Toxicological Safety Assessment of

Make-up : P6DH.Pearl Purple/ P3WH.Pearl Blue/ P42H.Gold/ P5C.Pearl Green/ P8G.Pearl Black/ P9E.Pearl White

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

Lucky Art Industrial Co., Ltd. **Formulation Ref:** FS-16RP

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
PARAFFIN WAXES	20.00	100	20	64742-43-4/ 64742-51-4 (8002-74-2)	265-145-6/ 265-154-5 (232-315-6)
PETROLATUM	18.00	100	18	8009-03-8 / 8063-27-2	232-373-2
GLYCERIN	10.00	100	10	56-81-5 / 8013-25-0	200-289-5
CALCIUM CARBONATE	23.80	100	23.8	471-34-1 / 1317-65-3	207-439-9
ETHOXYLATED ALCOHOL	4.40	100	4.4	68439-49-6/ 68439-50-9/ 78330-21-9	POLYMER
ETHYLHEXYLGLYCERIN & PHENOXYETHANOL	0.40	100	.4	70445-33-9 & 122-99-6	408-080-2 & 204-584-7
DISODIUM EDTA	0.20	100	.2	139-33-3 / 6381-92-6	205-358-3
SODIUM BENZOATE	0.20	100	.2	532-32-1	208-534-8
ACACIA SENEGAL GUM	0.80	100	.8	9000-01-5	232-519-5
DEXTRIN	14.20	100	14.2	9004-53-9	232-675-4
AQUA	1.00	100	1	7732-18-5	231-791-2
MICA (CI 77019)	7.00	100	7	12001-26-2	310-127-6
MAY CONTAIN (+/-)					
CI 15850:1 (D&C RED NO.7 CALCIUM LAKE)	0.413	100	.413	5858-81-1/5281-04-9	226-109-5
CI 77891 (TITANIUM DIOXIDE)	1.82	100	1.82	13463-67-7	236-675-5
CI 19140 (FD&C YELLOW 5)	0.84	100	.84	1934-21-0	217-699-5
CI 77510	1.701	100	1.701	14038-43-8 / 12240-15-2 / 25869-00-5	237-875-5 / - / 247-304-1
CI 77499 (BLACK IRON OXIDE)	2.45	100	2.45	12227-89-3	235-442-9
CI 77163 (BISMUTH OXYCHLORIDE)	0.35	100	.35	7787-59-9	232-122-7
ZINC OXIDE (CI 77947)	0.63	100	.63	1314-13-2	215-222-5

LABELLED WARNINGS & INSTRUCTIONS OF USE

Keep away from eyes.

Discontinue use if irritation or rash develops

CONSUMER EXPOSURE

Product Class: Face paint
IFRA Product type: Face Paint
IFRA Category: Category 5
Targeted Population: Children 16.7kg (Mean)
Amount per application/g: 1.400
Skin Surface Area of Application/cm^2: 475.000
Total Amount applied per day/g: 1.4
Estimated Daily Exposure mg/kg/day: -
Amount Per Unit Area of Skin per day mg/cm^2/day: 3.000
Retention factor: 1.00
Exposure Time Neat: 480 minutes
Exposure Time Dilute: Not Applicable
Exposure time Solvent Inhalation: Not Applicable
Exposure time Aerosol Inhalation: Not Applicable

Number of applications per day: Once per day
Physical form: Solid
Part of body exposed to undiluted Face and hands

This product has been assessed taking into account that it will be used by children above three years of age.

MICROBIOLOGICAL QUALITY

To comply with the Guidelines on the Microbiological Quality (SCCNFP/0004/98), the following maximum limits apply:
Category 1: Products specifically intended for children under 3 years, eye area and mucous membranes.
TVC:- 100 cfu/g or ml in 0.5 g or ml of the product.
Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans must not be detectable in 0.5 g or ml of the cosmetic product
Category 2: Other cosmetic products.
TVC:- 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

The microbiological specifications for the product have not been supplied at this time and will need to be reviewed by the assessor. This product currently does not comply with Article 3 and 10 of Cosmetic Regulation (EC) No 1223/2009.
The preservative challenge test results for this product have not been supplied at this time and will need to be reviewed by the safety assessor. This product currently does not comply with Article 3 and 10 of Cosmetic Regulation (EC) No 1223/2009.

STABILITY OF COSMETIC PRODUCT

The stability test report was not supplied at the time of safety assessment. The stability of this cosmetic product(s) under reasonably foreseeable storage conditions can not be determined and this product may not comply with Article 3 and 10 of Cosmetic Regulation (EC) No 1223/2009.

PACKAGING COMPATIBILITY

The packaging stability test results for this product ands its packaging have not been supplied at this time and will need to be reviewed by the safety assessor. This product currently does not comply with Article 3 and 10 of Cosmetic Regulation (EC) No 1223/2009.

SERIOUS / UNDESIRABLE EFFECTS

On request, the supplier has not supplied information of any reports known to him of serious undesirable effect or undesirable effects on the cosmetic product, or where relevant, other similar cosmetic products and this cannot be commented upon. If the supplier is aware of an abnormally high level of customer complaints the supplier must bring this to the attention of the safety assessor and submit this formulation for reassessment and notify the competent authorities of corrective actions taken.

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.

