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 401-402, WINS Business Center, NO. 78 Jiefangzhuang Road, Baiyun District, Guangzhou, 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	% Max Active	Max Active in Product	CAS No	Einecs No
DI-HEMA TRIMETHYLHEXYL DICARBAMATE	45	100	45	72869-86-4/41137-60-4	276-957-5/ 255-239-5
HEMA (HYDROXYETHYL METHACRYLATE)	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
P- METHOXYPHENOL	0.02	100	.02	150-76-5	205-769-8
CI 77266 (CARBON BLACK)	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
CI 73360	2	100	2	2379-74-0	219-163-6
CI 15880	2	100	2	6417-83-0	229-142-3
CI 74160	2	100	2	147-14-8	205-685-1
CI 74260	1	100	1	1328-53-6	215-524-7
CI 19140	1	100	1	1934-21-0	217-699-5
CI 60725	1	100	1	81-48-1	201-353-5
CI 77007	4	100	4	1302-83-6/1345-00-2 /12769 -96-9/1325-79-7	215-111-1
CI 77000 (ALUMINUM POWDER)	8	100	8	7429-90-5	231-072-3
MICA	10	100	10	12001-26-2	310-127-6

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

LABELLED WARNINGS & INSTRUCTIONS OF USE

For professional use only
Avoid skin contact
Read directions for use

CONSUMER EXPOSURE

Product Class: Nail Nourishing gel
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 product:	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

This product is intended for adult use only.

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. The total viable count for aerobic mesophyllic microorganisms should not exceed 1000 cfu/g or 1000 cfu/ml, , Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans must not be detectable in 0.1 g or 0.1 ml of the cosmetic product
Microbiological specifications for the product have been supplied and meet the 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

It is assumed that the responsible person has selected all pertinent criteria required to evaluate the stability of this cosmetic product during reasonable foreseeable conditions of storage. The stability report provided by the supplier and based upon the conclusions made therein, this cosmetic product appears to be stable under reasonably foreseeable storage conditions.

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.

Package 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-forming agent, photoinitiator and colorants is designed to be activated under LED/UV lamp and polymerized to form artificial nails.

The MoS calculated was more than 100 based on the available NOAEL and dermal absorption, and the colorants used in the product were approved under the EU Regualtion 1223/2009, hydroxyethyl methacrylate used in this formulation are presenting irritating and skin sensitization potential. Di-HEMA Trimethylhexyl Dicarbamate was classified as Skin Sens. 1. However, the ingredients will be fully polymerized after reacting under UV light and hence to reduce the toxicity significantly. It was not excluded that sensitization or skin irritation was caused by the residual monomer when the polymerization was not fully. the colorants used in the cosmetics should meet purity criteria as set out in Comission Directive 95/45/EC (where available).

p-Hydroxyanisol is listed in EU Annex III, and it was only approved used in the Artificial nail systems, and "For professional use only","Avoid skin contact" "Read directions for use" should be indicated in the labelling.

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.

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.

Exposure to the formulation as supplied may produce allergy by skin contact especially after prolonged and/or repeated skin exposure.

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. They must comply with the relevant purity standards. The product must be manufactured in accordance with EU guidance on Good Manufacturing Practice.

For professional use only
Avoid skin contact
Read directions for use

Under normal or reasonably foreseeable conditions of use, product made to this formulation is unlikely to produce an abnormally high number of adverse reactions. The product will give users the level of safety they can reasonably expect.

Cosmetic Regulations Product Safety Assessor

Rainbow Zhang, Ph.D, Toxicologist

Intertek Testing Services Shenzhen Limited

7/F, Shekou Technology Main Building, Industrial 7th Road. Shekou, Nanshan District Shenzhen, China **Date:** 01 Aug 2017

SUMMARY OF TOXICOLOGICAL INFORMATION OF SUBSTANCES

Remark: Substance toxicological summary was listed in this section and used only for MoS calculation, please refer to Toxicological Profiles of Substances for full information.

