

## Toxicological Safety Assessment of

Face & Body Crayons: N1C.Neon Red/ N2C.Neon Yellow/ N3C.Neon Blue/ N4C.Neon Orange/ N5C.Neon Green.

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: FC-16RPN

### 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	36.00	100	36	64742-43-4/ 64742-51-4 (8002-74-2)	265-145-6/ 265-154-5 (232-315-5)
PETROLATUM	30.00	100	30	8008-03-8 / 8063-27-2	232-373-2
GLYCERIN	15.00	100	15	56-81-5 / 8013-25-0	200-289-5
CALCIUM CARBONATE	11.25	100	11.25	471-34-1 / 1317-65-3	207-439-9
ETHYLHEXYLGLYCERIN & PHENOXYETHANOL	0.40	100	.4	70445-33-9 & 122-99-6	408-080-2 & 204-584-7
SODIUM BENZOATE	0.35	100	.35	532-32-1	208-534-8
POLYESTER-3	6.1425	100	6.1425	284862-70-0	248-421-0
MAY CONTAIN (+/-)					
CI 15850:1 (D&C RED NO.7 CALCIUM LAKE)	0.14	100	.14	5858-81-1/5281-04-9	228-109-5
CI 77891 (TITANIUM DIOXIDE)	0.70	100	.7	13469-67-7	236-675-5
CI 42090:1 (BLUE 1 ALUMINIUM LAKE)	0.21	100	.21	2850-18-2, 53026-57-6, 15792-67-3	220-168-0
CI 77007	3.22	100	3.22	1302-83-6 / 101357-30-6 / 57455-37-5/ 67053-79-6	215-111-1, 309-928-3
CI 47005:1 (YELLOW 10 LAKE)	0.77	100	.77	8004-92-0 / 94891-32-4 / 95193-83-2 / 68814-04-0	305-632-3 / 305-897-5
CI 45410	0.1162	100	.1162	13473-26-2 / 15876-58-1 / 18472-87-2	236-747-6 / 242-355-8
CI 45380 (ACID RED 87)	0.000004	100	.000004	17372-97-1	241-409-9
DISODIUM DISTYRYLBIPHENYL DISULFONATE	0.3395	100	.3395	27344-41-8	248-421-0
CI 45350 (ACID YELLOW 73)	0.2261	100	.2261	518-47-8	208-253-0
CI 45370 (ORANGE 5)	0.0336	100	.0336	598-03-2 / 4372-02-5	209-876-0 / 224-468-2

### LABELLED WARNINGS & INSTRUCTIONS OF USE

Keep away from eyes.

Discontinue use if irritation or rash develops

**CONSUMER EXPOSURE**

Product Class: Body and Face crayon

IFRA Product type: Body Paint for Children

IFRA Category: Category 3

Targeted Population: Children 16.7kg (Mean)

Amount per application/g: 18.460

Number of applications per day: Once per day

Skin Surface Area of Application/cm<sup>2</sup>: 11883.000

Physical form: Solid

Total Amount applied per day/g: 18.46

Part of body exposed to undiluted

Face, cheeks, neck, hands, legs and

Estimated Daily Exposure mg/kg/day: -

Amount Per Unit Area of Skin per day mg/cm<sup>2</sup>/day: 0.644

Retention factor: 1.00

Exposure Time Neat: Left on for 8 hours

Exposure Time Dilute: Rinsed off after 8 hours

Exposure time Solvent Inhalation: Not Applicable

Exposure time Aerosol Inhalation: Not Applicable

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 and 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 evaluation as per IFRA code of practice is not applicable to this product.

