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

Product Safety Assessment

Margarita

Darlly Europe Limited

Reference	F4S003
Issue	1
Issue Date	29-Jun-20

Margarita

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
Hexyl Cinnamal	101-86-0	0.216
Benzyl Salicylate	120-51-4	0.070
Butylphenyl Methylpropional	80-54-6	0.040
Alpha-Isomethyl Ionone	127-51-5	0.025
Citronellol	106-22-9, 26489-010-0	0.012
Linalool	78-70-6	0.007
Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde	31906-04-4 / 51414-25-6	0.006
Eugenol	97-53-0	0.006
Geraniol	106-24-1	0.004

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Methyl 2-Octynoate	111-12-6	0.001
CI 47005	18472-87-2	0.000
Citral	5392-40-5	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, Hexyl Cinnamal, Benzyl Salicylate, Butylphenyl Methylpropional, Alpha-Isomethyl Ionone, Citronellol, CI 47005

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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Hexyl Cinnamal	101-86-0	0.216	0.000	1.080		
Benzyl Salicylate	120-51-4	0.070	0.000	0.352		
Butylphenyl Methylpropional	80-54-6	0.040	0.000	0.201	4125	20521.9
Alpha-Isomethyl Ionone	127-51-5	0.025	0.000	0.123	70866	575605
Citronellol	106-22-9, 26489-010-0	0.012	0.000	0.006	50	8258.62
Linalool	78-70-6	0.007	0.000	0.035	500	14214.3
Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde	31906-04-4 / 51414-25-6	0.006	0.000	0.030		
Eugenol	97-53-0	0.006	0.000	0.030		
Geraniol	106-24-1	0.004	0.000	0.019	1000	53914.9
Methyl 2-Octynoate	111-12-6	0.001	0.000	0.003		
CI 47005	18472-87-2	0.000	0.000	0.000	50	454545
Citral	5392-40-5	0.000	0.000	0.000	1400	4E+07

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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 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, and consequently needs to be listed if present at a high enough level.

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 Food and Drug Administration (FDA) has approved the use of Alpha-Isomethyl Ionone as a flavoring agent.

Due to its sensitisation potential the IFRA standards limit its use in this category of product, but the limit is many orders of magnitude greater than it is used in this product so this raises no issues.

The NOAEL used is not strictly speaking appropriate to assess the risk of systemic absorbtion, given that it is from a study into sensitisation. However it is highly unlikely to have a lower value for systemic toxicity. Even if this margin of safety calculation is disregarded, the material's use as flavouring indicates that there is no reason to doubt its safety at the use level in this product.

IFRA standards 43rd Amedment 2009.

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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 Methylpropional 80-54-6

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.

Due to its sensitisation potential the IFRA standards limit its use in this category of product, but the limit is many orders of magnitude greater than it is used in this product so this raises no issues.

The NOAEL used is not strictly speaking appropriate to assess the risk of systemic absorbtion, given that it is from a study into sensitisation. However it is highly unlikely to have a lower value for systemic toxicity giving no reason to doubt its safety at the use level in this product.

IFRA standards 43rd Amedment 2009.

CI 47005 18472-87-2

CI 47005 or Yellow 10 is also known as Acid Yellow 3 and has been used widely in food and cosmetic products. It carries the name E104 for the purposes of food labelling. Its intense colour means it is usually used at quite low levels and has not given rise to any obvious health issues.

An extensive review of the safety data for this dye in the context of its use as a hair dye was carried out in 2004 by the SCCS. It conculuded that it was safe for use for that purpose. The use level in this product is much lower and the potential for absorbtion considerably lower so as would be expected the margin of safety is even greater in this case.

It is fully approved for use in cosmetics at any level in the EU, but it is mandatory to comply with the purity requirements laid down in directive 95/45/EC for E104.

SCCNFP/0789/04 Opinion of the Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers concerning Acid Yellow 3 2004

EU List of Approved Colours Annex IV of EU1223/2009.

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Citral 5392-40-5

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.

Citral is a naturally occuring material that is a common part of the regular diet. It does however have the potential to be a sensitiser and to provoke allergic reactions. Allergic reactions are impossible to avoid completely, but research has been carried out to assess if there is a level below which dermal sensitisation can be eliminated. Research is still limited in this area and it is likely that formulation factors as yet unstudied will strongy affect the sensitisation process. The figure used for the NOAEL calculation is derived from work in this area and shows that at the level in this formulation a sensitisation reaction is very unlikely indeed.

The IFRA standards booklet lists this material as restricted, with the following limits on particular categories -.

Lip Products -0.04%
Deodorants/Antiperspirants 0.05%
Hydroalcoholics for Shaved Skin 0.2%
Hydroalcoholics for Unshaved Skin 0.6%
Hand Cream 0.3%
Mouthwash 1%
Intimate Wipes 0.1%
Hair Styling Aids 1.4%
Rinse-off Hair Conditioners 5%

The level in this product is compliant with these guidelines.

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

Regul Toxicol Pharmacol. 2008 Oct;52(1):62-73. doi: 10.1016/j.yrtph.2008.01.006. Epub 2008 Jan 26. Citral: identifying a threshold for induction of dermal sensitization.Lalko J, Api AM.

IFRA Standards Booklet 47th Amendment 2013

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Citronellol 106-22-9, 26489-010-0

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 IFRA guidelines limit citronellol to below 1.1%, a limit this product complies with.

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

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

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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Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde 31906-04-4 / 51414-25-6

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.

There is no NOAEL value availabe to carry out a margin of safety calculation, but the LD50 values derived from studies in rabbits and rats are 11.3mL/kg and 3.25mL/kg respectively. This indicates a low level of toxicity. In fact, these data are reported as LD50 values but since they relate to a behavioural change as the defined end point rather than actual death, treating them as LD50 values considerably exagerrates the actual level of toxicity. With these considerations it is possible to conclude that given the very low level used in this product it can be concluded to be safe as used even in the absence of a margin of safety calculation.

EU Cosmetic Regulations Annex III Chapter 79

National Technical Information Service. Vol. OTS0535072

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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Methyl 2-octynoate 111-12-6

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.

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

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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 for this category of product.

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