



OXFORD BIOSCIENCES
Safety Assessment, Analysis, Research & Testing

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COSMETIC PRODUCT SAFETY REPORT

PRODUCT: Sanitex Luxury Liquid 800 ml TEXRL016-B

DATE: 21 May 2021

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



PART A – Cosmetic Product Safety Information

1. Quantitative and qualitative composition

	Ingredient INCI name	CAS	Function	Limits	Amount
1	Aqua	7732-18-5	Solvent		85.2179
2	Sodium laureth sulfate	3088-31-1 / 9004	Cleansing, emulsifying,		7.70
3	Cocamidopropyl betaine	61789-40-0	Antistatic, cleansing, foam		2.32
4	Sodium Chloride	7647-14-5	Bulking, fragrance, oral		1.987
5	Glycerin	56-81-5	Denaturant, hair		1.032
6	Coco-glucoside	110615-47-9	Cleansing, foaming,		0.31
7	Glyceryl oleate	25496-72-4 / 111	Emollient, emulsifying,		0.31
8	Styrene/acrylates copolymer	9010-92-8	Film forming, opacifying		0.30
9	Parfum		Fragrance, perfuming		0.30
10	Citric acid	77-92-9 / 5949	Buffering, chelating,		0.245
11	Sodium benzoate	532-32-1	Anticorrosive, fragrance,	V/1	0.18
12	Potassium Sorbate	24634-61-5 / 590	Preservative	V/4	0.09
13	Sodium lauryl sulfate	151-21-3	Cleansing, denaturant,		0.0075
14	Sodium hydroxide	1310-73-2	Buffering, denaturant	III/15a	0.0003
15	Tocopherol	1406-66-2 /	Antioxidant, fragrance, skin		0.0002
16	Hydrogenated palm glycerides citrate	91744-68-2	Emollient, skin conditioning		0.0001

Allergens present in this product and estimated amounts*:

Hexyl cinnamal: 0.06%; Benzyl Salicylate: 0.015%; Linalol: 0.015%; Alpha-isomethylionone: 0.015%; Hydroxycitronellal: 0.003%; Citral: 0.003%; Limonene: 0.015%

* 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 **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. 2 **Sodium laureth sulfate**

Sodium laureth sulfate, also known as sodium lauryl ether sulfate (SLES), is an anionic detergent and surfactant used as a foaming agent in personal care products. SLES is prepared by ethoxylation of dodecyl alcohol. The resulting ethoxylate is converted to a half ester of sulfuric acid, which is neutralized by conversion to the sodium salt. Its molecular formula is $CH_3(CH_2)_{11}(OCH_2CH_2)_nOSO_3Na$.

Ref. 1. 3 **Cocamidopropyl betaine**

Cocamidopropyl betaine (CAPB), a zwitterionic compound consisting of both a quaternary ammonium cation and a carboxylate with the molecular formula $C_{19}H_{38}N_2O_3$, is used primarily by the cosmetic industry as a pseudoamphoteric surfactant in shampoos, conditioners, and other cleansing preparations. CAPB is considered a pseudoamphoteric because the quaternary nitrogen of the betaine group cannot donate a proton at pHs above its pKa, never becoming anionic. Manufacture of CAPB involves preparation of dimethylaminopropyl cocoamide (3-cocamidopropyldimethylamine) by reacting coconut oil or (hydrolysed, glyceryl-free) coconut acid with dimethylaminopropylamine in aqueous solution. The dimethylaminopropyl cocoamide, a tertiary amine, is then reacted with sodium chloroacetate to form CAPB and sodium chloride. In 2012 the Cosmetic Ingredient Review Expert Panel reasserted its 1991 conclusion that Cocamidopropyl betaine is safe in cosmetic products in its current concentration as described in this safety assessment when formulated to be non-sensitising.

Ref. 1. 4 **Sodium Chloride**

Sodium chloride, also known as salt, common salt, or halite, is a compound with equal proportions of sodium and chlorine with the molecular formula $NaCl$ representing a 1:1 ratio of sodium and chloride ions. In addition to being an important component of food, the US FDA includes Sodium chloride on its list of substances considered Generally Recognised as Safe (GRAS) as a substance migrating to food from packaging. The Cosmetic Ingredient Review (CIR) has deferred evaluation of this ingredient because the safety has already been assessed by FDA. Sodium chloride is commonly consumed and presents no safety issues whatsoever in this cosmetic product.