TOXICOLOGICAL & REGULATORY REVIEW

This is a preserved and emulsified mixture of predominantly antioxidant stabilised waxy / oily ingredients with bulking, thickening / viscosity controlling, skin conditioning, chelating agents and colour pigments dispersed. The product is intended to be used for painting the face by consumers of target age group from over three years old. The most relevant route for systemic exposure is therefore the skin and less so the eyes; ingestion and inhalation may occur with the younger age group bearing in mind the behaviour of children (e.g. direct and indirect hand-to-mouth contact, hand-to-eye contact) which can result in misuse or abuse of a product (*Bremmer, H.J and van Veen, M.P. 2002. RIVM report 612810012/200 - To assess the risks for the consumer. Table 2: Relationship between exposure category and type of toys - face paints).* Application on the skin of the face can also be accompanied by application near the eyes, and hand-to-eyes contact being also a route of exposure. Vapour generated from this product would be expected to be low and so inhalation would be an unlikely route of exposure. The MSDS supplied for the predominant ingredients, petroleum derived waxes indicated that they are both of food, cosmetic and pharmaceutical grades. Ingestion of them is therefore likely to pose a negligible risk to health (LD50: species not specified > 5000 mg/kg, MSDS information for Petroleum Wax, CAS # 64742-43-4). Note that this CAS # 8002-74-2 (Synthetic Wax) given in the compositional form differs from that supplied in the MSDS. The MSDS also stated that prolonged or repeated inhalation of the vapour or mist may cause irritation of the respiratory tract and deposits of the oil droplets in the lungs may cause fibrosis and reduced pulmonary function. Inhalation however is not a major route of exposure of this product. The viscosity controlling / skin conditioning agent, Glycerin, has a minimum potential to irritate the skin and the eye. Data obtained from animal and human exposure have indicated that Glycerin is not a skin sensitiser and structural and long-term studies do not suggest potential for mutagenicity and/or carcinogenicity. Acacia Senegal gum is a thickening / viscosity controlling / stabilising ingredient commonly used in food. It is equated to Gum Arabic and thus the safety data obtained from the toxicological evaluation of the latter was used here (CIR, 2011). The powder has been associated with severe eye irritation and a respiratory allergen noted particularly in printing workers. It may also cause skin sensitisation in susceptible individuals. In US products, its use is recommended to be restricted to 9% (CIR, 2010); the concentration in this product is thus within the maximum recommended level. The low absorption rate observed due to its large molecular weight and water solubility suggested that when used at a low concentration in a formulation, its irritancy potential may be considerably reduced. There is a concern with regards to PCB/pesticide contamination (not to exceed 40 ppm) and impurities from certain heavy metals advised to have the following appropriate limits: Arsenic (3 mg/kg maximum), heavy metals (0.002% maximum), and Lead (5 mg/kg maximum) (CIR, 2011). The presence of the chelating agent in the formulation may minimise the heavy metals effect. The bulking agents are Mica, Calcium carbonate and Dextrin. Calcium carbonate has little or no acute or chronic irritant or allergenic potential in contact with the skin. However, the powder may cause a foreign body reaction in contact with the eye and it may irritate the nose and respiratory system upon inhalation. In this product therefore, it poses a low to negligible risk of skin irritation. The nature of the formulation makes its inhalation impractical. Mica is not classified as an eye or skin irritant nor a skin sensitiser. As well as a bulking agent, it also imparts opaqueness to the product. It is practically inert and the form supplied for this formulation is described a "may cause delayed respiratory disease if dust is inhaled over a prolonged period" (Product name: MICA325/ MICA1000/ MICA2000 from Goodwill Chemical Corporation, not dated). However in this formulation, the amount used is low and is dedusted by its blending into an oily / waxy medium thus reducing any potential for inhalation that would result in 'delayed respiratory disease'. Consequently, it is of a low toxicological concern. Mica is permitted for use in cosmetic products in the EU and U.S. Dextrin, a high molecular weight glucose polymer has a low potential to cause irritancy or allergy. Its presence in this product is therefore expected to pose a negligible risk to the user of this product. The emulsifying agent, Ethoxylated Alcohol, as supplied is classified as harmful if swallowed, irritating to skin and can cause risk of serious damage to eyes. It is not known as a skin sensitiser. However at a low concentration in a formulation, it is expected to pose a reduced irritancy risk. The preservatives are EU approved and are within the maximum permitted concentrations for this type of leave-on product. The mixture, Ethylhexylglycerin & Phenoxyethanol, has the potential to cause severe eye irritation but not at the concentration present in this product. The Certificate of Analysis supplied for the other preservative, Sodium Benzoate, indicated that its minimum purity to be 99% and maximum to be 100.5% and was stated to meet all USP-National Formulary (NF), Food Chemicals Codex (FCC), EP and BP specifications (Emerald Performance Materials LLC, 2010). The colour pigments are all EU approved but in the USA, the following pigment (called color additive in the USA) is not approved near the eye area (CI 15850 (D&C Red 6) along with its Calcium Lake, D&C Red 7). Consequently in the USA, the Face Paints containing this colour additive should be labelled 'Keep away from the eyes' and the use of this product by children age 3 - 11 years old should be accompanied by adult supervision. The MSDS supplied for the colour pigment, CI 19140 (FD & C Yellow 5), indicated adverse acute effects such as contact with eyes may cause slight mechanical eye irritation, skin exposure may cause slight skin irritation in sensitive people, it may be harmful if swallowed and may cause respiratory irritation if inhaled (Sensient Colors Inc., October 2008). Repeated exposure may result in allergic reactions in very susceptible individuals. Subsequently, the product containing this colour should be labelled to warn sensitive individuals to discontinue use if this product disagrees with them. Consequently, this product complies to the EU Directive 76/768/EEC and U.S. regulatory requirements.

