OXFORD BIOSCIENCES
Safety Assessment, Analysis, Research & Testing

Oxford Biosciences Ltd.
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# COSMETIC PRODUCT SAFETY REPORT

**PRODUCT:** Invisible Gloves

**DATE:** 15 May 2020

Responsible Person: Giovanna Mantini
**Dani & Jo Ltd**
[redacted]
Arundel BN18 0LE

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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 **Alcohol denat**

Alcohol is the name given by convention to ethanol as used in cosmetics, and Alcohol denat. is the name given to denatured Alcohol for use in cosmetics. Alcohol denat. is prepared by adding one or more denaturing agents to potable Alcohol, making it unfit for beverage or internal human medicinal use. Alcohol may be completely denatured (CD Alcohol) or specially denatured (SD Alcohol) depending on the type(s) of denaturant(s) used. Alcohol Denat. and SD Alcohols can be prepared using a wide variety of denaturants. Because dermal application or inhalation of cosmetic products containing these ingredients will not produce significant systemic exposure to ethanol (also known as Alcohol for purposes of cosmetic ingredient labelling), the Cosmetic Ingredient Review (CIR) Expert Panel concluded that safety of the ingredients should be predicated on the safety of the denaturants used. The Panel considered that the adverse effects known to be associated with Alcohol ingestion included in this safety assessment do not suggest a concern for Alcohol Denat. or SD Alcohols because of the presence of the denaturants, which are added for the express purpose of making the Alcohol unpotable. The CIR Expert Panel has previously conducted safety assessments of t-Butyl alcohol, Diethyl phthalate, Methyl alcohol, Salicylic acid, Sodium salicylate, and Methyl salicylate in which each was affirmed safe or safe with qualifications. Given their use as denaturants are at low concentrations of use in Alcohol, the CIR Expert Panel determined that Alcohol denat. denatured with t-Butyl alcohol, Diethyl phthalate, Methyl alcohol, Salicylic acid, Sodium salicylate, and Methyl salicylate is safe as used in cosmetic formulations with no qualifications. Likewise, because they are denatured with either t-Butyl Alcohol, Diethyl phthalate, or Methyl alcohol, SD Alcohols 3-A, 30, 39-B, 39-C, and 40-C all are considered safe as used. The available data, however, were not sufficient to support the safety of Quassin, Brucine, and Brucine sulfate, Alcohol denat. denatured with those denaturants, or SD Alcohol 39 and SD Alcohol 40 (because these SD Alcohols are denatured with Quassin, Brucine, and/or Brucine sulfate). In 2008 the CIR Expert Panel concluded that Alcohol denat., SD Alcohol 3-A, SD Alcohol 30, SD Alcohol 39-B, SD Alcohol 39-C, SD Alcohol 40-B, and SD Alcohol 40-C denatured with t-Butyl alcohol, Denatonium benzoate, Diethyl phthalate, or Methyl alcohol are safe in the practices of use and concentration as described in this safety assessment, and, that Denatonium benzoate is safe as a denaturant. The CIR Expert Panel concluded that the available data are insufficient to support the safety of Alcohol Denat., SD Alcohol 39, and SD Alcohol 40 denatured with Quassin, Brucine, and Brucine sulfate in cosmetic products, and that the available data are insufficient to support the safety of Quassin, Brucine, and Brucine sulfate as denaturants. RP has confirmed that the denaturant in this product is not Quassin, Brucine, or Brucine sulfate.

#### Ref. 1. 2 **Aqua**

Aqua (water) is a liquid at standard temperature and pressure with the chemical formula $H_2O$: one molecule of water has two hydrogen atoms covalently bonded to a single oxygen atom.

#### Ref. 1. 3 **Methyl salicylate**

Methyl salicylate is the methyl ester of Salicylic acid with the formula $C_8H_8O_3$. The safety of Salicylic acid and its salts and esters has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated scientific data and concluded that Methyl salicylate was safe as used when formulated to avoid skin irritation and when formulated to avoid increasing the skin's sun sensitivity, or, when increased sun sensitivity would be expected, directions for use include the daily use of sun protection.