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. 5 **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.

Ref. 1. 6 **Coco-glucoside**

Coco-glucoside is an alkyl glucoside produced by the condensation of coconut alcohol with glucose. The Duhring Chamber Test lists Coco-glucoside as having the lowest irritation score of all common surfactants. In 2013, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Coco-glucoside is safe in the present practices of use and concentration when formulated to be non-irritating.

Ref. 1. 7 **Glyceryl oleate**

Glyceryl oleate is composed of glycerin and oleic acid, a naturally occurring fatty acid. Molecular formula: $C_{21}H_{38}O_5$

The Food and Drug Administration (FDA) includes Glyceryl oleate on its list of direct food substances considered Generally Recognized As Safe (GRAS). The safety of Glyceryl oleate has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Glyceryl oleate was safe as a cosmetic ingredient in the present practices of use and concentration. In 2004, as part of the scheduled re-evaluation of ingredients, the CIR Expert Panel considered available new data on Glyceryl oleate and reaffirmed the above conclusion.

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. 8 **Styrene/acrylates copolymer**

Styrene/acrylates copolymer is a polymer of styrene and a monomer consisting of acrylic acid, methacrylic acid or one of their simple esters.

The Food and Drug Administration (FDA) has reviewed the safety of Styrene/acrylates copolymer and permits the use as indirect food additives for use in coatings of food packaging. 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 Styrene/acrylates copolymer was safe for use in cosmetics and personal care products when formulated to avoid skin irritation.

Ref. 1. 9 **Parfum**

Ref. 1. 10 **Citric acid**

Citric acid is a hygroscopic α and β hydroxytricarboxylic acid, naturally found in citrus fruits, with the molecular formula $C_6H_8O_7$. Structurally Citric acid is an α -hydroxy acid (AHA) and is a slightly stronger acid than typical carboxylic acids because the anion can be stabilised by intramolecular hydrogen-bonding from other protic groups on citric acid. Industrial Citric acid is produced by mycological fermentation of crude sugar stocks by strains of *Aspergillus niger*. The FDA has listed Citrus acid as Generally Recognized As Safe (GRAS) and it is commonly used in the food industry as an acidifier and flavouring agent and has the food additive number E330. In 2014 the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Citric acid is safe in the present practices of use and concentration, as described in this safety assessment.

Ref. 1. 11 **Sodium benzoate**

Sodium benzoate is the sodium salt of benzoic acid with the molecular formula $C_7H_5NaO_2$ and is a widely used food preservative, with the E number E211. In 2001 the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Sodium benzoate is safe to use in cosmetic products. In September 2011 the CIR Expert Panel reassessed Sodium benzoate and reconfirmed that it is safe in the present practices of use and concentration as described in this safety assessment.

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. 12 **Potassium Sorbate**

Potassium sorbate is the potassium salt of sorbic acid with the molecular formula $C_6H_7KO_2$. Potassium sorbate is prepared by reacting sorbic acid with an equimolar portion of potassium hydroxide. The US Food and Drug Administration (FDA) reviewed the safety of Potassium sorbate and determined that it was Generally Recognised As Safe (GRAS) as preservatives for direct addition to food. The safety of Potassium sorbate has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Potassium sorbate is safe for use in cosmetics and personal care products. In 2006, as part of the scheduled re-evaluation of ingredients, the CIR Expert Panel considered available new data on Potassium sorbate and reaffirmed the above conclusion.

Ref. 1. 13 **Sodium lauryl sulfate**

Sodium lauryl sulfate (SLS), Sodium dodecyl sulfate (SDS or NaDS), sodium lauril sulfate is an organic compound with the formula $CH_3(CH_2)_{11}OSO_3Na$. SLS is synthesised by treating lauryl alcohol with sulfur trioxide gas (commonly), oleum, or chlorosulfuric acid to produce hydrogen lauryl sulfate. The resulting product is then neutralised by adding sodium hydroxide or sodium carbonate. SLS is a salt of an organosulfate consisting of a 12-carbon tail attached to a sulfate group, giving the material the amphiphilic properties required of a detergent and is used as an anionic surfactant in many cleaning and hygiene products.