Thus, review of the toxicology of the ingredients for this product indicated the potential for low to negligible risk from irritation, allergy, ingestion, inhalation, corrosivity, phototoxicity, photosensitization, if used as directed, either for a prolonged period or repeatedly. Also, there are no known or documented carcinogenic, mutagenic or reprotoxic effects of the ingredients to cause adverse effects when used as directed. However, the possibility cannot be discounted that a small number of consumers may experience an allergic reaction or other idiosyncratic reaction to an ingredient in the formulation if they have been previously sensitised to the ingredient to the health of the majority of consumers.

Where the NOAEL value has been derived, the margin of safety calculated at even 100% dermal absorption supported the safe use of this product for the targeted age group.

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.

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 only minimal skin irritation even if exposure is prolonged and/or repeated.

There are low concentrations of substances present in this product which have allergenic activity. The concentrations present are sufficiently low for the level of use to ensure that people do not become sensitised. However, people who are already sensitised to a substance may react adversely to any product containing that substance even when present at extremely low concentrations.

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

The particulate matter within the product may cause a foreign body reaction should it accidentally enter 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 neat product if swallowed is unlikely to cause harm.

Effects of inhaling the product

Inhalation is an unlikely route of exposure

Overall Assessment Conclusion

The ingredients are legally permitted as per EU Directive 76/768/EEC 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.

The ingredients are legally permitted as per the Federal Food, Drug, and Cosmetic Act (FD&C Act - CFR21) and its amendments. They must comply with the relevant purity standards. The product must be manufactured in accordance with FD&C guidance on Good Manufacturing Practice.

Keep away from eyes.

Discontinue use if irritation or rash develops

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

Intertek

M U Iwobi BSc, MSc, PhD, C Biol, MSB, EurProBiol

Centre Court, Meridian Business Park, Leicester. LE19 1WD **Date:** 29 Aug 2012

TOXICOLOGICAL PROFILE OF SUBSTANCES

Chemical Substance: PARAFFIN WAXES

EU INCI NAME: PARAFFIN

CAS: 64742-43-4/ 64742-51-4 (8002-74-2)

EINECS 265-145-6/ 265-154-5 (232-315-6)

Appearance: -

Log Kow: -

Water Solubility: -

Melting Point: -

Boiling Point: -

Vapour Pressure: -

Cosmetic Regulatory Summary:

EU Cosmetics Status: Controlled

ASEAN Cosmetics Status: -

Saudi Cosmetics Status: -

US Cosmetics Status: -

Canadian Cosmetics Status: -

Regulatory Summary:

EU Classification: -

GHS Classification: -

REACh Annex XVII controlled: -

REACh SVHC Candidate List: -

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 4.666 No NOAEL Available

SED Child mg/kg bw/day: 16.766 No NOAEL Available

SED Baby mg/kg bw/day: 47.457 No NOAEL Available

Toxicological Summary:

Cosmetic Functions : Emollient / Fragrance Ingredient / Skin Conditioning / Viscosity Controlling / Viscosity Increasing-Nonaqueous. A paraffin wax with minimal skin and eye irritancy potential. Unlikely to cause allergy. Must not contain >0.1% Butadiene. Paraffin waxes (petroleum), hydrotreated or clay-treated. A complex combination of hydrocarbons obtained by treating a petroleum wax with hydrogen in the presence of a catalyst. It consists predominantly of straight chain paraffinic hydrocarbons having carbon numbers predominantly in the range of about C20 through C50. CIR expert panel concludes this is safe at the present uses and concentrations in a cosmetic product (up to 99%).

Chemical Substance: PETROLATUM

EU INCI NAME: PETROLATUM

CAS: 8009-03-8 / 8063-27-2

EINECS 232-373-2

Function: Moisturiser

Cosmetic Regulatory Summary:

EU Cosmetics Status: Controlled

Saudi Cosmetics Status: Not controlled by Saudi legislation

US Cosmetics Status: up to 82% typically (CIR 2009)

Regulatory Summary:

EU Classification: unclassified

GHS Classification: unclassified

REACh Annex XVII controlled: Not Controlled

REACh SVHC Candidate List: Not Controlled

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 4.200 No NOAEL Available

SED Child mg/kg bw/day: 15.089 No NOAEL Available

SED Baby mg/kg bw/day: 42.711 No NOAEL Available

Toxicological Summary:

Cosmetic Functions : Antistatic / Emollient / Hair & Skin Conditioning Agent / Skin Protectant. A highly refined very soft waxy jelly / oil with low potential to cause irritation of the skin or eye. If ingested may accumulate in the liver and spleen. Commonly used in skin application products, face and body and in colour cosmetics including around the eye area and lipsticks. The grade used should have low levels of polynuclear hydrocarbons and should be free of carcinogenic potential. US or European Pharmacopoeia-standard white petroleum jelly must be used. No known allergenic potential

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Chemical Substance: GLYCERIN

