

Magdalen Centre, The Oxford Science Park, Oxford OX4 4GA +44 (1865) 419110

PART A - Cosmetic Product Safety Information

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search & Testing

1. Quantitative and qualitative composition

		Ingredient INCI name	CAS	Function	Limits	Amount
ŀ	1	Polyethylmethacrylate	9003-42-3	Viscosity controlling		85.000000
	2	Polymethyl methacrylate	9011-14-7	Anticaking, opacifying		30.000000
	3	Mica	12001-26-2	Opacifying, Colorant,		5.000000
	4	CI 77891 CONFIDENTIAL	13463-67-7 🛬 🔍	Cosmetic colorant COI	IV/143	2.000000
	5	CI 77266	1333-86-4 / 7440	Cosmetic colorant	IV/126	1.000000
	6	CI 73360	2379-74-0	Cosmetic colorant,	IV/100	1.000000
ľ	7	CI 15880	6417-83-0	Cosmetic colorant	IV/29	1.000000
8 9 1 1	8	CI 74160	147-14-8	Cosmetic colorant	IV/105	1.000000
	9	CI 74260	1328-53-6	Cosmetic colorant	IV/107	1.000000
	10	CI 19140	1934-21-0	Cosmetic colorant, hair	IV/44, III/189	1.000000
	11	CI 60725 ZENTIAL	81-48-1	Cosmetic colorant	IV/89	1.000000
	12	CI 77007	12769-96-9 /	Cosmetic colorant	IV/120	1.000000
ļ	13	Benzoyl peroxide	94-36-0	Oxidising	III/94	0.300000









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Allergens present in this product and estimated amounts*: None

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* The presence of these allergens must be indicated in the list of ingredients when their concentration exceeds: 0.001% in leave-on products or 0.01% in rinse-off products

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2. Physical & chemical properties and stability

- 2.1.1 Physical/chemical properties of ingredients (substances or mixtures)
 - See section 1. Quantitative and qualitative composition additional specification of ingredients.

Ref. 1. 1 Polyethylmethacrylate

Polyethylmethacrylate is an ester of ethyl alcohol and methacrylic acid with the molecular formula is $C_6H_{10}O_2$. Polyethylmethacrylate is used in nail enhancement systems to aid polymerisation. The CIR Expert concluded that Polyethylmethacrylate is safe as used in nail enhancement products when skin contact is avoided and appropriate label warnings are used.

Ref. 1.2 Polymethyl methacrylate

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Polymethyl methacrylate (PMMA) is the synthetic polymer of methyl methacrylate, molecular formula $(C_5O_2H_8)_n$. It belongs to the family of polymers confident acrylates.

Ref. 1. 3 Mica

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Mica, or CI 77019, is a sheet silicate (phyllosilicate) mineral which includes several closely related materials having close to perfect basal cleavage. All are monoclinic, with a tendency towards pseudohexagonal crystals, and are similar in chemical composition. The nearly perfect cleavage, which is the most prominent characteristic of mica, is explained by the hexagonal sheet-like arrangement of its atoms.

The Food and Drug Administration (FDA) lists Mica as a color additive exempt from certification. Mica, is safe for use in coloring products, including cosmetics and personal care products applied to the lips, and the area of the eye. FDA also includes aluminum and potassium silicate (Mica) on the list of indirect food additives and permits its use as a colorant for polymers with incidental contact with food. The Cosmetic Ingredient Review (CIR) has deferred evaluation of Mica because the safety has been assessed by FDA. This deferral of review is according to the provisions of the CIR Procedures.



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2. Physical & chemical properties and stability

- 2.1.1 Physical/chemical properties of ingredients (substances or mixtures) See section 1. Quantitative and gualitative composition – additional specification of ingredients.
 - Ref. 1. 4 CI 77891

Titanium dioxide, pigment white or titanium white, is the naturally occurring oxide of titanium with the molecular formula TiO₂. Titanium dioxide occurs in nature as minerals ilmenite, rutile, anatase and brookite, and additionally as two high pressure forms, a monoclinic baddeleyite-like form and an orthorhombic a-PbO₂-like form. It is mainly sourced from ilmenite ore. Titanium dioxide is the most widely used white pigment because of its brightness and very high refractive index. Its high refractive index, its strong UV light absorbing capabilities and its resistance to discolouration under ultraviolet light enhances its stability and ability to protect the skin from ultraviolet light. Titanium dioxide is used as a UV filter in sunscreen products to protect the skin from harmful UV rays when exposed to sunlight. Particles in nano form (also named 'nanomaterials', 'nanoparticles' or 'micronized materials') refer to very small sized materials and components that have a particle size range of 1 to 100 nanometre (one nanometre is one millionth of a millimetre.