Ref. 1. 14 **Sodium hydroxide**

Sodium hydroxide is a metallic base and alkali salt with the molecular formula NaOH. It is produced by treating oxides with water, known as brine electrolysis. In June 2015 The Cosmetic Ingredient Review Expert Panel noted that in humans, sodium hydroxide was irritating at concentrations as low as 0.5%. The US Food and Drug Administration (FDA) includes Sodium hydroxide on its list of substances affirmed as Generally Recognised as Safe (GRAS) for direct addition to food. Sodium hydroxide is safe in the present practices of use and concentration as described in this safety assessment.

Ref. 1. 15 **Tocopherol**

Tocopherol is a series organic compounds with vitamin E activity consisting of various methylated phenols which feature a chromanol ring, with a free hydroxyl group on the aromatic ring that can donate a hydrogen atom to reduce free radicals, and a hydrophobic side chain which allows for penetration into biological membranes.

The Food and Drug Administration (FDA) includes Tocopherol on its list of nutrients considered Generally Recognized As Safe (GRAS).

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. 16 **Hydrogenated palm glycerides citrate**

Hydrogenated palm glycerides citrate is a citric acid ester of Hydrogenated palm glycerides.

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	Milky white
Aroma	Fresh
pH	5.00 - 7.00

*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 PAO 12M 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 PAO 12M 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: SM 021 20-1452

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).

This product was subjected to Preservative Efficacy Testing and proved that it did not support microbial growth. PET reference: SM 021 20-1452

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.

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	Hand
Product type: Leave-on or Rinse-off	Rinse Off
Duration and frequency	10
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)	20.00 g
Estimated retention factor according to the SCCS	.01
Target group	Adult
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	3.33

7. Exposure to the ingredients

	Ingredient INCI name	Concentration	SED
1	Aqua	0.85218	0.02838
2	Sodium laureth sulfate	0.07700	0.00256
3	Cocamidopropyl betaine	0.02320	0.00077
4	Sodium Chloride	0.01987	0.00066
5	Glycerin	0.01032	0.00034
6	Coco-glucoside	0.00310	0.00010
7	Glyceryl oleate	0.00310	0.00010
8	Styrene/acrylates copolymer	0.00300	0.00010
9	Citric acid	0.00245	0.00008
10	Parfum	0.00300	0.00010
11	Sodium benzoate	0.00180	0.00006
12	Potassium Sorbate	0.00090	0.00003
13	Sodium lauryl sulfate	0.00008	0.00000
14	Sodium hydroxide	0.00000	0.00000
15	Tocopherol	0.00000	0.00000
16	Hydrogenated palm glycerides citrate	0.00000	0.00000

SED: Systemic Exposure Dose

8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Aqua	3523911.05980
2	Sodium laureth sulfate	780000.78000
3	Cocamidopropyl betaine	8931345.13820
4	Sodium Chloride	4533975.34420
5	Glycerin	36664571.54830
6	Coco-glucoside	79434272.98270
7	Glyceryl oleate	513416642.44890
8	Styrene/acrylates copolymer	50050050.05010
9	Citric acid	36771465.34290
10	Parfum	0.00000
11	Sodium benzoate	52385719.05240
12	Potassium Sorbate	164164164.16420
13	Sodium lauryl sulfate	515715715.71570
14	Sodium hydroxide	1001001001.00100
15	Tocopherol	75075075075.07510
16	Hydrogenated palm glycerides citrate	60060060060.06010

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 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.

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*:

Hexyl cinnamal: 0.06%; Benzyl Salicylate: 0.015%; Linalol: 0.015%; Alpha-isomethylionone: 0.015%; Hydroxycitronellal: 0.003%; Citral: 0.003%; Limonene: 0.015%

* 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.

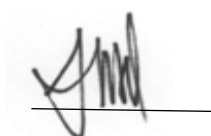
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The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

21 May 2021
Date