EU INCI NAME: GLYCERIN
CAS: 56-81-5 / 8013-25-0
EINECS 200-289-5
Appearance: liquid
Log Kow: 1.76
Water Solubility: miscible with water

Function: Denaturant / Humectant / Perfuming / Solvent / Fragrance Ingredient / Hair & Skin Conditioning Agent / Oral Care Agent / Skin Protectant / Viscosity Decreasing Agent

Melting Point: ~18°C
Boiling Point: 290°C
Vapour Pressure: <0.01 mm Hg @ 20

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled
Saudi Cosmetics Status: Not controlled by Saudi legislation
US Cosmetics Status: Not controlled
Canadian Cosmetics Status: Controlled

Regulatory Summary:

EU Classification: unclassified
GHS Classification: unclassified
REACh Annex XVII controlled: Not Controlled
REACh SVHC Candidate List: Not Controlled

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 2.333 MoS - Adult 60kg: 857.1
SED Child mg/kg bw/day: 8.383 MoS - Child 16.7kg: 238.5
SED Baby mg/kg bw/day: 23.728 MoS - Baby 5.9kg: 84.2
NO(A)EL mg/kg bw day: 2000

Toxicological Summary:

Function: Denaturant / Humectant / Solvent /Conditioner, Viscosity Decreasing Agent. If ingested in massive amounts it may induce osmotic effects in the gastro-intestinal tract manifesting as tremour and hyperaemia with LD50 in excess of 4000 mg/kg bw for both oral and dermal toxicity (Toxnet search - author anonymous. *Screening Information Data Set for High Production Volume Chemicals.* 2005, 178. Abstract). Repeated ingestion may produce localised GI irritation. It is a polyhydric alcohol with a minimum potential to irritate the skin and the eye. Human and animal data and the wide exposure to Glycerol indicate that it is not a skin sensitiser. Free from structural alerts, which raise concern for mutagenicity & does not induce gene mutations in bacterial strains, chromosomal effects in mammalian cells or primary DNA damage *in vitro.* Experimental data from a limited 2 year dietary study in the rat does not provide any basis for concerns in relation to carcinogenicity. No effects on fertility and reproductive performance were observed in a two generation study with glycerol administered by gavage (NOAEL 2000 mg/kg bw/day). No maternal toxicity or teratogenic effects were seen in the rat, mouse or rabbit at the highest dose levels tested in a guideline comparable teratogenicity study (NOEL 1180 mg/kg bw/day), For inhalation exposure to aerosols, the NOAEC for local irritant effects to the upper respiratory tract is 165 mg/m3 and 662 mg/m3 for systemic effects. Canada, Hotlist March 2011; Manufacturers of oral and leave-on products containing glycerin must ensure the raw material used is within the specifications of an accepted pharma-copoeia with respect to diethylene glycol (DEG) impurities (e.g. Glycerin Official Monograph in the most current edition of the USP). As well as in cosmetics, Glycerin finds wide application in various sector of life such as pharmaceuticals, tobacco, food and drinks and many other products such as paints, resins and paper. Specific consumer exposure is through the oral and dermal routes, inhalation route may also occur following intake particularly from smoking. Consequently exposure to this substance is extensive however, it has been associated with a low hazard potential.

In the United States, it may be used as an active ingredient in OTC drug products and as a cough remedy. Typical suitable amounts for adults are 10 ml in water 4 times per day. For children 1-4 years 2.5ml diluted in water 3-4 time a day. In Canada, Cosmetic Ingredient Hotlist September 2009 states; Manufacturers of oral and leave-on products containing glycerin must ensure the raw material used is within the specifications of an accepted pharmacopoeia with respect to diethylene glycol (DEG) impurities (e.g. Glycerin Official Monograph in the most current edition of the USP).

QSAR predictions and weight of evidence have led t the conclusion that Glycerol (Glycerin) has low toxicity to aquatic organisms Toxnet search - author anonymous. *Screening Information Data Set for High Production Volume Chemicals.* 2005, 178. Abstract). . Experiments have provided the lowest LC50 for fish is a 24-h LC50 of >5000 mg/l for Carassius auratus (Goldfish) and for aquatic invertebrates, a 24h EC50 of >10000 mg/l for Daphnia magna is the lowest EC50. A calculated half-life for photo-oxidation have been obtained as approximately 7 hours without it being susceptible to hydrolysis (Data suggest that it is readily biodegradable under aerobic conditions and Fugacity modelling predicts that it partitions 100% to aquatic compartment and is not expected to bioacumulate Toxnet search - author anonymous. *Screening Information Data Set for High Production Volume Chemicals.* 2005, 178. Abstract). .

Chemical Substance: CALCIUM CARBONATE

EU INCI NAME: CALCIUM CARBONATE
CAS: 471-34-1 / 1317-65-3
EINECS 207-439-9

Cosmetic Regulatory Summary:

EU Cosmetics Status: Approved colour all products

Regulatory Summary:

EU Classification: unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 5.553 No NOAEL Available
SED Child mg/kg bw/day: 19.952 No NOAEL Available
SED Baby mg/kg bw/day: 56.474 No NOAEL Available

Toxicological Summary:

Cosmetic Functions : Abrasive / Buffering / Bulking / Opacifying / Oral Care. A mineral also considered as an approved colouring agent-CI 77220. An inorganic salt with little or no irritant or allergenic potential in contact with the skin. The powder may cause a foreign body reaction in contact with the eye and irritate the nose and respiratory system. Unlikely to cause adverse effects at the typical concentrations used in cosmetics.