---

**TOXICOLOGICAL & REGULATORY REVIEW**

---

This is a preserved mixture of predominantly waxy / oily ingredients with thickening / viscosity controlling, skin conditioning agents and colour pigments dispersed. The product is intended to be used for painting the face and body 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 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 from 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 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 humectant / 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. The bulking agent, 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 eyes 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. The preservatives are EU/US 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 it is of minimum purity of 99% and maximum of 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 pigments (color additives) are not approved near the eye area (CI 47005:1 (Yellow 10 Lake) and CI 15850 (D&C Red 6) along with its Calcium Lake, D&C Red 7). Consequently in the USA, the Face and Body Paints containing these colour additives 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. Repeated exposure may result in allergic reactions in very susceptible individuals (Sensient Colors Inc., October 2008). Subsequently, the product containing this colour should be labelled to warn sensitive individuals to discontinue use if this product disagrees with them.

From the review of the ingredients used, frequency and type of exposure, this product has been assessed to pose a low risk to the majority of consumers if used as directed. There may however be some sensitive individuals for whom this product may not be agreeable for sensitivity or other idiosyncratic reasons. It is therefore advisable to label this product to discontinue use if it does not agree with you. The product is not expected to pose a risk to the health of the majority of consumers by means of irritation, allergy, ingestion, inhalation, corrosivity, phototoxicity, photosensitization nor from any known or documented carcinogenic, mutagenic or reprotoxic effects of the ingredients.

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. Contact with the eyes may also result in a transient film formation.

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



*M. U. Iwobi*

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

Centre Court, Meridian Business Park, Leicester. LE19 1WD

Date: 15 Jun 2012

Face & Body Crayons: N1C.Neon Red/ N2C.Neon Yellow/ N3C.Neon Blue/ N4C.Neon Orange/ N5C.Neon Green.

## 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)

#### Cosmetic Regulatory Summary:

EU Cosmetics Status: Controlled

#### Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 110.760 No NOAEL Available

SED Child mg/kg bw/day: 397.940 No NOAEL Available

SED Baby mg/kg bw/day: 1126.372 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: 92.300 No NOAEL Available

SED Child mg/kg bw/day: 331.616 No NOAEL Available

SED Baby mg/kg bw/day: 938.644 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

**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: 46.150 MoS - Adult 60kg: 43.3

NO(A)EL mg/kg bw day: 2000

SED Child mg/kg bw/day: 165.808 MoS - Child 16.7kg: 12.0

SED Baby mg/kg bw/day: 469.322 MoS - Baby 5.9kg: 4.2

**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 bioaccumulate 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: 34.612 No NOAEL Available

SED Child mg/kg bw/day: 124.356 No NOAEL Available

SED Baby mg/kg bw/day: 351.991 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: ETHYLHEXYLGLYCERIN & PHENOXYETHANOL**

EU INCI NAME: ETHYLHEXYLGLYCERIN &amp; PHENOXYETHANOL

CAS: 70445-33-9 &amp; 122-99-6

EINECS 408-080-2 &amp; 204-584-7

Function: Preservative

**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 SVHC Candidate List: Not Controlled

**Systemic Exposure Dosage / Margin of Safety:**

SED Adult mg/kg bw/day: 1.230 No NOAEL Available  
 SED Child mg/kg bw/day: 4.421 No NOAEL Available  
 SED Baby mg/kg bw/day: 12.515 No NOAEL Available

**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: 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: 1.076 MoS - Adult 60kg: 1012.2 NO(A)EL mg/kg bw day: 1090  
 SED Child mg/kg bw/day: 3.868 MoS - Child 16.7kg: 281.7  
 SED Baby mg/kg bw/day: 10.950 MoS - Baby 5.9kg: 99.5

**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: POLYESTER-3

EU INCI NAME: Polyester-3

CAS: 284662-70-0

EINECS 248-421-0

Appearance: Solid

Log Kow: -

Water Solubility: Insoluble

Function: Colour

Melting Point: No available

Boiling Point: N/A

Vapour Pressure: N/A

Cosmetic Regulatory Summary:

EU Cosmetics Status: Not controlled

ASEAN Cosmetics Status: -

Saudi Cosmetics Status: Not controlled

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: -

Systemic Exposure Dosage / Margin of Safety:

