OXFORD BIOSCIENCES
Safety Assessment, Analysis, Research & Testing

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# COSMETIC PRODUCT SAFETY REPORT

**PRODUCT:** Poly Gel

**DATE:** 22 March 2021

Responsible Person: Zoe Lavender
**Lisa Kon**
Unit 2 Amberon House
Aspen Way
Paignton TQ4 7QR

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# PART A – Cosmetic Product Safety Information

## 1. Quantitative and qualitative composition

| | Ingredient INCI name | CAS | Function | Limits | Amount |
|---|---|---|---|---|---|
| 1 | Acrylates copolymer | 25133-97-5 / | Antistatic, binding, film | | 30.00 |
| 2 | Polyethylene terephthalate | 25038-59-9 | Film forming | | 30.00 |
| 3 | Trimethylolpropane triacrylate | 15625-89-5 | Film forming, hair | | 30.00 |
| 4 | Polymethyl methacrylate | 9011-14-7 | Film forming | | 30.00 |
| 5 | Ethyl methacrylate | 97-63-2 | Viscosity controlling | | 30.00 |
| 6 | Dimethicone | 63148-62-9 / | Antifoaming, emollient, | | 8.00 |
| 7 | Cera microcristallina | 63231-60-7 / | Binding, emulsion | | 5.00 |
| 8 | CI 77510 | 14038-43-8 / | Cosmetic colorant | IV/138 | 0.50 |
| 9 | Mica | 12001-26-2 | Opacifying | | 0.50 |
| 10 | CI 77491 | 1309-37-1 / 1345 | Cosmetic colorant | IV/135 | 0.50 |
| 11 | CI 42090 | 3844-45-9 | Cosmetic colorant | IV/63 | 0.50 |
| 12 | CI 77163 | 7787-59-9 | Cosmetic colorant | IV/123 | 0.50 |
| 13 | CI 15850 | 5858-81-1 | Cosmetic colorant | IV/27 | 0.50 |
| 14 | CI 60725 | 81-48-1 | Cosmetic colorant | IV/89 | 0.50 |
| 15 | CI 19140 | 1934-21-0 | Cosmetic colorant, hair | IV/44, III/189 | 0.50 |
| 16 | CI 73360 | 2379-74-0 | Cosmetic colorant, | IV/100 | 0.50 |
| 17 | CI 15880 | 6417-83-0 | Cosmetic colorant | IV/29 | 0.50 |
| 18 | CI 77266 | 1333-86-4 / 7440 | Cosmetic colorant | IV/126 | 0.50 |

Allergens present in this product and estimated amounts*:
None

* 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 **Acrylates copolymer**

Acrylates copolymer is composed of acrylic acid and methacrylic acid.
The safety of copolymers and polymers that contain the acrylic acid monomer has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Acrylates copolymer was safe for use in cosmetics and personal care products when formulated to avoid skin irritation.

Ref. 1. 2 **Polyethylene terephthalate**

Polyethylene terephthalate consists of polymerized units of the monomer ethylene terephthalate. Molecular formula: $(C_{10}H_8O_4)n$

Ref. 1. 3 **Trimethylolpropane triacrylate**

Trimethylolpropane triacrylate (TMPTA) is a trifunctional monomer acrylic acid ester which, when cured, provides high crosslinked density and chemical resistance. It has the molecular formula $C_{15}H_{20}O_6$. Since Trimethylolpropane triacrylate avoids the sensitising potential of the Methacrylates used in similar applications, according to the Cosmetic Ingredient Review (CIR) Expert Panel, Trimethylolpropane triacrylate is safe in cosmetics in the present practices of use and concentration described in the safety assessment.

Ref. 1. 4 **Polymethyl methacrylate**

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

Ref. 1. 5 **Ethyl methacrylate**

Ethyl methacrylate (EMA) is a type of acrylic monomer with molecular formula $C_6H_{10}O_2$.