Chemical Substance: ETHOXYLATED ALCOHOL

EU INCI NAME: -
CAS: 68439-49-6/ 68439-50-9/ 78330-21-9
EINECS polymer
Appearance: -
Log Kow: not known
Water Solubility: n/a

Melting Point: 47.5
Boiling Point: -
Vapour Pressure: 133.322368

Cosmetic Regulatory Summary:

EU Cosmetics Status: -
ASEAN Cosmetics Status: -
Saudi Cosmetics Status: Not controlled by Saudi legislation
US Cosmetics Status: -
Canadian Cosmetics Status: -

Regulatory Summary:

EU Classification: R22-38-41
GHS Classification: -
REACh Annex XVII controlled: -
REACh SVHC Candidate List: -

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 1.026 No NOAEL Available
SED Child mg/kg bw/day: 3.688 No NOAEL Available
SED Baby mg/kg bw/day: 10.440 No NOAEL Available

Toxicological Summary:

Cosmetic Function : Surfactant. An ethoxylated fatty alcohol which are usually harmful if swallowed so ingestion will cause irritation of the GI tract. Also irritating to skin and eyes when supplied but when diluted in a formulation unlikely to make a major contribution to irritancy. Will interact with other surfactants to give reduced overall irritancy. Not a known sensitiser. When used in a formulation the concentration will be reduced and the irritant properties reduced but effects on the eye will still be noted. Widely used in household and personal products with good acceptance in the marketplace.

Chemical Substance: ETHYLHEXYLGLYCERIN & PHENOXYETHANOL

EU INCI NAME: ETHYLHEXYLGLYCERIN & PHENOXYETHANOL
CAS: 70445-33-9 & 122-99-6
EINECS 408-080-2 & 204-584-7
Appearance: -
Log Kow: -
Water Solubility: -

Function: Preservative

Melting Point: -
Boiling Point: -
Vapour Pressure: -

Cosmetic Regulatory Summary:

EU Cosmetics Status: Approved preservative (phenoxyethanol 1%)
ASEAN Cosmetics Status: Approved preservative (phenoxyethanol 1%)
Saudi Cosmetics Status: Approved preservative (phenoxyethanol 1%)
US Cosmetics Status: Not controlled
Canadian Cosmetics Status: Approved preservative (phenoxyethanol)

Regulatory Summary:

EU Classification: R41-52/53, R22-36
GHS Classification: Not Controlled
REACh Annex XVII controlled: -
REACh SVHC Candidate List: Not Controlled

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.093 MoS - Adult 60kg: 857.1
SED Child mg/kg bw/day: 0.335 MoS - Child 16.7kg: 238.5
SED Baby mg/kg bw/day: 0.949 MoS - Baby 5.9kg: 84.2

NO(A)EL mg/kg bw day: 80
NOAEL test method: The oral (gavage), repeated-dose 90 day in rats

Toxicological Summary:

A mixture of phenoxyethanol permitted under EU regulations together with a humectant. The active ingredient is permitted at 1%. Ethylhexylglycerin as supplied classified as severely irritating to eyes but a 5% solution in water is said to be non irritating to eyes . Not a skin sensitiser . Unlikely to cause irritancy or allergy when used at up to 5% in a cosmetic product. Phenoxyethanol a widely used preservative. Works well in combination with other preservatives. Max permitted concentration 1%. The manufacturer recommend the use of this preservative system within the range 0.5-1.0% for leave on products.

Chemical Substance: DISODIUM EDTA

EU INCI NAME: Disodium EDTA
CAS: 139-33-3 / 6381-92-6
EINECS 205-358-3

Function: Additive

Cosmetic Regulatory Summary:

Saudi Cosmetics Status: Not controlled by Saudi legislation
US Cosmetics Status: <1% (CIR, 2009).

Regulatory Summary:

EU Classification: Xi R36-52/53
REACh Annex XVII controlled: Not Controlled
REACh SVHC Candidate List: Not Controlled

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.046 No NOAEL Available
SED Child mg/kg bw/day: 0.167 No NOAEL Available
SED Baby mg/kg bw/day: 0.474 No NOAEL Available

Toxicological Summary:

Cosmetic Functions : Chelating / Viscosity Controlling.
EDTA is used as a chelating agent in cosmetic formulations. The CIR expert panel concluded that a maximum safe concentration of EDTA and its salts is 25% for inhalation of aerosol products so no concerns over adverse effects from typical concentrations. The ability of these complexes to aid penetration of certain compounds, particularly calcium based compounds, must also be taken into account when used with other chemicals that are considered safe because they are not significantly absorbed. Unlikely to add to the toxicity of rinse off products.

