Colin's Cosmetic Consultancy Ltd
5 Lombard Street
Petworth
West Sussex
GU28 0AG

Product Safety Assessment

Blue Lagoon

Darlly Europe Limited

Reference	F4S002
Issue	1
Issue Date	29-Jun-20

Blue Lagoon

Sponsor

Darlly Europe Limited
Unit 18 Cedar Court
Halesfield 17
Telford
Shropshire

Part A

Section 1 - Quantitative and Qualitative Composition

Ingredient	CAS Number	%w/w
Sodium Chloride	7647-14-5	98.995
Parfum	n/a	1.005
Linalool	78-70-6	0.119
Amyl Cinnamal	122-40-7	0.043
Hexyl Cinnamal	101-86-0	0.036
Geraniol	106-24-1	0.027
Benzyl salicylate	120-51-4	0.014
Limonene	5989-27-5	0.014
Eugenol	97-53-0	0.011
Alpha Isomethyl ionone	127-51-5	0.008
Butylphenyl Methylpropianol	80-54-6	0.007

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CI 42090	2650-18-2 / 3844-45-9 / 68921-42-6 / 155792-67-3 / 71701-18-3 / 71701-19-4	0.000

Quantities below third decimal place not reported on this table, but have been used in calculations later in the report.

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Section 2 - Product Characteristics

Ingredient List

Sodium Chloride, Parfum, Linalool, Amyl Cinnamal, Hexyl Cinnamal, Geraniol, Benzyl salicylate, Limonene, Eugenol, CI 42090

Adult or Child Adult

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Section 3 - Microbiological Quality

Soap has a low water content and high pH. Consequently it raises no microbiological issues and its long history of very extensive problem free use confirms this. This reasoning is consistent with ISO 29621 Microbiology -- Guidelines for the risk assessment and identification of microbiologically low-risk products.

Section 4 - Impurities and packaging

This formulation does not contain any ingredients with toxicologically relevant impurities.

There are no known or likely interactions with the pack that have any safety implications.

Section 5 - Normal and Foreseeable Use

This product is intended for topical application to a limited body area in small quantities.

Section 6 - Exposure

Where Used This product is applied to the skin

Estimated Daily Amount Used 30 g

Frequency Of Use Daily

Assumed Body Weight 60 Kg

Rinse Status Rinse Off

Section 7 - Exposure to Ingredients

Ingredient	CAS Number	%w/w	Dose	SED	NOAEL	MoS
Sodium Chloride	7647-14-5	98.995	0.000	4.975		
Parfum	n/a	1.005	0.000	5.025		

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Linalool	78-70-6	0.119	0.000	0.593	500	843.785
Amyl Cinnamal	122-40-7	0.043	0.000	0.215	23	106.797
Hexyl Cinnamal	101-86-0	0.036	0.000	0.179		
Geraniol	106-24-1	0.027	0.000	0.136	1000	7358.64
Benzyl salicylate	120-51-4	0.014	0.000	0.072		
Limonene	5989-27-5	0.014	0.000	0.070	250	3571.68
Eugenol	97-53-0	0.011	0.000	0.054		
Alpha Isomethyl ionone	127-51-5	0.008	0.000	0.042	30	708.268
Butylphenyl Methylpropianol	80-54-6	0.007	0.000	0.036		
CI 42090	2650-18-2 / 3844-45-9 / 68921-42-6 / 155792-67-3 / 71701-18-3 / 71701-19-4	0.000	0.000	0.000	631	5736360

The Margin of Safety (MoS) is calculated by working out the maximum feasible exposure and comparing it to the level at which no adverse effect is observed (the NOAEL). If the MoS is 100 then the use level is one hundredth the level at which any effect is observed. Any level above 100 is considered to be acceptable.

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Section 8 - Toxicological Profile of Ingredients

Alpha Isomethyl Ionone 127-51-5

This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

Its use as a food additive has been considered by the World Health Organisation, who found that it raised no concerns.

