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

COSMETIC PRODUCT SAFETY REPORT

PRODUCT: No Wipe Top Coat

DATE: 22 March 2021

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

OXFORD BIOSCIENCES
Safety Assessment, Analysis, Research & Testing

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

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		68.00
2	HEMA	868-77-9	Film forming	III/314	20.00
3	Pentaerythrityl tetramercaptopropionate	7575-23-7	Film forming		8.00
4	Trimethylbenzoyl diphenylphosphine	75980-60-8	Skin conditioning	III/311	4.00

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

OXFORD BIOSCIENCES
Safety Assessment, Analysis, Research & Testing

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

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 **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.

Ref. 1. 3 **Pentaerythrityl tetramercaptopropionate**

Pentaerythrityl tetramercaptopropionate is a pentaerythrityl tetraester compound with the molecular formula $C_{17}H_{28}O_8S_4$. In 2015 the Cosmetic Ingredient Review (CIR) Expert panel confirmed that pentaerythrityl tetraesters are safe in the present practices of use and concentration described in this safety assessment.

Ref. 1. 4 **Trimethylbenzoyl diphenylphosphine oxide**

Trimethylbenzoyl diphenylphosphine, or Diphenyl(2,4,6-trimethylbenzoyl) phosphine oxide (TPO) is used as a key processing aid in form of a chemical photo-initiator for polymerisation in artificial nail systems, primarily in UV-curable one-component gel systems. TPO is a Norrish Type 1 or alpha-cleavage photo- initiator. This means that TPO splits into two free radical fragments, which subsequently become incorporated into the polymer as chain ends. Therefore, TPO will be consumed rapidly during the polymerisation process and even in the unlikely event that very minor residual amounts remain, they will be trapped in the rapidly hardened polymer matrix of the formed nail coating. The current and anticipated use concentrations in the gels are in the range between 0.5% - 5.0%.

The SCCS is of the opinion that Trimethylbenzoyl diphenylphosphine oxide (TPO) is safe when used as a nail modelling product at a concentration of at maximum 5.0%.

Cosmetics Europe considers Trimethylbenzoyl diphenylphosphine oxide (TPO) a CMR substance and requires additional notification on electronic portals. CMR substances are substances that are carcinogenic, mutagenic or toxic to reproduction (CMR). They are of specific concern due to the long term and serious effects that they may exert on human health. Under GHS, CMR substances can be classified into 3 categories depending on the severity of hazards. Trimethylbenzoyl diphenylphosphine oxide (TPO) is classed as CMR 2. CMR Category 2 defines a substance which is a suspected carcinogen (H341), mutagen (H351) or reproductive toxicant (H361) based on limited evidence from animal and/or human studies.

OXFORD BIOSCIENCES
Safety Assessment, Analysis, Research & Testing

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

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

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

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.

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

5. Normal and reasonably foreseeable use

The current label advice:

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. For professional use only.

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

OXFORD BIOSCIENCES
Safety Assessment, Analysis, Research & Testing

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

7. Exposure to the ingredients

	Ingredient INCI name	Concentration	SED
1	Acrylates copolymer	0.68000	0.00286
2	HEMA	0.20000	0.00084
3	Trimethylbenzoyl diphenylphosphine oxide	0.04000	0.00017
4	Pentaerythrityl tetramercaptopropionate	0.08000	0.00034

***SED**: Systemic Exposure Dose*

OXFORD BIOSCIENCES
Safety Assessment, Analysis, Research & Testing

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

8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Acrylates copolymer	700280.11200
2	HEMA	6011904.76190
3	Trimethylbenzoyl diphenylphosphine oxide	29761904.76190
4	Pentaerythrityl tetramercaptopropionate	3446428.57140

***MOS**: Margin of Safety*

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

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.

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

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

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

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.

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.

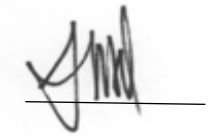
Oxford Biosciences Ltd.
Magdalen Centre,
The Oxford Science Park,
Oxford OX4 4GA
+44 (1865) 419110

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