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/ 255-239-5 Melting Point: <-20

Log Kow: 0.598 Boiling Point: >250

Water Solubility: 0.003 g/l

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

Regulatory Summary:

EU DSD/DPD Classification> Not Classifed

EU CLP Harmonised Classification> Not Classified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.15000 MoS - Adult 60kg: 200.0 NOAEL mg/kg bw day: 30

SED Child mg/kg bw/day: 0.53892 MoS - Child 16.7kg: 55.6

SED Baby mg/kg bw/day: 1.52542 MoS - Baby 5.9kg: 19.6

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. Acute Toxicity: oral LD 50 for rats is >5000 mg/kg via weight of evidence; the dermal LD 50 is >5000 mg/kg via weight of evidence; Di-Hema Trimethylhexyl Dicarbamate is not acute inhalation toxic by read-across from its analogues and the LC 50 is considered to between 2 to 200 mg/L via weight of evidence. Irritation and Corrosivity: Not irritating. Skin Sensitisation:: might be a skin sensitizer.
Repeated Dose Toxicity:the NOEL was considered to be 30 mg/kg by read-across from HEMA via weight of evidence.
Mutagenicity/Genotoxicity: Di-HEMA Trimethylhexy Dicarbamate is not mutagenic or genotoxic.
Carcinogenicity:Di-HEMA Trimethylhexy Dicarbamate is not carcinogenicity by read-across from its analogues.
Reproductive and Developmental Toxicity: Di-HEMA Trimethylhexy Dicarbamate is not reproductive or developmental toxicity by read-across from HEMA, and the NOAEL is 1000 mg/kg/day for both reproduction (both sexes, adults) and developmental (offspring) toxicity.
No-Observed-Adverse-Effect Level (NOAEL) and Rationale: The NOEL from repeated toxicity study was 30 mg/kg. The NOAEL for reproductive or developmental toxicity was 1000 mg/kg.
The CIR Expert Panel decided that Methacrylates should be restricted to the nail and must not be in contact with the skin.

Chemical Substance: HEMA (HYDROXYETHYL METHACRYLATE)

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 (cause serious eye irritation), H315 (cause skin irritation) and H317 (may cause an allergic skin reaction).

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.08333 No NOAEL Available

SED Child mg/kg bw/day: 0.29940 No NOAEL Available

SED Baby mg/kg bw/day: 0.84745 No NOAEL Available

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.
Acute Toxicity: oral LD 50 for rats is >5000 mg/kg via weight of evidence; for mouse is 3275 mg/kg; for guinea pigs is 4680 mg/kg via weight of evidence; the dermal LD 50 is >5000 mg/kg via weight of evidence; HEMA is not acute inhalation toxic by read-across from its analogues and the LC 50 is considered to between 2 to 200 mg/L via weight of evidence.
Irritation and Corrosivity:HEMA is not irritating to skin via weight of evidence; moderately irritating to eyes via weight of evidence. Skin Sensitisation: HEMA might be a skin sensitizer via weight of evidence.
Repeated Dose Toxicity: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. Mutagenicity/Genotoxicity:HEMA is not mutagenic in bacteria but might be clastogenic and induce polyploidy in mammalian cells in vitro. HEMA is not genotoxic in vivo. Carcinogenicity: HEMA is not carcinogenicity by read-across from its analogues.
Reproductive and Developmental Toxicity: HEMA is not reproductive or developmental toxicity and the NOAEL was 1000 mg/kg. No-Observed-Adverse-Effect Level (NOAEL) and Rationale: According to repeated oral toxicity study, 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. The NOAEL for reproductive or developmental toxicity was 1000 mg/kg.
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.