Chemical Substance: SODIUM BENZOATE
EU INCI NAME: SODIUM BENZOATE
CAS: 532-32-1
EINECS 208-534-8
Function: preservatives

Cosmetic Regulatory Summary:
EU Cosmetics Status: Approved preservative
Saudi Cosmetics Status: Permitted preservative - all products. Max conc 0.5%.
US Cosmetics Status: Safe for use in all cosmetic formulations up to 5%: insufficient data to support safety in
Canadian Cosmetics Status: Approved preservative

Regulatory Summary:
EU Classification: Unclassified

Systemic Exposure Dosage / Margin of Safety:
SED Adult mg/kg bw/day: 0.046 MoS - Adult 60kg: 23357.1 NO(A)EL mg/kg bw day: 1090
SED Child mg/kg bw/day: 0.167 MoS - Child 16.7kg: 6501.0
SED Baby mg/kg bw/day: 0.474 MoS - Baby 5.9kg: 2296.7

Toxicological Summary:

Cosmetic Functions : Anticorrosive / Masking / Preservative. A well established preservative with a long history of safe use. The WHO established an ADI of 5 mg/kg for Sodium Benzoate and benzoic acid. Given GRAS status in the US for food use. Not found to be reprotoxic or a developmental toxin in mice and rats. Not genotoxic. Non carcinogenic. Found to produce non-immunologic contact urticaria. 2% Benzoic Acid was found not to be a sensitizer at 2% (Maximization test). The main concern for this ingredient was the ability to cause contact urticaria and other cutaneous reaction. It was noted that in a study examining these reactions, all panelists showed a positive reaction stated to be possibly involving a cholinergic mechanism and not IgE mediated. The CIR panel concluded that sodium benzoate and benzoic acid was safe for use up to 5%. Maximum concentration permitted for cosmetics in the EU = 0.5%. SCCP/0891/05 opinion concludes that benzoic acid and sodium benzoate are safe to use in oral care products up to a maximum concentration of 1.7% and cosmetic rinse off products upto 2.5%. The maximum legal limits below apply for preservation purposes only. Rinse-off products, except oral care products: 2,5 % (acid); Oral care products: 1,7 %(acid); Leave-on products: 0,5 % (acid).

Chemical Substance: ACACIA SENEGAL GUM
EU INCI NAME: ACACIA
CAS: 9000-01-5
EINECS 232-519-5
Function: viscosity controlling agents

Cosmetic Regulatory Summary:
US Cosmetics Status: Up to 9% for the gum and 0.001% for the extract (CIR. 2010).

Regulatory Summary:
EU Classification: R36

Systemic Exposure Dosage / Margin of Safety:
SED Adult mg/kg bw/day: 0.186 No NOAEL Available
SED Child mg/kg bw/day: 0.670 No NOAEL Available
SED Baby mg/kg bw/day: 1.898 No NOAEL Available

Toxicological Summary:

Widely used as a stabiliser/thickener in food. Reports of allergy usually caused by preservatives added to the material. When the resin per se is used at up to 1% as a thickener, unlikely to cause irritancy or allergy.
As supplied, in powder form, this is severely irritating to the eyes and has been reported to be a respiratory allergen in printing workers. It may also give rise to skin sensitisation in sensitive individuals. When used at a low concentration in a cosmetic product it is unlikely to produce skin irritation or allergy. However due to its potential as a respiratory allergen it should not be used in aerosols or spray preparations. Some institutions have classified this as R42, R36. Gum arabic is has been given GRAS status by the FDA and considered as suitable as a direct food additive. The CIR panel (2006) concluded that the toxicity data indicates little or no acute, short-term or subchronic toxicity. However there is some evidence of sensitization though considering the extensive safety testing the CIR concluded gum arabic was safe for use in cosmetic products. A negative result was given for all 25 subjects in a human maximization study from a mascara contain 8% acacia gum and it was concluded that through normal use in a cosmetic product sensitization is unlikely.

Chemical Substance: DEXTRIN
EU INCI NAME: DEXTRIN
CAS: 9004-53-9
EINECS 232-675-4
Function: absorbents / binders / viscosity controlling agents

Cosmetic Regulatory Summary:
Saudi Cosmetics Status: Not controlled by Saudi legislation

Regulatory Summary:
EU Classification: Unclassified

Systemic Exposure Dosage / Margin of Safety:
SED Adult mg/kg bw/day: 3.313 No NOAEL Available
SED Child mg/kg bw/day: 11.904 No NOAEL Available
SED Baby mg/kg bw/day: 33.694 No NOAEL Available

Toxicological Summary:

Cosmetic Functions : Absorbent / Binding / Bulking / Viscosity Controlling / Viscosity Increasing Agent-Aqueous. A high molecular weight glucose polymer. Low potential to cause irritancy or allergy.

Chemical Substance: AQUA
EU INCI NAME: AQUA
CAS: 7732-18-5
EINECS 231-791-2
Appearance: Liquid
Water Solubility: highly soluble
Function: Solvent
Melting Point: 0
Boiling Point: 100

Cosmetic Regulatory Summary:
EU Cosmetics Status: Not controlled
ASEAN Cosmetics Status: Not controlled
Saudi Cosmetics Status: Not controlled by Saudi legislation
US Cosmetics Status: Not controlled
Canadian Cosmetics Status: Not controlled

Regulatory Summary:
EU Classification: Unclassified
GHS Classification: Unclassified
REACh Annex XVII controlled: Not Controlled
REACh SVHC Candidate List: Not Controlled

Systemic Exposure Dosage / Margin of Safety:
SED Adult mg/kg bw/day: 0.233 No NOAEL Available
SED Child mg/kg bw/day: 0.838 No NOAEL Available
SED Baby mg/kg bw/day: 2.372 No NOAEL Available

Toxicological Summary:
Cosmetic function : Solvent. Simply water unlikely to cause irritation, allergy or harm. Used in many cosmetic products as a solvent and necessary to sustain biological life. The source of water should be known, monitored to GMP and either a deionised or high purity grade free from toxins, pollutants and bacteriological contamination should be used in cosmetic products.