SED Adult mg/kg bw/day: 18.898 No NOAEL Available

SED Child mg/kg bw/day: 67.898 No NOAEL Available

SED Baby mg/kg bw/day: 192.187 No NOAEL Available

NOAEL test method: -

Toxicological Summary:

A fluorescent colourant of synthetic polymer formed from the reaction between ethylene glycol and terephthalic acid, isophthalic acid, cyclohexanedimethanol and norbornanediamine (ICI Dictionary and Handbook, 2008, 12th Edition). Acts as a film-former. Residual monomers include: isophthalic acid (1400 ppm), cyclohexane dimethanol (34.4 ppm) and norbornanediamine (< 100 ppm), terephthalic acid (<500 ppm) and ethylene glycol (20 ppm). This polymer usually acts as a substrate for pigments with low concentration of a surfactant / viscosity adjusting agent. Due to the polymeric nature, it would be expected to have a low to negligible solubility and thus a low risk of irritation and potential allergenic reaction. Provided it is fully cured, prolonged or repeated contact with the skin should not in systemic exposure that would result in chronic effects. Unlikely to cause adverse health effect but may contribute minimally towards the potential of the product to cause eye irritation.

Chemical Substance: MAY CONTAIN (+/-)

EU INCI NAME: -

CAS: \_\_\_\_\_

EINECS \_\_\_\_\_

Appearance: -

Log Kow: -

Water Solubility: -

Function: \_\_\_\_\_

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

EINECS 226-109-5

Appearance: -

Log Kow: -

Water Solubility: -

Function: Colour

Melting Point: -

Boiling Point: -

Vapour Pressure: -

**Cosmetic Regulatory Summary:**

EU Cosmetics Status: Approved colour all products

ASEAN Cosmetics Status: -

Saudi Cosmetics Status: Permitted colour field 1 All products

US Cosmetics Status: Cosmetics generally 74.2307 except eye area (CI 15850:1)

Canadian Cosmetics Status: -

**Regulatory Summary:**

EU Classification: R20/22

GHS Classification: -

REACH Annex XVII controlled: -

REACH SVHC Candidate List: -

**Systemic Exposure Dosage / Margin of Safety:**

SED Adult mg/kg bw/day: 0.430 MoS - Adult 60kg: ??

SED Child mg/kg bw/day: 1.547 MoS - Child 16.7kg: ??

SED Baby mg/kg bw/day: 4.380 MoS - Baby 5.9kg: ??

**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

EINECS 236-675-5

Appearance: -

Log Kow: -

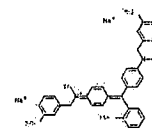
Water Solubility: -

Function: Colour

Melting Point: -

Boiling Point: -

Vapour Pressure: -



Chemical Structure:

**Cosmetic Regulatory Summary:**

EU Cosmetics Status: Approved colour all products

ASEAN Cosmetics Status: -

Saudi Cosmetics Status: Permitted colour field 1 All products

US Cosmetics Status: CI 77891 No restrictions 73.2575

Canadian Cosmetics Status: Approved colour all products including eyes

**Regulatory Summary:**

EU Classification: unclassified

GHS Classification: -

REACH Annex XVII controlled: -

REACH SVHC Candidate List: -

**Systemic Exposure Dosage / Margin of Safety:**

SED Adult mg/kg bw/day: 2.153 MoS - Adult 60kg: ??

SED Child mg/kg bw/day: 7.737 MoS - Child 16.7kg: ??

SED Baby mg/kg bw/day: 21.901 MoS - Baby 5.9kg: ??