Titanium dioxide (nano) has been approved as a food additive since 1996 by the Food and Drug Administration (FDA). Moreover, the European Commission's Scientific Committee on Food (SCF), the Joint Expert Committee on Food Additives of the Food and Agriculture Organization/World Health Organization (JECFA), and the European Food Safety Authority (EFSA)'s Scientific Panel on Food Additives, Flavorings, Processing Aids and Materials in Contact with Food have also approved the daily intake of nano-TiO2 in general food stuff. Most studies performed in humans or animals showed that nano-TiO2 did not penetrate beyond the outer layers of the skin's stratum corneum to viable cells and did not reach the general circulation, either in healthy or in compromised skin. The European Commission's Scientific Committee on Consumer Safety



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CI 77266 CONFIDENTIAL

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CI 77266 is also known as carbon black. CI 77266 may be safely used for colouring cosmetics and personal care products. Molecular formula: C

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2. Physical & chemical properties and stability

- 2.1.1 Physical/chemical properties of ingredients (substances or mixtures) See section 1. Quantitative and qualitative composition – additional specification of ingredients.
 - Ref. 1.6 CI 73360

CI 73360 is also known as Red 30, Red 30 Lake, thioindigoid colour, and 6-Chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3H)-ylidene)-4-methylbenzo [b]thiophene-3(2H)-one. The Food and Drug Administration (FDA) has reviewed the safety of Red 30 and Red 30 Lake and determined that they may be safely used for colouring cosmetics and personal care products, and well as drugs (including products intended for use on the lips) when conforming to specifications set by FDA. These ingredients are not permitted for use in products intended to be used in the area of the eye. According to U.S. regulations, all Red 30 and Red 30 Lake manufactured for use in products is subject to certification by the FDA. This certification process ensures that the strict chemical and identity specifications set by FDA are met. The Cosmetic Ingredient Review (CIR) has deferred evaluation of these ingredients because the safety has been assessed by FDA. This deferral of review is according to the provisions of the CIR procedures. Cosmetics Europe does not place a restriction on the area of use on CI 73360 therefore it is safe to use in cosmetic products.

Ref. 1.7 CI 15880

Cl 15880, also known as Pigment red 63 or Red 34, has the molecular formula $C_{21}H_{12}CaN_2O_6S$. The FDA reviewed the safety of Red 34 and Red 34 Lake and determined that they may be safely used for colouring externally applied cosmetics and personal care products, as well as externally applied drugs, when these ingredients conform to FDA specifications.

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Ref. 1.8

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CI 74160 CONFIDENTIAL

CI 74160, also know as Copper phthalocyanine pigment is a blue-green coloured aromatic macrocyclic compound. CI 74160 may be safely used for colouring cosmetics and personal care products.

Ref. 1. 9 CI 74260

CI 74260, also known as pigment green 7, polychloro copper phthalocyanine. CI 74260 may be safely used for colouring cosmetics and personal care products. CI 74260 is not to be used on or around the eye area.

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2. Physical & chemical properties and stability

2.1.1 Physical/chemical properties of ingredients (substances or mixtures) See section 1. Quantitative and gualitative composition – additional specification of ingredients.

Ref. 1. 10 CI 19140

CI 19140, also known as yellow, acid yellow 23, tartrazine and E102, has the molecular formula $C_{16}H_9N_4Na_3O_9S_2$ The FDA has reviewed the safety of CI 19140 and determined that it may be safely used for colouring cosmetics and personal care products, including products intended for use on the lips, and in products intended for use in the area of the eye, when these ingredients conforms to FDA specifications. CI 19140 is also permitted as to be used as a colour in food and drugs. The Cosmetic Ingredient Review (CIR) has deferred evaluation of these ingredients because the safety has been assessed by FDA. This deferral of review is according to the provisions of the CIR Procedures.

Ref. 1. 11 CI 60725

CI 60725, also known as Solvent violet 13, has the molecular formula $C_{21}H_{15}NO_3$. CI 60725 may be safely used for colouring cosmetics and personal care products.

Ref. 1. 12 CI 77007

CI 77007, also known as lazurite, ultramarine blue, and pigment blue 29. Ultramarines may be safely used for colouring cosmetics and personal care products. Molecular formula: $Na_{e}AI_{4}Si_{e}S_{4}O_{20}$

Ref. 1. 13 Benzoyl peroxide

Benzoyl peroxide is an organic compound with two benzoyl groups bridged by a peroxide link, with the molecular formula $C_{14}H_{10}O_4$. Benzoyl peroxide is used as a chemical initiator for polymerisation of the powder component of dry acrylic polymers and pigments of the 2 component artificial nail systems. It is at a maximum concentration in the powder of 2% and as maximum concentration of 0.7% at the start of the polymerisation process. Benzoyl peroxide is used at concentrations up to 10% topical treatment of acne. It is probably the most widely used first-line drug in the management of mild acne.