A review of this material by the Research Institute for Fragrance Materials concluded that it posed no risk to human development.

The result of the margin of safety calculation is satisfactory.

Toxicol Sci 2006 Mar;90(1-S):190 Evaluation Of The Developmental Toxicity Of Alpha-Iso-Methylionone In Rats. Politano VT, Lewis EM, Hoberman AM, Christian MS, Diener RM, Api A

Safety evaluation of certain food additives. Ionones and structurally related substances WHO Food Additives Series Vol:42 (1999) pp 335-52

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Amyl Cinnamal 122-40-7

This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

Although listed as an allergen, sensitivity to this compound is rare. One study has investigated and suggested that cross sensitisation might be the explanantion for at least some of the small number of reports of allergic reaction to it.

It is used as a food additive which would be the main exposure for most people, and a small quantity applied topically is unlikely to have any toxic significance by comparison.

The result of the margin of safety calculation is acceptable.

J Am Acad Dermatol. 1983, Jan; 8(1):76-80.Sensitivity to alpha-amylcinnamic aldehyde and alpha-amylcinnamic alcohol Guin JD, Haffley P

Food Cosmet Toxicol; 11 (5). 1973 725-734 Short-term toxicity of amyl cinnamic aldehyde in rats. CarpaniniF MB, Gaunt IF, Wright MG, Grasso P, Gangolli SD

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Benzyl Salicylate 120-51-4

This material is rarely used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

The very high LD50 of this material in rats indicates an exceptionally low level of toxicity.

A survey of patch test data indicated that this material has a low level of potential to cause sensitisation reactions. A RIFM review classed it as a weak allergen.

In vitro work has indicated that benzyl salicylate does have a measurable level of estrogenic activity. This is indicative of a potential for carcinogenicty, but no other work supports this link. Given the widespread use of this material both in cosmetics and foodstuffs the weight of evidence must be that no such link exists.

No NOAEL figure is available, but it is possible to conculde that this material is safe even without carrying out a margin of safety calculation.

Food and Cosmetics Toxicology. Vol. 11, Pg. 1029, 1973.

Food Chem Toxicol. 1983 Dec;21(6):741-4. Benzyl salicylate: a survey of consumer patch-test sensitization. Kohrman KA, Booman KA, Dorsky J, Rothenstein AS, Sedlak RI, Steltenkamp RJ, Thompson GR.

Food Chem Toxicol. 2007;45 Suppl 1 Sep 14. Fragrance material review on benzyl salicylate. Lapczynski A1, McGinty D, Jones L, Bhatia S, Letizia CS, Api AM.

J Appl Toxicol. 2009 Jul;29(5):422-34. Oestrogenic activity of benzyl salicylate, benzyl benzoate and butylphenylmethylpropional (Lilial) in MCF7 human breast cancer cells in vitro. Charles AK1, Darbre PD.

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Butylphenyl Methylpropianol 80-54-6

Butylphenyl Methylpropianol is also known as Liliestralis 22 and lilial. It occurs in cosmetics only as a fragrance ingredient. It is required to be listed on the ingredient lists if its level exceeds 0.01% in a wash off product and 0.001% in a leave on product.

The SCCS reviewed fragrance ingredients with the potential to cause allergic reactions in 2011 and included Butylphenyl Methylpropianol in the list of ingredients for which there was evidence that allergic reactions were possible. It was a relatively low risk according to this analysis rating as only 2 points on a 5 point scale, the reference quoted being for an in vitro test rather than for actual incidence of allergic reactions in humans. Consequently the potential for the low level used in this product to cause any allergic reactions cannot be considered to be very great and is clearly well within the expected levels that would be associated with this kind of product.

No NOAEL value is avialable in the literature for this material, but its published LD50 values of 700mg/Kg in the mouse and 1390mg/Kg in the rat indicate that it has a very low level of toxicity and its low use level in this product reinforces the idea that this material is safe as used in this product even in the absence of a margin of safety calculation.

