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COSMETIC PRODUCT SAFETY REPORT

PRODUCT: Sanitex Instant Hand Gel 800 ml TEXRH016-B

DATE: 21 May 2021

Responsible Person: Robert Dix
Vectair Systems Ltd
Unit 3, Trident Centre
Armstrong Road
Basingstoke, Hampshire RG24 8NU

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Safety Assessment, Analysis, Research & Testing

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PART A – Cosmetic Product Safety Information

1. Quantitative and qualitative composition

	Ingredient INCI name	CAS	Function	Limits	Amount
1	Alcohol	64-17-5	Antifoaming, antimicrobial,		70.00
2	Aqua	7732-18-5	Solvent		27.804962
3	Glycerin	56-81-5	Denaturant, hair		1.0062
4	Isopropyl alcohol	67-63-0	Antifoaming, perfuming,		0.6970
5	Carbomer	9007-20-9 / 9003	Emulsion stabilising, gel		0.3
6	Aminomethyl propanol	124-68-5	Buffering		0.107350
7	t-Butyl alcohol	75-65-0	Denaturant, perfuming,		0.0836
8	Denatonium benzoate	3734-33-6	Denaturant, fragrance		0.000888

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 **Alcohol**

Alcohol (Ethyl alcohol, Ethanol) is a 2-carbon alcohol in which the carbon of a methyl group (CH3–) is attached to the carbon of a methylene group (–CH2–), which is attached to the oxygen of a hydroxyl group (–OH). Alcohol has the molecular formula C_2H_6O.
The US Food and Drug Administration (FDA) includes Alcohol on its list of food additives allowed to be added directly to food as a diluent in colour additives for marking food.

The majority of Alcohol evaporates upon dermal contact. Extensive studies (including "Quantity of ethanol absorption after excessive hand disinfection ..."; Kramer A., Below H. et al) have proven that the highest absorbed amount of Alcohol (Ethanol) is 1.1%. Alcohol has a long history of safe use in both perfumery and dermal sanitation.

In 2008 the Cosmetic Ingredient Review Expert Panel reviewed the scientific evidence and concluded that Alcohol is safe in its practice of use and concentration as described in this safety assessment.

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 **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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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. 4 **Isopropyl alcohol**

Isopropyl alcohol is a secondary alcohol, with the molecular formula C_3H_8O. Isopropyl alcohol occurs in nature in crude fusel oils and as fermentation and decomposition product of various vegetables. Isopropyl alcohol is primarily manufactured by the indirect hydration of propene. First, a mixture of mono- and diisopropyl sulfate esters is formed from reaction of propene with sulfuric acid. The sulfate esters are then hydrolysed to product 2-propanol in a second step. The Food and Drug Administration (FDA) includes Isopropyl alcohol on its list of food additives allowed to be added directly to food as a flavouring or adjuvant. Isopropyl alcohol is also on the list of secondary direct food additives allowed for use as solvents, lubricants, release agents, and related substances.

The majority of Isopropyl alcohol evaporates upon dermal contact. Extensive studies (including 'Dermal and pulmonary absorption of propan-1-ol and propan -2-ol from hand rubs'; Below H. et al) have proven that the highest absorbed amount of Isopropyl alcohol (propan-2-ol) is 0.5%.

In 2012 the Cosmetic Ingredient Review Expert Panel reviewed the scientific evidence and concluded that Isopropyl alcohol is safe in its practice of use and concentration as described in this safety assessment.

Ref. 1. 5 **Carbomer**

Carbomer is a synthetic, high molecular weight, nonlinear polymer of acrylic acid, cross-linked with a polyalkenyl polyether. The Carbomer polymers are used in cosmetics and emulsifying agents at concentrations up to 50%. Acute oral animal studies showed that Carbomers-910, -934, -934P, -940, and -941 have low toxicities when ingested. These polymers are hygroscopic and, when exposed to sunlight, they undergo oxidative degradation. Reported impurities for the Carbomer resins include water, benzene, propionic acid, acetic acid, acrylic acid, heavy metals, iron, arsenic, and lead. In 1982 the Cosmetic Ingredient Review Expert Panel called attention to the presence of benzene as an impurity in Carbomers and recommended that every effort be made to reduce it to the lowest possible value. In 1982 the CIR Expert Panel concluded that on the basis of the available information presented and as qualified in the report, the Carbomers are safe as cosmetic ingredients. In its re-review published in March 2003 the Panel acknowledged the industry practice of removing benzene from Carbomers resulting in levels which should be below those shown to have no risk to human health. In its re-review published in 2003 the Panel concluded that the Carbomers are safe as cosmetic ingredients in the present practices of use and concentration.