**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 TiO<sub>2</sub> 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 42090:1 (BLUE 1 ALUMINIUM LAKE)**

EU INCI NAME: CI 42090

CAS: 2650-18-2, 53026-57-6, 15792-67-3

EINECS 220-168-0

Appearance: -

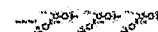
Log Kow: -

Water Solubility: -

Melting Point: -

Boiling Point: -

Vapour Pressure: -



Chemical Structure:

**Cosmetic Regulatory Summary:**

EU Cosmetics Status: Approved colour all products

ASEAN Cosmetics Status: -

Saudi Cosmetics Status: Permitted colour field 1 All products

US Cosmetics Status:

**Generally, including cosmetics 74.2101 (including the Aluminum Lake) &**

Canadian Cosmetics Status: Approved colour all products including eyes

**Regulatory Summary:**

EU Classification: unclassified

GHS Classification: -

REACH Annex XVII controlled: -

REACH SVHC Candidate List: -

**Systemic Exposure Dosage / Margin of Safety:**

SED Adult mg/kg bw/day: 0.646 MoS - Adult 60kg: ??

SED Child mg/kg bw/day: 2.321 MoS - Child 16.7kg: ??

SED Baby mg/kg bw/day: 6.570 MoS - Baby 5.9kg: ??

**Toxicological Summary:**

The aluminium lake of a dye used widely in food. High LD50. Soluble form of dye low potential to irritate. This insoluble form of the dye is unlikely to cause adverse effects at the typical concentrations used in lipsticks and other leave-on products like Hair Dyes.

**Chemical Substance: CI 77007**

EU INCI NAME: CI 77007

CAS: 1302-83-6 / 101357-30-6 / 57455-37-5 / 67053-79-6

Appearance: -

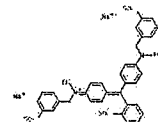
Log Kow: -

Water Solubility: -

Melting Point: -

Boiling Point: -

Vapour Pressure: -



Chemical Structure:

**Cosmetic Regulatory Summary:**

EU Cosmetics Status: Approved colour all products

ASEAN Cosmetics Status: -

Saudi Cosmetics Status: Permitted colour field 1 All products

US Cosmetics Status: CI 77007 Blue, Green, Pink, Red &amp; Violet, Externally including eye area 73.2725

Canadian Cosmetics Status: -

**Regulatory Summary:**

EU Classification: unclassified

GHS Classification: -

REACH Annex XVII controlled: -

REACH SVHC Candidate List: -

**Systemic Exposure Dosage / Margin of Safety:**

SED Adult mg/kg bw/day: 9.906 MoS - Adult 60kg: ??

SED Child mg/kg bw/day: 35.593 MoS - Child 16.7kg: ??

SED Baby mg/kg bw/day: 100.747 MoS - Baby 5.9kg: ??

**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 47005:1 (YELLOW 10 LAKE)**

EU INCI NAME: CI 47005:1

CAS: 8004-92-0 / 94891-32-4 / 95193-83-2 / 68814-04-0

EINECS 248-421-0

Appearance: -

Log Kow: -

Water Solubility: -

Melting Point: -

Boiling Point: -

Vapour Pressure: -

**Cosmetic Regulatory Summary:**

EU Cosmetics Status: Approved colour all products

ASEAN Cosmetics Status: -

Saudi Cosmetics Status: Permitted colour field 1 All products

US Cosmetics Status: Except Eye Area 74.2710 Lip products (3% max) Mouthwashes/dentifrices

Canadian Cosmetics Status: -

**Regulatory Summary:**

EU Classification: Unclassified

GHS Classification: -

REACH Annex XVII controlled: -

REACH SVHC Candidate List: -

**Systemic Exposure Dosage / Margin of Safety:**

SED Adult mg/kg bw/day: 2.369 MoS - Adult 60kg: ??

SED Child mg/kg bw/day: 8.511 MoS - Child 16.7kg: ??

SED Baby mg/kg bw/day: 24.091 MoS - Baby 5.9kg: ??

**Toxicological Summary:**

The insoluble aluminium lake of a food grade dye unlikely to cause problems in cosmetics at typical levels of use. EU Cosmetics shows this colorant as field of application 1-colouring agent allowed in all cosmetic products.

Latest U.S. FDA 'Color Additive Status List' states for drug and cosmetic use. (None of these colors may be used in products that are for use in the area of the eye).