SCCS/1459/11 Scientific Committee on Consumer Safety Opinion on Fragrance Allergens in Cosmetic Products December 2011

Rifm. Local lymph node assay (LLNA) protocol summaries: Data presented at the 46th Congress of the European Societies of Toxicology. Research Institute for Fragrance Materials, Inc 2009.

National Technical Information Service. Vol. OTS053544

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CI 42090 2650-18-2 / 3844-45-9 / 68921-42-6 / 15

CI 42090 is the colour index number for Blue 1. The FDA reviewed the safety of Blue 1 and determined that it may be safely used in food, and for coloring cosmetics and personal care products.

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.

A 2004 review by the SCCS quotes an NOAEL of 631 for female oral consumption. Although the relevance to topical application is questionable, a MoS calculated using this value gives a margin that is extremely comfortable.

SCCNFP/0787/04 Opinion of the Scientific Committee on Cosmetic Products and Non Food Products intended for Consumers concerning Acid Blue 9 2004

Reports of fthe Scientific Committee on Cosmetology (seventh series) 1986

Eugenol 97-53-0

Eugenol's name derives from the latin name for cloves, and it is the main constituent of clove oil. It is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

Eugenol both as a flavouring agent itself and as a constituent in clove oil is used in cooking and consequently is widely ingested. Despite this it does have some toxic effects. Adverse effects from ingestion have been reported, but at levels considerably in excess of any foreseeable absorbtion across the skin even from the neat oil, indeed the FDA classify eugenol as Generally Recognised As Safe (GRAS). The Joint FAO/WHO Expert Committee on Food Additives (JECFA) established an Acceptable Daily Intake for Eugenol of up to 2.5 mg/kg body weight when used as a flavoring agent. No NOAEL is appropriate.

The use level in this formulation is well below the limit stipulated in the IFRA standard for this category of product.

IFRA Standards 48th Amendment

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Geraniol 106-24-1

Geraniol is pale-yellow oil with a rose odour.

This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

The MoS calculation despite its very conservative assumptions does not lead to any toxicological concerns.

The use level is well within the IFRA guideline for this material in this class of product, IFRA's main concern being to limit the risk of sensitisation.

Food and Chemical Toxicology Volume 46, Supplement 11, November 2008 Toxicologic and Dermatologic Assessment of Cyclic and Non-Cyclic Terpene Alcohols The RIFM EXPERT Panel, D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin,A.E. Rogers , J.H. Saurat , I.G. Sipesi, H. Tagami

Hexyl Cinnamal 101-86-0

Hexyl cinnamal is a derivative of cinnamaldehyde, the main component that gives cinnamon its distinctive flavour.

This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

The use level is well within the IFRA guideline for this material in this class of product, IFRA's main concern being to limit the risk of sensitisation. There is no obviously applicable NOAEL in the literature, but given the low level used in this product a MoS calculation is extremely unlikely to give rise to any reason for concern.

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Limonene 5989-27-5

Limonene is a terpene that is found in citrus fruits and consequently is commonly ingested. As such it is listed by the FDA as generally recognised as safe (GRAS). Given this, a NOAEL is not particularly relevant to the assessment of its safety. A review of flavouring ingredients by EFSA confirmed this assumption. Even so a value has been assigned to it and when an MoS is calculated it is acceptable.

This material is not often used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products. Its concentration in this product conforms to IFRA guidelines.

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) . Scientific Opinion on Flavouring Group Evaluation 25, Revision 2 (FGE.25Rev2): Aliphatic and aromatic hydrocarbons from chemical group 31 . EFSA Journal 2011; 9(6):2177. [126 pp.]. doi:10.2903/j.efsa.2011.2177. Available online: www.efsa.europa.eu/efsajournal

J Toxicol Environ Health B Crit Rev. 2013;16(1):17-38. doi: 10.1080/10937404.2013.769418.
Safety evaluation and risk assessment of d-Limonene. Kim YW, Kim MJ, Chung BY, Bang du Y, Lim SK, Choi SM, Lim DS, Cho MC, Yoon K, Kim HS, Kim KB, Kim YS, Kwack SJ, Lee BM.