Ref. 1. 6 **Dimethicone**

Dimethicone, or polymethylsiloxane (PDMS), is a fluid mixture of fully methylated linear siloxane polymers end-blocked with trimethylsiloxy units. PDMS is the most widely used silicon-based organic polymer, and is particularly known for its unusual rheological properties. PDMS is optically clear, and, in general, inert, non-toxic, and non-flammable. It is also commonly referred to as dimethicone and is one of several types of silicone oil (polymerised siloxane). Clinical and animal absorption studies reported that dimethicone was not absorbed following oral or dermal exposure. Dimethicone is not acutely toxic following oral exposure. Its molecular formula is $(C_2H_6OSi)n$.

The Cosmetic Ingredient Review (CIR) also evaluated the scientific data and concluded that dimethicone is safe for use in cosmetics.

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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. 7 **Cera microcristallina**

Cera microcristallina (Microcrystalline wax) is a hydrocarbon wax produced by de-oiling petrolatum, as part of the petroleum refining process. Cera microcristallina contains a higher percentage of isoparaffinic (branched) hydrocarbons and naphthenic hydrocarbons than paraffin wax resulting in a complex combination of long, branched chain hydrocarbons obtained form residual oils by solvent crystallisation consisting predominantly of saturated straight and branched chain hydrocarbons predominantly greater than C35. Hydrocarbon waxes have a long history of use in the cosmetic industry and present no safety issue when used in the present practice of use and concentration detailed in this safety assessment.

Ref. 1. 8 **CI 77510**

CI 77510, also known as or Ferric ferrocyanide or Prussion blue, CI 77510 may be safely used for colouring cosmetics and personal care products. Molecular formula: $C_{18}Fe7N_{18.}$

The Food and Drug Administration (FDA) lists Ferric ferrocyanide as a color additive exempt from certification. Ferric ferrocyanide a is safe for use in coloring externally applied cosmetics and personal care products, including products applied to the area of the eye, when these ingredients conform to FDA specifications. Ferric ferrocyanide is also allowed to be used in externally applied drugs. These ingredients are not allowed to be used in products intended for use on the lips (in USA). The Cosmetic Ingredient Review (CIR) has deferred evaluation of this ingredient because the safety has been assessed by FDA. This deferral of review is according to the provisions of the CIR Procedures

Ref. 1. 9 **Mica**

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 qualitative composition – additional specification of ingredients.

Ref. 1. 10 **CI 77491**

CI 77491, also known as diiron trioxide, ferric oxide. CI 77491 may be safely used for colouring cosmetics and personal care products. Molecular formula: $Fe_2$-$O_3$

Ref. 1. 11 **CI 42090**

CI 42090, also known as brilliant blue, acid blue 9. CI 42090 may be safely used for colouring cosmetics and personal care products. Molecular formula: $C_{16}H_9N_4Na_3O_9S_2$

Ref. 1. 12 **CI 77163**

CI 77163, also known as bismuth chloride oxide. CI 77163 may be safely used for colouring cosmetics and personal care products. Molecular formula: $B_iC_{lO}$

Ref. 1. 13 **CI 15850**

CI 15850 is a synthetic red disodium salt of an Azo dye, also known as Red lake 6 and Lithol rubine B, with the molecular formula $C_{18}H_{14}N_2O_6S{\cdot}2Na$ . CI 15850 may be safely used for colouring cosmetics and personal care products, although the US FDA prohibits its use be used in products that are for use in the area of the eye. Cosmetics Europe does not place this restriction on its use.

Ref. 1. 14 **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. 15 **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.

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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. 16 **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. 17 **CI 15880**

CI 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.

Ref. 1. 18 **CI 77266**

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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## PART A – Cosmetic Product Safety Information *continued*

2. Physical & chemical properties and stability *continued*

2.1.2 Physical/chemical properties of the cosmetic product

| | |
|---|---|
| **Appearance** | Solid/Pressed Powder |
| **Colour** | Clear |
| **Aroma** | Fragrance free |
| **pH** | n/a |

*RP: Responsible Person: Lisa Kon

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 24M period.

2.2.1 Lisa Kon confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 Lisa Kon uses a PAO 24M based on the results of Lisa Kon '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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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

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

| | |
|---|---|
| **Container** | Pot |
| **Container Material** | HDPE |
| **Airless Container** | No |

A linear polymer, High-density polyethylene (HDPE) is prepared from ethylene by a catalytic process. The absence of branching results in a more closely packed structure with a higher density and somewhat higher chemical resistance than LDPE. Impact, wear resistant, and antioxidant, HDPE also has good chemical resistant properties.

