

COSMETIC PRODUCT SAFETY REPORT

PRODUCT: pH Bond Primer

DATE: 22 March 2021

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



PART A – Cosmetic Product Safety Information

1. Quantitative and qualitative composition

| | Ingredient INCI name | CAS | Function | Limits | Amount |
|---|-----------------------------|------------|--------------------|---------------|---------------|
| 1 | Ethyl acetate | 141-78-6 | Perfuming, solvent | | 85.00 |
| 2 | Isopropylidenediphenyl | 1565-94-2 | Film forming | | 10.00 |
| 3 | HEMA | 868-77-9 | Film forming | 111/314 | 10.00 |

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

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 **Ethyl acetate**

Ethyl acetate is the ester of ethanol and acetic acid with the molecular formula $C_4H_8O_2$.

The Food and Drug Administration (FDA) includes Ethyl acetate on its list of substances considered Generally Recognized As Safe (GRAS) for use as a synthetic flavoring substance and adjuvant. It is also permitted to be used as a secondary food additive as a solvent, lubricant or release agent. The safety of Ethyl acetate has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Ethyl acetate is safe as cosmetic ingredients in the present practices of use and concentration. In 2006, as part of the scheduled re-evaluation of ingredients, the CIR Expert Panel considered available new data on Ethyl Acetate and reaffirmed the above conclusion.

Ref. 1. 2 **Isopropylidenediphenyl bisoxyhydroxypropyl methacrylate**

Isopropylidenediphenyl bisoxyhydroxypropyl methacrylate is a methacrylate ester monomer which undergoes rapid polymerisation to form a hard material on the nail that is then shaped. Genotoxicity data indicated that some Methacrylates could produce chromosome damage in mammalian cells. In consideration of all the data, in 2005 the Cosmetic Ingredient Review (CIR) Expert Panel decided that many Methacrylates should be restricted to the nail and must not be in contact with the skin. There is concern that the exotherms created from the monomers' rapid polymerisation could damage the nail. Test data showed 50% polymerisation in 3 to 4 minutes at 5% concentrations. However, the products do not produce significant levels of exotherms and clients rarely notice a slight warming of the nail during application. Based on the available data, the CIR Expert Panel concluded that Methacrylates are safe as used in nail enhancement products when skin contact is avoided. Products containing Isopropylidenediphenyl bisoxyhydroxypropyl methacrylate should be accompanied with directions to avoid skin contact, because of the sensitising potential of Isopropylidenediphenyl bisoxyhydroxypropyl methacrylate.

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. 1.3 **HEMA**

HEMA, 2-hydroxyethyl methacrylate, is a methacrylate ester monomer which undergoes rapid polymerisation to form a hard material on the nail that is then shaped. Genotoxicity data indicated that some Methacrylates could produce chromosome damage in mammalian cells. In consideration of all the data, in 2005 the Cosmetic Ingredient Review (CIR) Expert Panel decided that many Methacrylates should be restricted to the nail and must not be in contact with the skin. There is concern that the exotherms created from the monomers' rapid polymerisation could damage the nail. Test data showed 50% polymerisation in 3 to 4 minutes at 5% concentrations. However, the products do not produce significant levels of exotherms and clients rarely notice a slight warming of the nail during application. Based on the available data, the CIR Expert Panel concluded that HEMA is safe as used in nail enhancement products when skin contact is avoided. Products containing HEMA should be accompanied with directions to avoid skin contact, because of the sensitising potential of HEMA.

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 | Liquid |
| 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

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 | Bottle |
| Container Material | Glass |
| Airless Container | No |

Glass is resilient and resistant to most solvents and represents a low hazard in terms of chemical leaching. Glass can be attacked by weak acids or bases and thus can leach sodium and calcium ions into the cosmetic product.

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.

5. Normal and reasonably foreseeable use

The current label advice:

Apply to nail plate, do not touch the skin - allow to dry for 15 seconds before applying any products. 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 |

7. Exposure to the ingredients

| | Ingredient INCI name | Concentration | SED |
|---|--|---------------|---------|
| 1 | Ethyl acetate | 0.85000 | 0.00357 |
| 2 | Isopropylidenediphenyl bisoxyhydroxypropyl | 0.10000 | 0.00042 |
| 3 | HEMA | 0.10000 | 0.00042 |

SED: Systemic Exposure Dose

8. Toxicological profile of the ingredients in the formulation

| | Ingredient INCI name | MOS |
|---|---|----------------|
| 1 | Ethyl acetate | 1574229.69190 |
| 2 | Isopropylidenediphenyl bisoxyhydroxypropyl methacrylate | 4761904.76190 |
| 3 | HEMA | 12023809.52380 |

MOS: Margin of Safety

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.

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

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.

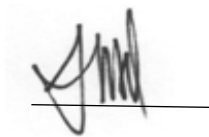
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The 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.

4. Assessor's credentials and approval of Part B

Safety Assessor: Allison Wild
Oxford Biosciences Ltd.
The Oxford Science Park
Magdalen Centre
Oxfordshire
OX4 4GA

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