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: 0.08333 No NOAEL Available

SED Child mg/kg bw/day: 0.29940 No NOAEL Available

SED Baby mg/kg bw/day: 0.84745 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: 0.00833 No NOAEL Available

SED Child mg/kg bw/day: 0.02994 No NOAEL Available

SED Baby mg/kg bw/day: 0.08474 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)

Water Solubility: 442 mg/L in water at room temperature (PH 7)

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: 0.00833 MoS - Adult 60kg: 12000.4 NOAEL mg/kg bw day: 100

SED Child mg/kg bw/day: 0.02994 MoS - Child 16.7kg: 3340.4 NOAEL test method: 28-day oral in rats

SED Baby mg/kg bw/day: 0.08474 MoS - Baby 5.9kg: 1180.9

Toxicological Summary:

Cosmetic Functions : Binding / Artificial Nail Builder.
Acute Toxicity: oral LD 50 for rats is >2500 mg/kg, but <5000 mg/kg; the dermal LD 50 is >5000 mg/kg; LC 50 is >1000 mg/m3. Irritation and Corrosivity: not irritating to skin and eyes. Skin Sensitisation:not a skin sensitizer.
Repeated Dose Toxicity: from 28-day repeated oral toxicity study, the NOAEL is 300 mg/kg.
Mutagenicity/Genotoxicity: not mutagenic or genotoxic.
No-Observed-Adverse-Effect Level (NOAEL) and Rationale: 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.

Chemical Substance: P- METHOXYPHENOL

CAS: 150-76-5

EINECS 205-769-8

Cosmetic Regulatory Summary:

EU Cosmetics Status: Controlled

Regulatory Summary:

EU DSD/DPD Classification> R22-36-43

EU CLP Harmonised Classification>

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.00006 No NOAEL Available

SED Child mg/kg bw/day: 0.00023 No NOAEL Available

SED Baby mg/kg bw/day: 0.00067 No NOAEL Available

Toxicological Summary:

For professional use only. Harmful if swallowed, by skin contact and by inhalation. Severely irritating to eye, irritating to skin. Usually used at ppm level as a stabiliser or as a UV inhibitor. Causes depigmentation of the skin. Permitted for use only in a professional use product in artificial nail systems up to a maximum of 0.02% after mixing for use. Product must be labelled as follows 'Avoid skin contact and Read directions for use'

Not permitted for use in the US because of skin depigmentation based on findings from the CIR report.

Chemical Substance: CI 77266 (CARBON BLACK)

EU INCI NAME:CI 77266

CAS: 1333-86-4 / 7440-44-0 Function: Colour

EINECS 215-609-9 / 231-153-3

Appearance: Solid

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: 0.00333 MoS - Adult 60kg: 7800000.0 NOAEL mg/kg bw day: 26000

SED Child mg/kg bw/day: 0.01197 MoS - Child 16.7kg: 2171000.0 NOAEL test method: chronic dermal irritation study

SED Baby mg/kg bw/day: 0.03389 MoS - Baby 5.9kg: 766999.9

Toxicological Summary:

The ingredient is not acutely toxic by the oral, dermal or inhalation routs. It is not a skin irritant, ocular irritant and is not sensitising. It does not penetrate the skin and does not bioaccumulate. It is not a reproductive toxicant. The product may has mutagenic potential and may cause cancer by inhalation. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics.

Chemical Substance: TITANIUM DIOXIDE (CI 77891)

EU INCI NAME:CI 77891 (Titanium Dioxide)

CAS: 13463-67-7/ 1317-70-0/ 1317-80-2 Function: Colour/UV filter/UV absorber/Opacifying

EINECS 236-675-5/ 205-280-1/ 215-282-2

Appearance: powder (SCCNFP, 2000)

Water Solubility: insoluble (ECHA, 2013b)

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: 0.01666	MoS - Adult 60kg: 22499.9	NOAEL mg/kg bw day: 375
SED Child mg/kg bw/day: 0.05988	MoS - Child 16.7kg: 6262.4	NOAEL test method: rats
SED Baby mg/kg bw/day: 0.16949	MoS - Baby 5.9kg: 2212.5	

Toxicological Summary:

The ingredient is not acutely toxic by oral, dermal or inhalation routes. It is non to slightly dermal irritating, non to moderately eye irritating and non skin sensitising. It is non mutagenic, non genotoxic and non phototoxic or photosensitizing. Titanium Dioxide is suspected of causing cancer by inhalation route. No evidence that it is carcinogenic by other routes. No information is readily available on the ingredient's reproductive/developmental toxicity. It has no bioaccumulation potential and has no percutaneous absorption. The margin of safety of Titanium Dioxide is not calculated as there appears to be no percutaneous absorption of the products tested. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics.