Ref. 1. 6 **Aminomethyl propanol**

Aminomethyl propanol is a clear, colorless liquid that neutralizes acids to form salts and water. It is an alkanolamine with the molecular formula $C_4H_{11}NO$.

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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 **t-Butyl alcohol**

t-Butyl alcohol is a tertiary aliphatic alcohol that is used as a solvent or an alcohol denaturant and as a perfume carrier in cosmetics. In 2005 the Cosmetic Ingredient Review (CIR) Expert Panel concluded that t-Butyl alcohol is safe for use as a cosmetic ingredient in the present practice of use and concentration detailed in this safety assessment.

Ref. 1. 8 **Denatonium benzoate**

Denatonium benzoate s a quaternary ammonium cation. It is a compound of a salt with an inert anion like benzoate or saccharide with the molecular formula $C_{28}H_{34}N_2O_3$.

Denatonium benzoate has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel and found safe for use in cosmetic products.

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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	Colourless
Aroma	Fragrance Free
pH	7.0-7.5

*RP: Responsible Person: Vectair Systems 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 period.

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

2.2.2 Vectair Systems Ltd uses a based on the results of Vectair Systems Ltd 's stability testing, including shelf life stability testing.

2.2.3 This product was subjected to Preservative Efficacy Testing and proved that it did not support microbial growth. PET reference: PET not required due to high level of alcohol.

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).

This product was subjected to Preservative Efficacy Testing and proved that it did not support microbial growth. PET reference: PET not required due to high level of alcohol.

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	LDPE
Airless Container	No

Low-density polyethylene (LDPE) is a thermoplastic made from the monomer ethylene. It is not reactive at room temperatures, except by strong oxidising agents, and some solvents cause swelling. It can withstand temperatures of 80 °C continuously, and 95 °C for a short time. LDPE offers excellent resistance to dilute and concentrated acids, alcohols, bases and esters, good resistance to aldehydes, ketones and vegetable oils, and only limited resistance to aliphatic and aromatic hydrocarbons, mineral oils, and oxidising agents. LDPE is susceptible to UV degradation where tertiary carbon bonds in its chain structures are the centres of attack. The ultra-violet rays activate these bonds to form free radicals, which then react further with oxygen in the atmosphere, producing carbonyl groups in the main chain. The exposed surfaces of products may then discolour and crack, although in bad cases, complete product disintegration can occur. Since LDPE is liable to chain degradation from exposure to heat and sunlight (a source of UV radiation) unless antioxidants have been added to the polymer to prevent polymer degradation, normal label warnings to store the product in cool and dark conditions apply.

Vectair Systems 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:

For external use only. Keep out of the reach of children. Flammable. Keep away from heat or flame. Avoideye contact. Store between 15-30 C

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.

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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7. Exposure to the ingredients

	Ingredient INCI name	Concentration	SED
1	Alcohol	0.70000	9.15600
2	Aqua	0.27805	3.63689
3	Glycerin	0.01006	0.13161
4	Isopropyl alcohol	0.00697	0.09117
5	Carbomer	0.00300	0.03924
6	Aminomethyl propanol	0.00107	0.01404
7	t-Butyl alcohol	0.00084	0.01093
8	Denatonium benzoate	0.00001	0.00012

***SED**: Systemic Exposure Dose*

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8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Alcohol	77107.90740
2	Aqua	27496.02730
3	Glycerin	95736.70760
4	Isopropyl alcohol	140400.75640
5	Carbomer	50968.39960
6	Aminomethyl propanol	206532.40640
7	t-Butyl alcohol	320076.67210
8	Denatonium benzoate	5578973.46890

***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 Vectair Systems 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 15-30°C.

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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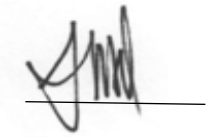
Experience and qualifications:

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



Signature

21 May 2021

Date