IFRA Standards 20

Linalool 78-70-6

This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

The MoS calculation despite its very conservative assumptions does not lead to any toxicological concerns.

Int J Toxicol. 2008 Mar-Apr;27(2):183-8 Evaluation of the developmental toxicity of linalool in rats. Politano VT, Lewis EM, Hoberman AM, Christian MS, Diener RM, Api AM.

Food and Chemical Toxicology Volume 46, Supplement 11, November 2008 Toxicologic and Dermatologic Assessment of Cyclic and Non-Cyclic Terpene Alcohols The RIFM EXPERT Panel, D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin,A.E. Rogers , J.H. Saurat , I.G. Sipesi, H. Tagami

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Parfum n/a

The fragrance blend has been formulated in compliance with IFRA guidelines for this product to ensure that its safety is satisfactory. Components do not need to be listed, except for those designated as allergens under EU cosmetic legislation which are present at the level above the cut off point in the legislation.

EU Cosmetic Regulations EU1223/2009

Sodium Chloride 7647-14-5

Sodium Chloride, or table salt, is a white crystalline solid and is one of the most familiar ingredients in food with a track record that predates recorded history. In cosmetics and personal care products, Sodium Chloride is used in the formulation of oral hygiene products, shampoos, fragrance, skin, hair, nail, cleansing, suntan, makeup and bath products.

The Food and Drug Administration (FDA) reviewed the safety of Sodium Chloride and approved its use as an active ingredient in Over-The-Counter (OTC) drug products for the eyes at concentrations of 2 to 5%.

In addition to being an important component of food, FDA includes Sodium Chloride on its list of substances considered Generally Recognized 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 been assessed by FDA. Sodium chloride is a foodstuff and a regular component of the body'. There are issues with prolonged consumption but the tiny contribution made to the diet by any sodium chloride absorbed from cosmetic products is obviously trivial and no margin of safey calculation is appropriate.

Select Committee on GRAS Substances (SCOGS) Opinion: Sodium Chloride Report 102 21 CFR Section: 182.70

Section 9 - Undesirable Effects

No undesirable effects are foreseen with this product when used under conditions of normal and foreseeable use.

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Part B

Section 1- Assessment Conclusion

This product has been assessed and found to comply with the requirements of current EU and US cosmetic regulations. The ingredients selected have been reviewed and are used at levels suitable to ensure that the end user will experience the level of safety they can reasonably expect for this kind of product when used in accordance with the manufacturers instructions, and when manufactured following a suitable cosmetic GMP procedure.

Section 2- Labels and Warnings

This product does not require any specific warnings over and above those customary in this category.

Section 3- Reasoning

Soap has a very long history of safe use, going back at least as far as the Roman Empire, and is well understood by consumers. Consequently the safety of this product is unlikely to be problematic.

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Signed

Colin Sanders  08/09/2020

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Appendix - Credentials of Assessor

Colin Sanders Bsc(Hons) FRSB Dip SCS
Date of Birth 19.5.1960

Academic Qualifications

Bachelor of Science in Environmental Science from Leicester Polytechnic, lower second with honours awarded in 1983.

Diploma in Cosmetic Science awarded by the Society of Cosmetic Science awarded in 1985

Membership of Professional Bodies

Society of Cosmetic Scientists

Fellow of the Royal Society of Biology

Experience

Development Chemist at Intergen Cosmetics 1983-1987
Quality Assurance W.M.Stills 1987-1990
Formulation Scientist/Formulation Laboratory Manager Stiefel Laboratories 1990-2004
Head of Product Formulation Medex/Montagne Jeunesse 2004-2013