Chemical Substance: CI 73360

EU INCI NAME:CI 73360

CAS: 2379-74-0 Function: cosmetic colorants

EINECS 219-163-6

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: 0.00666	No NOAEL Available
SED Child mg/kg bw/day: 0.02395	No NOAEL Available
SED Baby mg/kg bw/day: 0.06779	No NOAEL Available

Toxicological Summary:

A water insoluble dye permitted in all cosmetic products. High oral LD50 and minimally irritating to skin and eye.
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

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: 0.00666	No NOAEL Available
SED Child mg/kg bw/day: 0.02395	No NOAEL Available
SED Baby mg/kg bw/day: 0.06779	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

EU INCI NAME:cl 74160

CAS: 147-14-8 Function: Colour

EINECS 205-685-1

Appearance: Solid

Log Kow: 6.6 (calculated) (IUCLID Dataset, 2000)

Water Solubility: Insoluble

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: 0.00666	MoS - Adult 60kg: 29999.9	NOAEL mg/kg bw day: 200
SED Child mg/kg bw/day: 0.02395	MoS - Child 16.7kg: 8350.1	NOAEL test method: 28-day oral toxicity studies in rats
SED Baby mg/kg bw/day: 0.06779	MoS - Baby 5.9kg: 2950.1	

Toxicological Summary:

The ingredient is not acutely toxic by oral, dermal and inhalation routes. It is not a skin or eye irritant, also not a skin sensitizer. It is not mutagenic, carcinogenic or a reproductive toxicant. It has no bioaccumulative potential and there is no safety-related test data to identify it's phototoxic or not. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics.

Chemical Substance: CI 74260

EU INCI NAME:CI 74260

CAS: 1328-53-6

EINECS 215-524-7

Cosmetic Regulatory Summary:

EU Cosmetics Status: Approved colour but not close to eyes & Prohibited as a hair dye substance

Regulatory Summary:

EU DSD/DPD Classification> Unclassified

EU CLP Harmonised Classification>

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.00333 No NOAEL Available

SED Child mg/kg bw/day: 0.01197 No NOAEL Available

SED Baby mg/kg bw/day: 0.03389 No NOAEL Available

Toxicological Summary:

A phthalocyanine colour is unlikely to cause skin or eye irritancy at the typical levels of use in a rinse off product. When used in a chalk unlikely to cause skin or eye irritancy. Is not based on carcinogenic amines.
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

EU INCI NAME:cl 19140

CAS: 1934-21-0 Function: Colour

Appearance: Powder

Log Kow: -10.17

Water Solubility: Soluble in water

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: 0.00333 MoS - Adult 60kg: 792000.0 NOAEL mg/kg bw day: 2640

SED Child mg/kg bw/day: 0.01197 MoS - Child 16.7kg: 220440.3 NOAEL test method: 2-generation oral rat carcinogenicity study

SED Baby mg/kg bw/day: 0.03389 MoS - Baby 5.9kg: 77879.9

Toxicological Summary:

The ingredient is not acutely toxic by oral administration. It is not an eye irritant, a skin sensitizer, mutagenic, carcinogenic or a reproductive toxicant. No data was available for skin irritation. Its bioaccumulative potential cannot be determined from the available data. Available data is inconclusive, but suggests that it is possibly phototoxic. Based on this information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics when formulated to be non-phototoxic and non-irritating.

Chemical Substance: CI 60725

EU INCI NAME:CI 60725

CAS: 81-48-1 Function: Colour

EINECS 201-353-5

Appearance: Powder

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: 0.00333 No NOAEL Available NOAEL mg/kg bw day: -

SED Child mg/kg bw/day: 0.01197 No NOAEL Available NOAEL test method: -

SED Baby mg/kg bw/day: 0.03389 No NOAEL Available

Toxicological Summary:

The ingredient is not carcinogenic. No data was available for acute toxicity, skin and eye irritation, skin sensitization, mutagenicity, reproductive toxicity, bioaccumulation and phototoxicity. As this ingredient is permitted in Europe in cosmetics as a colorant (EEC, 2009), and other scientific literature on this ingredient, safety concerns are not expected with this ingredient.