Lisa Kon 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:

*Remove polygel slice with a multipurpose tool and roll onto the nail. Next, shape the product into place, finally cure for 60 seconds with a 48W LED lamp. Caution keep out of reach of children, avoid skin and eye contact. If eye contact occurs, flush with water and seek medical attention. Discontinue use if sensitivity or irritation occurs and thoroughly rinse affected area. Keep out of sunlight.*

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.*

6. 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 |
| 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

| | Ingredient INCI name | Concentration | SED |
|---|---|---|---|
| 1 | Acrylates copolymer | 0.30000 | 0.00126 |
| 2 | Polyethylene terephthalate | 0.30000 | 0.00126 |
| 3 | Trimethylolpropane triacrylate | 0.30000 | 0.00126 |
| 4 | Polymethyl methacrylate | 0.30000 | 0.00126 |
| 5 | Ethyl methacrylate | 0.30000 | 0.00126 |
| 6 | Dimethicone | 0.08000 | 0.00034 |
| 7 | Cera microcristallina | 0.05000 | 0.00021 |
| 8 | CI 77510 | 0.00500 | 0.00002 |
| 9 | Mica | 0.00500 | 0.00002 |
| 10 | CI 77491 | 0.00500 | 0.00002 |
| 11 | CI 42090 | 0.00500 | 0.00002 |
| 12 | CI 77163 | 0.00500 | 0.00002 |
| 13 | CI 15850 | 0.00500 | 0.00002 |
| 14 | CI 60725 | 0.00500 | 0.00002 |
| 15 | CI 19140 | 0.00500 | 0.00002 |
| 16 | CI 73360 | 0.00500 | 0.00002 |
| 17 | CI 15880 | 0.00500 | 0.00002 |
| 18 | CI 77266 | 0.00500 | 0.00002 |

***SED**: Systemic Exposure Dose*

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8. Toxicological profile of the ingredients in the formulation

| | Ingredient INCI name | MOS |
|---|---|---|
| 1 | Acrylates copolymer | 1587301.58730 |
| 2 | Polyethylene terephthalate | 7936507.93650 |
| 3 | Trimethylolpropane triacrylate | 4572222.22220 |
| 4 | Polymethyl methacrylate | 3968253.96830 |
| 5 | Ethyl methacrylate | 11587301.58730 |
| 6 | Dimethicone | 59523809.52380 |
| 7 | Cera microcristallina | 9523809.52380 |
| 8 | CI 77510 | 238095238.09520 |
| 9 | Mica | 714285714.28570 |
| 10 | CI 77491 | 476190476.19050 |
| 11 | CI 42090 | 95238095.23810 |
| 12 | CI 77163 | 1404761904.76190 |
| 13 | CI 15850 | 466666666.66670 |
| 14 | CI 60725 | 238095238.09520 |
| 15 | CI 19140 | 607142857.14290 |
| 16 | CI 73360 | 476190476.19050 |
| 17 | CI 15880 | 238095238.09520 |
| 18 | CI 77266 | 380952380.95240 |

***MOS**: Margin of Safety*

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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.

9. Undesirable effects and serious undesirable effects

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 Lisa Kon 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

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

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## 11. References


- THE SCCS'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC SUBSTANCES AND THEIR SAFETY EVALUATION 8TH REVISION
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF
- MSDS of ingredients
- Commission Implementing Decision of 25th November 2013 Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products
- SCCS - Opinions
  http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm
- CosIng: the European Commission database on cosmetic substances
  http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple
- REGULATION 1223/2009 ANNEXES
  http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=ref_data.annexes_v2

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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.*

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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4. Assessor's credentials and approval of Part B

Safety Assessor: Allison Wild
Oxford Biosciences Ltd.
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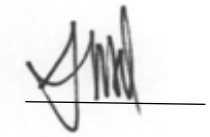
Experience and qualifications:

- MSc in Clinical Pharmacology, University of Oxford
- 15+ years experience formulating cosmetic products
- Full member of the Society of Cosmetic Scientists (SCS)
- Member of the British Pharmacological Society



*Signature*

22 March 2021

*Date*