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Ref. 1. 4 **Diethyl phthalate**

Diethyl phthalate (DEP) is a phthalate ester, the diethyl ester of phthalic acid with the molecular formula $C_{12}H_{14}O_4$. Diethyl phthalate is produced by the reaction of phthalic anhydride (the anhydride of phthalic acid) with ethanol in the presence of a catalytic amount of concentrated sulphuric acid. In 1985 the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Diethyl phthalate is safe for use as a cosmetic ingredient in the present practice of use and concentration detailed in this safety assessment. In 2012 the CIR Expert Panel reconfirmed that conclusion.

Ref. 1. 5 **Ricinus communis seed oil**

Ricinus communis seed oil is the fixed oil obtained from the seeds of Castor, Ricinus communis, Euphorbiaceae.

Typical fatty acid profile:

| | |
|---|---|
| Ricinoleic acid | 85-95% |
| Oleic acid | 2-6% |
| Linoleic acid | 1-5% |
| α-Linolenic acid | 0.5-1% |
| Stearic acid | 0.5-1% |
| Palmitic acid | 0.5-1% |
| Dihydroxystearic acid | 0.3-0.5% |
| Others | 0.2-0.5% |

Ref. 1. 6 **Glycerin**

Glycerin, or glycerol, is a simple polyol compound, with three hydroxyl groups, which is a colourless, odourless, viscous liquid. Glycerin is naturally occurring in all animals and plant matter in combined form as glycerides in fats and oils, or, in intracellular spaces, as lipids. The glycerol backbone is central to all triglycerides, and its molecular formula is $C_3H_8O_3$. In December 2014 the Cosmetic Ingredient Review (CIR) Expert Panel also noted the high frequency of use that is reported for glycerin and the low instances of reports of toxicity, irritation, and sensitisation and that glycerin is GRAS for food packaging and as a multiple-purpose food substance. When considering the safety of glycerin, the Panel noted that it is naturally occurring in animal and human tissues, including the skin and blood. The data demonstrated low oral and dermal toxicity for multiple animal species and humans, in both acute and long-term studies. The CIR Expert Panel concluded that glycerin is safe in the present practices of use and concentration described in this safety assessment.

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See section 1. Quantitative and qualitative composition – additional specification of ingredients.

Ref. 1. 7 **Panthenol**

Panthenol is the alcohol analogue of pantothenic acid thus is a provitamin of B5. Panthenol is a highly viscous transparent liquid at room temperature. It is soluble in water, alcohol and propylene glycol, soluble in ether and chloroform, and slightly soluble in glycerin. The US Food and Drug Administration (FDA) includes Panthenol (also called D-Pantothenyl alcohol) on its list of nutrients (Panthenol is a B vitamin) and/or dietary supplements Generally Recognised As Safe (GRAS). The safety of Panthenol was assessed by the Cosmetic Ingredient Review (CIR) Expert Panel in 1987. The CIR Expert Panel evaluated the scientific data and concluded that Panthenol is safe for use in cosmetics and personal care products. In 2004, the CIR Expert Panel considered available new data on Panthenol and reaffirmed the above conclusion.

Ref. 1. 8 **Xanthan gum**

Xanthan gum is a high molecular weight heteropolysaccharide gum secreted by the bacterium Xanthomonas campestris, commonly used as a food additive, rheology modifier, and a stabiliser with the molecular formula $C_{35}H_{49}O_{29}$. It is composed of pentasaccharide repeat units, comprising glucose, 6-acetyl mannose, 4,6-pyruvylated mannose and glucuronic acid in the molar ratio 2.0:2.0:1.0. Xanthan gum is produced by a pure culture fermentation of a carbohydrate (glucose, sucrose, or lactose) with Xanthomonas campestris and is composed of glucose, glucuronic acid, 6-acetyl mannose and 4,6-pyruvylated mannose residues. After a fermentation period, the polysaccharide is precipitated from a growth medium with isopropyl alcohol, dried, and ground into a fine powder. Xanthan gum has a long history of safe use worldwide. It was approved for use in foods in 1968 and is accepted as a safe food additive in the USA, Canada, and European countries, with the E number E415. In 2016 the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Xanthan gum is safe in the present practices of use and concentration, as described in this safety assessment.