Chemical Substance: MICA (CI 77019)
EU INCI NAME: MICA
CAS: 12001-26-2
EINECS 310-127-6
Appearance: solid
Log Kow: -
Water Solubility: -
Function: Opacifying
Melting Point: -
Boiling Point: -
Vapour Pressure: -

Cosmetic Regulatory Summary:
EU Cosmetics Status: Not controlled
ASEAN Cosmetics Status: Not controlled
Saudi Cosmetics Status: Not controlled
US Cosmetics Status: Mica No restrictions 73.2496.
Canadian Cosmetics Status: Not controlled

Regulatory Summary:
EU Classification: unclassified
GHS Classification: unclassified
REACh Annex XVII controlled: Not Controlled
REACh SVHC Candidate List: Not Controlled

Systemic Exposure Dosage / Margin of Safety:
SED Adult mg/kg bw/day: 1.633 No NOAEL Available
SED Child mg/kg bw/day: 5.868 No NOAEL Available
SED Baby mg/kg bw/day: 16.610 No NOAEL Available
NO(A)EL 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.

Chemical Substance: MAY CONTAIN (+/-)
EU INCI NAME: -
Function: ----------
Appearance: -
Log Kow: -
Water Solubility: -
Melting Point: -
Boiling Point: -
Vapour Pressure: -

Cosmetic Regulatory Summary:
EU Cosmetics Status: ----------
ASEAN Cosmetics Status: ----------
Saudi Cosmetics Status: ----------
US Cosmetics Status: ----------
Canadian Cosmetics Status: ----------

Regulatory Summary:
EU Classification: ----------
GHS Classification: ----------
REACh Annex XVII controlled: ----------
REACh SVHC Candidate List: ----------

Systemic Exposure Dosage / Margin of Safety:
SED Adult mg/kg bw/day: .000 No NOAEL Available
SED Child mg/kg bw/day: .000 No NOAEL Available
SED Baby mg/kg bw/day: .000 No NOAEL Available
NOAEL test method: -

Toxicological Summary:

Chemical Substance: CI 15850:1 (D&C RED NO.7 CALCIUM LAKE)
EU INCI NAME: CI 15850
CAS: 5858-81-1/5281-04-9 Function: Colour
EINECS 226-109-5

Cosmetic Regulatory Summary:
EU Cosmetics Status: Approved colour all products
Saudi Cosmetics Status: Permitted colour field 1 All products
US Cosmetics Status: Cosmetics generally 74.2307 except eye area (CI 15850:1)

Regulatory Summary:
EU Classification: R20/22

Systemic Exposure Dosage / Margin of Safety:

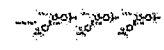
SED Adult mg/kg bw/day: 0.096	No NOAEL Available
SED Child mg/kg bw/day: 0.346	No NOAEL Available
SED Baby mg/kg bw/day: 0.980	No NOAEL Available

Toxicological Summary:

Cosmetic Function : Cosmetic Colorant. A pigment well tested in experimental studies and with a long history of safe use in cosmetics. It is insoluble in water and unlikely to cause adverse effects at the typical concentrations used in cosmetics.
Permitted for use in all cosmetic types under the EU Cosmetics Directive. Unlikely to cause adverse effects at the typical concentrations used in cosmetics.

For US only: Not approved for use in cosmetic products intended to come into contact with the eye area.

Chemical Substance: CI 77891 (TITANIUM DIOXIDE)
EU INCI NAME: CI 77891
CAS: 13463-67-7 Function: Colour
EINECS 236-675-5



Chemical Structure:

Cosmetic Regulatory Summary:
EU Cosmetics Status: Approved colour all products
Saudi Cosmetics Status: Permitted colour field 1 All products
US Cosmetics Status: CI 77891 No restrictions 73.2575

Regulatory Summary:
EU Classification: unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.424	No NOAEL Available
SED Child mg/kg bw/day: 1.525	No NOAEL Available
SED Baby mg/kg bw/day: 4.318	No NOAEL Available

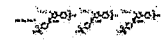
Toxicological Summary:

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.

Chemical Substance: CI 19140 (FD&C YELLOW 5)
EU INCI NAME: CI 19140
CAS: 1934-21-0
EINECS 217-699-5

Function: Colour

Chemical Structure:



Cosmetic Regulatory Summary:
EU Cosmetics Status: Approved colour all products
Saudi Cosmetics Status: Permitted colour field 1 All products
US Cosmetics Status: FD % C Yellow 5: Generally, including the eye area. Al lake also permitted for eye area. 74.2705

Regulatory Summary:
EU Classification: Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.196	No NOAEL Available
SED Child mg/kg bw/day: 0.704	No NOAEL Available
SED Baby mg/kg bw/day: 1.993	No NOAEL Available

Toxicological Summary:

Some people and children are particularly sensitive to products containing tartrazine. Unlikely to cause adverse effects at the typical concentrations used in cosmetics. Widely used and well accepted in cosmetic products. The Cosmetics Directive 2009/36/EC has amended the use of this colour to be used in rion oxidative hair dyes at a maximum concentration of 0.5%. This does not effect its use in other permitted cosmetic product types.

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."

