



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

Product Safety Assessment

Daiquiri

Darllly Europe Limited

Reference F4S005
Issue 1
Issue Date 29-Jun-20

Daiquiri

Sponsor Darllly 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
CI 15985	2783-94-0	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, CI 15985

Adult or Child

Adult



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Section 3 - Microbiological Quality

The preservative efficacy of this product is likely to be confirmed if challenged by a standard efficacy test given that the levels of preservative are at a level generally found to be of an appropriate microbiological standard.

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 Leave On

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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CI 15985	2783-94-0	0.000	0.000	0.000
<p>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.</p>				



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Section 8 - Toxicological Profile of Ingredients

CI 15985

2783-94-0

CI 15985 is still sometimes referred to by its old FDA name of FD&C Yellow No. 6, even though the current name is Yellow 6. CI 15985 is permitted at any level under the EU cosmetic regulations subject only to the proviso that the purity criteria as set out in Commission Directive 95/45/EC (E 110) are met - a condition that the grade used in this product meets.

It appears on the FDA's Food Additive Status List on List 1, permitted for use in food, cosmetics and pharmaceuticals.

BIBRA's Working Group found no evidence of toxic effects from this material. A long term study in mice revealed no toxic effects.

There is no suitable NOAEL available for this material in the literature, but given its widespread use as a food colouring (EFSA estimates consumption in children in UK could be as high as 1.19mg/Kg bw per day) a margin of safety calculation for small amount applied to the skin is not necessary.

EU Cosmetic Regulations EU1223/2009

FDA Food Additive Status List

BIBRA Working Group 1995 Sunset Yellow

Food Cosmet Toxicol; 12 (1). 1974 1-10 Long-term toxicity of Sunset Yellow FCF in mice Gaunt IF, Mason PL, Grasso P, Kiss IS

EFSA Journal 2011;9(9):2349 Revised exposure assessment for Sunset Yellow FCF based on the proposed revised maximum permitted levels of use as a food additive

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



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Sodium Chloride	7647-14-5
<p>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.</p> <p>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%.</p> <p>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.</p> <p>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 safety calculation is appropriate.</p> <p>Select Committee on GRAS Substances (SCOGS) Opinion: Sodium Chloride Report 102 21 CFR Section: 182.70</p>	

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 for this category of product.

Section 3- Reasoning

This is a standard product using conventional ingredients at normal levels. This category of products has a good track record of safe use and so can be presumed to be safe under normal and foreseeable conditions of use. Interactions between ingredients are unlikely to be problematic in this kind of product.



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Signed

Colin Sanders

A handwritten signature in black ink that reads "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