OXFORD BIOSCIENCES
Safety Assessment, Analysis, Research & Testing

Oxford Biosciences Ltd.
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COSMETIC PRODUCT SAFETY REPORT

PRODUCT: Well Gel

DATE: 11 September 2019

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PART A – Cosmetic Product Safety Information

1. Quantitative and qualitative composition

	Ingredient INCI name	CAS	Function	Limits	Amount
1	Di-HEMA trimethylhexyl dicarbamate	41137-60-4 /	Film forming		75.00
2	Hema	868-77-9	Film forming		25.00
3	Bis-Trimethylbenzoyl phenylphosphine	162881-26-7	Skin conditioning		5.00
4	Hydroxycyclohexyl phenyl ketone	947-19-3	Binding		5.00
5	CI 77492	51274-00-1	Cosmetic colorant	IV/136	5.00
6	CI 77891	13463-67-7	Cosmetic colorant	IV/143	5.00
7	CI 77491	1309-37-1 / 1345	Cosmetic colorant	IV/135	5.00
8	CI 77510	14038-43-8 /	Cosmetic colorant	IV/138	5.00
9	CI 77289	1308-14-1 /	Cosmetic colorant	IV/1	5.00
10	CI 77266	1333-86-4 / 7440	Cosmetic colorant	IV/126	5.00
11	CI 77742	10101-66-3	Cosmetic colorant	IV/140	5.00

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

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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 **Di-HEMA trimethylhexyl dicarbamate**

Di-HEMA trimethylhexyl dicarbamate, with chemical name 7,7,9 (or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate is an active component of topically applied artificial nail modelling systems cured by ultraviolet (UV) light. The Di-HEMA trimethylhexyl dicarbamate is used as film forming ingredient in nail products, where they are consumed within a few seconds to minutes during the polymerization induced by the UV-curing process.

Based on available data, the CIR Expert Panel concluded that Di-HEMA trimethylhexyl dicarbamate is safe as used in nail enhancement products when skin contact is avoided. Products containing these ingredients should be accompanied with directions to avoid skin contact, because of the sensitizing potential.

Ref. 1. 2 **Hema**

Hema, with chemical name 2-hydroxyethyl methacrylate is an active componentsof topically applied artificial nail modelling systems cured by ultraviolet (UV) light. The methacrylate ester monomers HEMA is used as film forming ingredient in nail products, where they are consumed within a few seconds to minutes during the polymerization induced by the UV-curing process.

Ref. 1. 3 **Bis-Trimethylbenzoyl phenylphosphine oxide**

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.

Ref. 1. 4 **Hydroxycyclohexyl phenyl ketone**

Hydroxycyclohexyl phenyl ketone is used as photoinitiator in UV-radiation-curable technologies which are used in various applications.

Ref. 1. 5 **CI 77492**

CI 77492, also known as iron oxide yellow. CI 77492 may be safely used for colouring cosmetics and personal care products. Molecular formula: $Fe_2O_3 \cdot H_2O$

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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 77891**

Titanium dioxide, pigment white or titanium white, is the naturally occurring oxide of titanium with the molecular formula TiO_2. 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 α-PbO_2-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.

Ref. 1. 7 **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. 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 **CI 77289**

CI 77289 also known as dochromiun trioxide, chromie oxide hydrated. CI 77289 may be safely used for colouring cosmetics and personal care products.

Ref. 1. 10 **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

Ref. 1. 11 **CI 77742**

Also known as ammonium manganese(3+) diphosphate or manganese violet. . CI 77742 may be safely used for colouring cosmetics and personal care products. Molecular formula: $H_4MnNO_7P_2$

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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	Cream/Paste/Gel
Colour	Various
Aroma	Fragrance free
pH	n/a

*RP: Responsible Person: Well Gel Ltd.

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 period.

2.2.1 Well Gel Ltd. confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 Well Gel Ltd. uses a PAO based on the results of Well Gel Ltd.'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.

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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 1. Quantitative and qualitative composition – specification of ingredients) submitted by ingredient suppliers, the ingredients do not contain impurities or trace amounts of forbidden substances.

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.

Well Gel Ltd. 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:

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	Di-HEMA trimethylhexyl dicarbamate	0.75000	0.00315
2	Hema	0.25000	0.00105
3	Bis-Trimethylbenzoyl phenylphosphine oxide	0.05000	0.00021
4	Hydroxycyclohexyl phenyl ketone	0.05000	0.00021
5	CI 77492	0.05000	0.00021
6	CI 77891	0.05000	0.00021
7	CI 77491	0.05000	0.00021
8	CI 77510	0.05000	0.00021
9	CI 77289	0.05000	0.00021
10	CI 77266	0.05000	0.00021
11	CI 77742	0.05000	0.00021

***SED:** Systemic Exposure Dose*

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8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Di-HEMA trimethylhexyl dicarbamate	3174603.17460
2	Hema	28571.42860
3	Bis-Trimethylbenzoyl phenylphosphine oxide	23809523.80950
4	Hydroxycyclohexyl phenyl ketone	11904761.90480
5	CI 77492	47619047.61900
6	CI 77891	119047619.04760
7	CI 77491	47619047.61900
8	CI 77510	23809523.80950
9	CI 77289	23809523.80950
10	CI 77266	38095238.09520
11	CI 77742	23809523.80950

***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 Well Gel Ltd.
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.
The Oxford Science Park
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Oxfordshire
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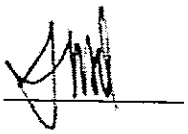
Experience and qualifications:

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



11 September 2019

Signature *Date*