permitted for use in US, Canada and Saudi regulatory regimes. High LD50 and not of toxicological concern (except for Mica that may contain crystalline quartz, which is known to be carcinogenic to humans [WHO, 2012; HSDB, 2012].

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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