Chemical Substance: CI 77007

EU INCI NAME:CI 77007

CAS: 1302-83-6/1345-00-2 /12769-96-9/1325-79-7

EINECS 215-111-1

Appearance: Powder

Water Solubility: 1.6 ± 0.1

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: 0.01333 MoS - Adult 60kg: 7500.1 NOAEL mg/kg bw day: 100

SED Child mg/kg bw/day: 0.04790 MoS - Child 16.7kg: 2087.4 NOAEL test method: Repeated dose/reproductive toxicity study for 8 week

SED Baby mg/kg bw/day: 0.13559 MoS - Baby 5.9kg: 737.4

Toxicological Summary:

An inorganic pigment permitted for use in all cosmetic products. Minimally irritating to the eye and skin. Unlikely to cause significant harm if ingested. At typical levels of use unlikely to cause allergy or irritancy when used in a cosmetic product.

The ingredient is not acutely toxic, sensitizing, mutagenic, carcinogenic, reproductively toxic, or bioaccumulative. It is, at most, slightly irritating to the skin and eyes. No relevant information was found regarding the ingredient's carcinogenicity, phototoxicity, skin penetration or bioaccumulation potential. This substance is also included in the Natural health Products Ingredients Database (Health Canada, 2013). Based on this information and other scientific literature on this ingredient, safety concerns not expected with this ingredient for use in cosmetics when formulated to be non-irritating.

Chemical Substance: CI 77000 (ALUMINUM POWDER)

EU INCI NAME:CI 77000

CAS: 7429-90-5 Function: Colour

EINECS 231-072-3

Cosmetic Regulatory Summary:

EU Cosmetics Status: Approved colour all products

Regulatory Summary:

EU DSD/DPD Classification> R15-17

EU CLP Harmonised Classification> H250, H261

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.02666	MoS - Adult 60kg: 599.9	NOAEL mg/kg bw day: 16	
SED Child mg/kg bw/day: 0.09580	MoS - Child 16.7kg: 167.5	NOAEL test method:	oral LOAEL
SED Baby mg/kg bw/day: 0.27118	MoS - Baby 5.9kg: 59.4		

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

EU INCI NAME:MICA

CAS: 12001-26-2 Function: Opacifying

EINECS 310-127-6

Appearance: Crystalline solid (HSDB, 2012)

Water Solubility: insoluble in water (HSDB, 2012)

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: 0.03333	No NOAEL Available	NOAEL mg/kg bw day: -	
SED Child mg/kg bw/day: 0.11976	No NOAEL Available	NOAEL test method:	-
SED Baby mg/kg bw/day: 0.33898	No NOAEL Available		

Toxicological Summary:

No relevant information was found regarding the ingredient's acute toxicity, skin irritancy, eye irritancy, skin sensitization potential, mutagenicity, carcinogenicity, reproductive toxicity, bioaccumulation or phototoxicity. However, mica is exempt from certification for the protection of the public health according to 21CFR§73 as it may be safely used as a diluent in color additive mixtures for food (21 CFR, 2013b) and it is permitted in cosmetics intended to be applied to the area of the eye (21 CFR, 2013a). Moreover, mica is permitted for use in lipsticks (21 CFR, 2012). Based on the available information and other scientific literature on this ingredient, safety concerns are not expected with this ingredient for use in cosmetics.

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.

The REACH dossier, IUCLID Datasheet, OECD SIDS and EU RAR often include unpublished data, not otherwise available; however, it must be noted that the authorities have issued legal disclaimers for the databases. The declaimer, among other cautions, stressed that the data in the dossier, datasheet, data set or report are not necessarily comprehensive, complete, accurate or up-to-date. Use of the data may also be subject to copyright laws. Therefore, data from the such resource are used as supporting information.