Chemical Substance: CI 77510
EU INCI NAME: CI 77510
CAS: 14038-43-8 / 12240-15-2 / 25869-00-5
EINECS 237-875-5 / - / 247-304-1

Cosmetic Regulatory Summary:
EU Cosmetics Status: Approved colour all products
Saudi Cosmetics Status: Permitted colour field 1 All products
US Cosmetics Status: Externally including eye area 73.2299 (CI 77510)

Regulatory Summary:
EU Classification: Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.396	No NOAEL Available
SED Child mg/kg bw/day: 1.425	No NOAEL Available
SED Baby mg/kg bw/day: 4.036	No NOAEL Available

Toxicological Summary:

An essentially inert iron pigment which is essentially insoluble in water and alcohol. Being inert and insoluble it has minimal toxic properties. Permitted for use in all cosmetic products. Its use in colour cosmetics in a compressed block form ensure that only minimal amounts would be available for inhalation. Unlikely to cause adverse effects at the typical concentrations used in cosmetics.

Chemical Substance: CI 77499 (BLACK IRON OXIDE)
EU INCI NAME: CI 77499
CAS: 12227-89-3
EINECS 235-442-9
Appearance: Powder
Water Solubility: Insoluble

Function: Colour
Melting Point: >1000

Cosmetic Regulatory Summary:
EU Cosmetics Status: Approved colour all products
Saudi Cosmetics Status: Permitted colour field 1 All products
US Cosmetics Status: Iron Oxides No restrictions 73.2250

Regulatory Summary:
EU Classification: Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.571	No NOAEL Available
SED Child mg/kg bw/day: 2.053	No NOAEL Available
SED Baby mg/kg bw/day: 5.813	No NOAEL Available

Toxicological Summary:

This inert iron oxide has minimal skin irritancy properties. It may cause mechanical eye irritation and is a nuisance dust. Its level of use and its inert nature makes it unlikely for this substance to provoke an adverse effect.

Chemical Substance: CI 77163 (BISMUTH OXYCHLORIDE)

EU INCI NAME: CI 77163
CAS: 7787-59-9
EINECS 232-122-7

Function: cosmetic colorants

Cosmetic Regulatory Summary:

EU Cosmetics Status: Approved colour all products
Saudi Cosmetics Status: Permitted colour field 1 All products
US Cosmetics Status: No restrictions 73.2162-Cosmetics generally including eye area use.

Regulatory Summary:

EU Classification: Unclassified

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.081 No NOAEL Available
SED Child mg/kg bw/day: 0.293 No NOAEL Available
SED Baby mg/kg bw/day: 0.830 No NOAEL Available

Toxicological Summary:

Cosmetic Function : Colorant. An essentially inert white substance. Being inert it is unlikely to cause any adverse effects when used in cosmetics. Approved for use in the EU for all products and in the US for cosmetics including eye area use.

Chemical Substance: ZINC OXIDE (CI 77947)

EU INCI NAME: CI 77947
CAS: 1314-13-2
EINECS 215-222-5

Function: cosmetic colorants

Cosmetic Regulatory Summary:

EU Cosmetics Status: Approved colour all products
Saudi Cosmetics Status: Permitted colour field 1 All products
US Cosmetics Status: CI 77947 No restrictions 73.2991

Regulatory Summary:

EU Classification: N R50/53

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 0.147 No NOAEL Available
SED Child mg/kg bw/day: 0.528 No NOAEL Available
SED Baby mg/kg bw/day: 1.494 No NOAEL Available

Toxicological Summary:

Cosmetic Functions: Colourant / Bulking / Skin Protecting / UV Absorber. In OTC drug products, it is used as a skin protectant and a sunscreen agent. Zinc Oxide works as a sunscreen agent by reflecting and scattering UV radiation. As supplied neat, some potential to irritate the skin and eyes. Normally used at levels less than 4% in a cosmetic but can be used at higher levels in skin creams and be unlikely to cause irritation. The SCCP considers that on basis of the dossier reviewed in 2003 the use of ZnO in its non-nano form (pigment grade, with particle sizes above 100 nm) is considered safe as a UV-filter up to 25%. The concern expressed in the SCCNFP opinion 0693/03 with regard to phototoxicity is not relevant for this form of ZnO due to the absence of dermal penetration (SCCP/1215/09).

Cosmeticinfo.org: The FDA has also approved the use of Zinc Oxide for use in OTC skin protectants and ano-rectal skin protectant drug products at concentrations up to 25%, and in sunscreen drug products at concentrations up to 25%. It is a colorant in cosmetics that is exempt from certification for the US.

Note: In the absence of NO(A)EL 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.
NO(A)EL: No Observed Adverse Effect Level; MoS: Margin of Safety; SED Systemic Exposure Dosage
Calculation of Margin of Safety: MoS = NO(A)EL / 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. SCCP Notes of Guidance For testing of Cosmetic Ingredients and their Safety Evaluation 6th Revision
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
11. SCCP Notes of Guidance For testing of Cosmetic Ingredients and their Safety Evaluation 7th Revision, 2011

This formulation has been safety assessed by Intertek in accordance with Directive 93/35/EEC, Article 7a, subsection 1d or Regulation (EC) No 1223/2009 as applicable.
The safety assessment is based on the chemical specification and toxicological profile of the ingredients as supplied at the time of assessment and an assessment of the final cosmetic product.

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.