Systemic exposure should be minimal from penetration of Benzoyl peroxide through the nail plate, since penetration through the nail plate is known to be limited from studies on topical anti-fungal drugs. Professional application of the artificial nail to the nail plate should not allow contact with skin. However, without due care, there could be skin contact at the cuticle and the side of the nails. Benzoyl peroxide is a technical aid in the polymerisation of polymers such as ethyl and methylacrylates, at low concentrations and are mainly consumed rapidly during polymerisation. The remaining residual is trapped in the hardened polymer matrix. This reduces the chance of possible systemic exposure, since

penetration through the nail plate is slight. In June 2002 The Scientific Committee on Cosmetic Products and Non-Food Products (SCCNFP) concluded that Benzoyl peroxide is safe for use for the indicated product with the restrictions and conditions of use as noted on the label warnings.

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- 2. Physical & chemical properties and stability continued
- 2.1.2 Physical/chemical properties of the cosmetic product

CONE		00
Appearance	Loose Powder	
Colour	Various	
Aroma	Fragrance free	
рН	n/a	

*RP: Responsible Person: LA Nails Artistry

2.2 Stability of the cosmetic product

The ingredients used in the production of the cosmetic product comply with the relevant legal regulations.

Both the product and constituent ingredients are stable under normal use and warehousing conditions during the entire time of the PAO 12M period.

2.2.1 LA Nails Artistry confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 LA Nails Artistry uses a PAO 12M based on the results of

LA Nails Artistry 's stability testing, including shelf life stability testing.

2.2.3 A Preservative Efficacy Test was not necessary since this is not a water-based product.

3. Microbiological quality

3.1.1 Microbiological specification of ingredients (substances and mixtures).

Based on available information from the ingredient specification (see section 1. Quantitative and qualitative composition – specification of ingredients), the ingredients used can be assessed as microbiologically safe.

3.1.2 Microbiological specification of the finished product

The given cosmetic product can be regarded as microbiologically safe for consumers' health

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O under the ISO 29621:2010 standard "Cosmetics -- Microbiology -- Guidelines for the risk assessment and identification of microbiologically low-risk products".

The microbiological harmlessness of the ingredients and the cosmetic product is assessed according to COLIPA: Guideline for Microbiological Quality Management (MQM).

A Preservative Efficacy Test was not necessary since this is not a water-based product.

4. Impurities, trace amounts of forbidden substances, & information about packaging material

4.1 Impurities and trace amounts of forbidden substances According to specifications (see section 2.1.1 Physical/chemical properties of ingredients (substances or mixtures) submitted by ingredient suppliers, the ingredients do not contain impurities or trace amounts of forbidden substances.

Any impurities or traces identified in any ingredient above standard tolerances are noted against each respective ingredient in section 2.1.1.

4.2 Information about packaging material

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The packaging material applied is suitable for the given type of cosmetic product and meets the ENTIAL predictable use requirements.

	_		
Container	Bottle		
Container Material	PET		
Airless Container	No		
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The available research suggests that the concentration of phthalates in the contents of PET bottles varies as a function of the contents of the bottle, with phthalates leaching into lower pH products. Temperature also appears to influence the leaching both of phthalates and of antimony from PET, with greater leaching at higher temperatures.

The evidence also suggests that PET bottles may yield endocrine disruptors under conditions of common use, particularly with prolonged storage and elevated temperature.

Therefore it is advisable, in using PET containers, to ensure a minimum pH of 4.0 and to store products at cooler temperatures using a shorter BBE period.

LA Nails Artistry confirms that the results of reference sample monitoring show no reaction between the packaging material and the product during the product's stated minimum useable life. During that life no changes to physical and chemical properties of the product were noticed that would affect its usability and safety.

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5. Normal and reasonably foreseeable use

The current label advice:

Preparation: Ensure nails are clean, dry and prepped with a base coat, gel or acrylic. Application: Step 1: Shake the OmbreAir spray bottle well before use. Step 2: Hold the bottle upright and at a distance of 6-8 inches from the nail surface. Step 3: Gently press the nozzle to release a fine mist of powder onto the nails. Step 4: Move the spray bottle in a sweeping motion for an even ombre affect. Step 5: Allow the powder to settle and adhere to the nail surface. Step 6: repeat as needed to achieve the desired intensity and gradient. Sealing: Once satisfied with the ombre effect, seal the design with a top coat to ensure durability and shine. Clean-Up: Clean any excess powder from the skin around the nails using a brush or a damp cloth. Wash hands immediately. Warnings: For professional use only. Use with a mask to avoid inhalation of fine powder. Ensure the work area is well-ventilated and use a suction fan to minimise airborne particles. Avoid contact with plenty of water and seek medical Do not use on damaged or infected nails. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Store in a cool, dry place, away from direct sunlight and heat sources.