**Chemical Substance: CI 45410**

EU INCI NAME: CI 45410

CAS: 13473-26-2 / 15876-58-1 / 18472-87-2

EINECS 236-747-6 / 242-355-6

Appearance: -

Log Kow: -

Water Solubility: -

Melting Point: -

Boiling Point: -

Vapour Pressure: -

**Cosmetic Regulatory Summary:**

EU Cosmetics Status: Approved colour all products

ASEAN Cosmetics Status: -

Saudi Cosmetics Status: Permitted colour field 1 All products

US Cosmetics Status: Cosmetics generally except eye area 74.2327 or 74.2328 Lip products Mouthwashes/dentifrices (GMP)

Canadian Cosmetics Status: Not controlled

**Regulatory Summary:**

EU Classification: unclassified

GHS Classification: -

REACH Annex XVII controlled: -

REACH SVHC Candidate List: -

**Systemic Exposure Dosage / Margin of Safety:**

SED Adult mg/kg bw/day: 0.357 MoS - Adult 60kg: ??

SED Child mg/kg bw/day: 1.284 MoS - Child 16.7kg: ??

SED Baby mg/kg bw/day: 3.635 MoS - Baby 5.9kg: ??

**Toxicological Summary:**

Function: Colourant. Unlikely to cause adverse effects at the typical concentrations used in cosmetics. Has some allergenic potential.

In line with EU requirements;- Must not contain more than 1% 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid and 2% 2-(bromo-6 hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid.

For US FDA approved for cosmetics generally (not including eye area use).

**Chemical Substance: CI 45380 (ACID RED 87)**

EU INCI NAME: Acid Red 87 / CI 45380

CAS: 17372-87-1

EINECS 241-409-6

Appearance: -

Log Kow: -

Water Solubility: -

Function: hair dyes

Melting Point: -

Boiling Point: -

Vapour Pressure: -

**Cosmetic Regulatory Summary:**

EU Cosmetics Status: Approved colour all cosmetics. Prohibited in cosmetic products in the EU when used as a substance in hair dye products Annex II/1334.

ASEAN Cosmetics Status: -

Saudi Cosmetics Status: -

US Cosmetics Status: -

Canadian Cosmetics Status: -

**Regulatory Summary:**

EU Classification: Unclassified

GHS Classification: -

REACH Annex XVII controlled: -

REACH SVHC Candidate List: -

**Systemic Exposure Dosage / Margin of Safety:**

SED Adult mg/kg bw/day: 0.000 MoS - Adult 60kg: ??

SED Child mg/kg bw/day: 0.000 MoS - Child 16.7kg: ??

SED Baby mg/kg bw/day: 0.000 MoS - Baby 5.9kg: ??

**Toxicological Summary:**

Prohibited in cosmetic products in the EU when used as a substance in hair dye products Annex II/1334. According to the CTPA CI 45380 is not permitted in temporary hair colourant sprays. This includes temporary hair colourants such as hair lacquers. The definition of hair dye remains unclear. CI 45380 is a cosmetic colourant and permitted in toy Finger Paints (EN71-7:2002). May cause eye irritation. Not more than 1% 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid and 2% 2-bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid. From the xanthene chemical family.

Not permitted as hair dye (II/1334, 2008/88/EC) from 14/10/09.

**Chemical Substance: DISODIUM DISTYRYLBIPHENYL DISULFONATE**

EU INCI NAME: DISODIUM DISTYRYLBIPHENYL DISULFONATE

CAS: 27344-41-8

Function: surfactants / viscosity controlling agents

**Regulatory Summary:**

EU Classification: R41

**Systemic Exposure Dosage / Margin of Safety:**

SED Adult mg/kg bw/day: 1.044 MoS - Adult 60kg: ??

SED Child mg/kg bw/day: 3.752 MoS - Child 16.7kg: ??

SED Baby mg/kg bw/day: 10.622 MoS - Baby 5.9kg: ??