Ref. 1. 9 **Sodium hyaluronate**

Sodium hyaluronate is the sodium salt of hyaluronic acid, a glycosaminoglycan found in various connective, epithelial, and neural tissues. Sodium hyaluronate is a long-chain polymer containing repeating disaccharide units of Na-glucuronate-N-acetylglucosamine.

The safety of Sodium hyaluronate has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Sodium hyaluronate was safe as a cosmetic ingredient.

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See section 1. Quantitative and qualitative composition – additional specification of ingredients.

#### Ref. 1. 10 **Phenoxyethanol**

Phenoxyethanol is an aromatic glycol ether with an alcohol moiety, used in cosmetics as a preservative at concentrations below 1%, with the molecular formula $C_8H_{10}O_2$ . Phenoxyethanol is made by reacting phenol with ethylene oxide in the presence of a basic catalyst under pressure and with heating; the resulting product is neutralised, and purified to the point where 4-8% of the Phenoxyethanol is converted to the diethoxylate, thereby reducing the free phenol content. In 1990 the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Phenoxyethanol is safe for use as a cosmetic ingredient in the present practice of use and concentration detailed in this safety assessment. In 2011 The CIR Expert Panel reconfirmed that conclusion.

#### Ref. 1. 11 **Ethylhexylglycerin**

Ethylhexylglycerin is an alkyl glyceryl ether in which the ethylhexyl group is bound to glycerin at one end by an ether linkage as the condensation product of 2-ethylhexanol and glycerin. Its molecular formula is $C_{11}H_{24}O_3$

Ethylhexylglycerin's efficacy as a preservative enhancer is derived by reducing interfacial tension on the cellular walls of micro-organisms, promoting rapid destruction across a wider spectrum. In 2013 the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Ethylhexylglycerin is safe for use as cosmetic ingredient in the present practice of use and concentration detailed in this safety assessment.

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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** | White |
| **Aroma** | Fragrance free |
| **pH** | 5.0 |

*RP: Responsible Person: Dani & Jo 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 BBE period.

2.2.1 Dani & Jo Ltd confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 Dani & Jo Ltd uses a BBE based on the results of Dani & Jo 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** | Tin |
| **Container Material** | Epoxy phenolic lined aluminium |
| **Airless Container** | No |

EPA is an epoxy phenolic resin. Phenolic resins are prepared by the reaction of phenol or substituted phenol with an aldehyde, especially formaldehyde, in the presence of an acidic or basic catalyst. With a large global production representing 1-5 million tonnes/year, these resins are ubiquitous and therefore have a long history of safe use. EPA polymers are high modulus, relatively heat resistant, and have good properties against chemical leaching.

The supplier provided test results which confirmed the epoxy did not leach into products in the containers.

Dani & Jo 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:

*Not for human or animal consumption.*

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. Flammable. Keep away from heat or flame. Do not use on children less than 2 months or on open wounds. When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Store between 15-30°C.*

6. Exposure to the cosmetic product

| | |
|---|---|
| Area of application | Hands |
| Product type: Leave-on or Rinse-off | Leave On |
| Duration and frequency | 8 |
| Possible additional routes of exposure | Body |
| Estimated skin surface area ($cm^2$) | 860 |
| Estimated amount of the product applied according to the SCCS (g/day) | 8 g |
| Estimated retention factor according to the SCCS | 1 |
| Target group | Adult |
| Calculated relative daily exposure according to the SCCS (mg/kg bw/day) | 13.08 |

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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.

In line with WHO guidelines, recommending a minimum value of 100, it is generally accepted that the MoS should at least be 100 to conclude that a substance is safe for use. Since the ingredients used in this formulation have a long worldwide history of use and have an MOS value above 100 then the conclusion is that they are safe for use in this formulation

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 Dani & Jo 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. Flammable. Keep away from heat or flame. Do not use on children less than 2 months or on open wounds. When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Store between 15-30ºC.*

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
Magdalen Centre
Oxfordshire
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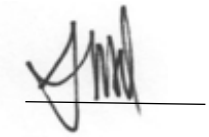
Experience and qualifications:

- 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



*Signature*

15 May 2020

*Date*