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19(1)(d) of Cosmetic Regulation (EC) No. 1223/2009:

For external use only. Keep out of reach of children. For professional use only. Avoid skin contact.

Exposure to the cosmetic product

	Area of application	Nails	
	Product type: Leave-on or Rinse-off	Leave On	
_	Duration and frequency	0.14	
	Possible additional routes of exposure	none	
	Estimated skin surface area (cm ²)	1.60	
	Estimated amount of the product applied according to the SCCS (g/day)	0.025 g	
	Estimated retention factor according to the SCCS	.01	CONFIDENTI
72	Target group	Adult	
	Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	0.42	



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7. Exposure to the ingredients

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	Ingredient INCI name	Concentration	SED
1	CI 77266	0.01000	0.00004
2	CI 77891	0.02000	0.00008
3	CI 73360	0.01000	0.00004
4	CI 15880 CONFIZENTIAL	0.01000	CON-0.00004 A
5	CI 74160	0.01000	0.00004
6	CI 74260	0.01000	0.00004
7	CI 19140	0.01000	0.00004
8	CI 60725	0.01000	0.00004
9	CI 77007	0.01000	0.00004
10	Mica	0.05000	0.00021
CON	Polyethylmethacrylate	CO0.85000	TIAL 0.00357
12	Polymethyl methacrylate	0.30000	0.00126
13	Benzoyl peroxide	0.00300	0.00001







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8. Toxicological profile of the ingredients in the formulation





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8. Toxicological profile of the ingredients in the formulation - continued

Based on the calculation of MoS (Margin of Safety) for ingredients that can be classified as hazardous to human health, the product does not contain ingredients with toxicologically significant profiles in terms of consumer health.

An ingredient with an MoS above 1000 is considered safe. An ingredient with an MoS above 100 but lower than 1000 must be further considered by the assessor.

Since all of the ingredients have a margin of safety above 1,000 this product is considered safe for consumers to use.

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9. Undesirable effects and serious undesirable effects

EN The cosmetic product with a similar composition has been supplied to the market in the long term and until nowadays, no undesired effects to human health have been noticed in relation to the use of this product. Therefore, no undesired effects are anticipated at the common and reasonably predictable application of the given cosmetic product.

After its launch, the cosmetic product will be further monitored by LA Nails Artistry in accordance to procedures detailed in *Cosmetic Regulation* (EC) No 1223/2009. The safety of the product should be reviewed on a regular basis. To that end, undesirable and serious undesirable effects on human health during in market use of the product should be filed (complaints during normal and improper use, and the follow-up done) and details forwarded to the safety assessor.

The safety assessor will then update the Cosmetic Product Safety Report (CPSR) based on the new findings and the adopted corrective measures.

10. Additional information on the product

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No additional information is available and no additional studies were carried out.



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PART B – Cosmetic Product Safety Assessment

1. Assessment conclusion

Based on the information supplied, the cosmetic product detailed in this report is safe for human health when used in common or reasonably predictable conditions in compliance with the instructions provided for the consumer.

This conclusion is only applicable to this cosmetic product with the composition, properties, purpose, and method of use of which are detailed in this documentation, and laboratory tests attached to this assessment, including the detailed production and labelling which has been assessed as meeting the requirements of *Cosmetic Regulation* (EC) No. 1223/2009 effective on the date this report was issued.

2. Labelled warnings and instructions of use

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19(1)(d) of *Cosmetic Regulation* (EC) No. 1223/2009:

For external use only. Keep out of reach of children. For professional use only. Avoid skin contact.

Allergens present in this product and estimated amounts*:

* The presence of these allergens must be indicated in the list of ingredients when their concentration exceeds: 0.001% in leave-on products or 0.01% in rinse-off products. Only the allergen, not the estimated amount, is required on the label.

3. Reasoning

Based on the formulation of this cosmetic product, its qualitative and quantitative composition according to its INCI ingredients, basic physical and chemical characteristics and microbiology, Preservation Challenge Test performed, classification of the cosmetic product type, including its purpose and method of application, and available toxicological information and safety sheets of the ingredients used, the cosmetic product safety has been assessed for the consumer by assessing the toxicological profile of all ingredients, their chemical structure, exposure level and Margin of Safety (MoS) depending on the purpose of use in this cosmetic product.

This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The evaluation of the entire composition and applied ingredient concentrations indicate that as a whole the composition of this cosmetic product complies with the requirements of *Cosmetic Regulation* (EC) No. 1223/2009 of the European Parliament and of the Council.



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