**Toxicological Summary:**

Cosmetic Functions : Hair Conditioning / Surfactant / UV Absorber / Viscosity Controlling / Surface Modifier. As supplied has marked potential to irritate the eye but at the low levels of use unlikely to cause eye irritancy. It is soluble in water to the extent of 2.5% at 20 degC so will be in solution within the formulation. When used at typical levels in an eye mascara the substance will be dispersed throughout the preparation and will make a minimal contribution towards the potential of the product to cause eye irritation.

**Chemical Substance: CI 45350 (ACID YELLOW 73)**

EU INCI NAME: CI 45350

CAS: 518-47-8

EINECS 208-253-0

Appearance: Yellow powder

Log Kow: -

Water Solubility: Insoluble

Function: hair dyes

Melting Point: Not available

Boiling Point: N/A

Vapour Pressure: N/A

**Cosmetic Regulatory Summary:**

EU Cosmetics Status: Prohibited in cosmetics in the EU when used as a hair dye substance Annex III/1332.  
 ASEAN Cosmetics Status: -  
 Saudi Cosmetics Status: Permitted colour field 1 All products  
 US Cosmetics Status: Externally except Eye Area 74.2707 Lip products (3% max) Mouthwashes/dentirices  
 Canadian Cosmetics Status: -

**Regulatory Summary:**

EU Classification: R36/38-43  
 GHS Classification: Eye Irrit.2, Skin Irrit.2, Skin Sens.1.  
 REACH Annex XVII controlled: -  
 REACH SVHC Candidate List: -

**Systemic Exposure Dosage / Margin of Safety:**

SED Adult mg/kg bw/day: 0.695 No NOAEL Available  
 SED Child mg/kg bw/day: 2.499 No NOAEL Available  
 SED Baby mg/kg bw/day: 7.074 No NOAEL Available

**Toxicological Summary:**

This is Disodium 2-(3-oxo-6-oxidoxanthen-9-yl)benzoate (or fluorescein sodium, INN name), known for labelling purposes for cosmetic colourant in the EU as CI 45350 and in the USA as Yellow 8 (certified) or Acid Yellow 73 Sodium Salt (not certified) (ICI Dictionary and Handbook, 2008, 12th Edition). It is synthetically derived. In the EU, it is **prohibited in cosmetics when used as a hair dye substance Annex III/1332**. However, approved for use in colour cosmetics in all fields but restricted to a maximum of 6% in the finished product (Directive 76/768/EEC as amended, Annex IV/1). Unlikely to cause adverse effects when used at up to the maximum concentration stipulated for cosmetic products. The MSDS supplied (Day-Glo Color Corp., USA, 2010) indicated that it has a low acute oral (LD50: albino rats, > 5000 mg/kg) and dermal (LD50: rabbits, > 5000 mg/kg) toxicity. May cause inhalation hazardous as a nuisance dust. No target organism was identified; it was not considered by OSHA as hazardous nor listed as a carcinogen or reprotoxic by California Proposition 65 (Day-Glo Color Corp., USA, 2010).

**Chemical Substance: CI 45370 (ORANGE 5)**

CAS: 596-03-2 / 4372-02-5;

EINECS 209-876-0 / 224-468-2

Function: Colour

**Cosmetic Regulatory Summary:**

EU Cosmetics Status: Prohibited in cosmetic products in the EU when used as a substance in hair dye products.  
 Saudi Cosmetics Status: Permitted colour field 1 All products  
 US Cosmetics Status: Externally except eye area 74.2255 Suitable for mouthwashes 5% max in lip products

**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: 0.103 MoS - Adult 60kg: ??  
 SED Child mg/kg bw/day: 0.371 MoS - Child 16.7kg: ??  
 SED Baby mg/kg bw/day: 1.051 MoS - Baby 5.9kg: ??

**Toxicological Summary:**

Prohibited in cosmetic products in the EU when used as a substance in hair dye products. Permitted in all other leave on and rinse-off cosmetic products. Unlikely to cause adverse effects at the typical concentrations used in cosmetics. Has some allergenic potential.

**Must not contain more than 1% 2(6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid and 2% 2-(bromo-6 hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid**

**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 cited 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. 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.