



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

Product Safety Assessment

Purple Rain

Darllly Europe Limited

Reference F4S006
Issue 1
Issue Date 29-Jun-20

Purple Rain

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
Methyl 2-Octynoate	111-12-6	0.020
Coumarin	91-64-5	0.005
Eugenol	97-53-0	0.002
Limonene	5989-27-5	0.000
CI 42090	2650-18-2 / 3844-45-9 / 68921-42-6 / 155792-67-3 / 71701-18-3 / 71701-19-4	0.000
CI 15850	5858-81-1	0.000



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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, Methyl 2-Octynoate, Coumarin, Eugenol, CI 42090, CI 15850

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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Methyl 2-Octynoate	111-12-6	0.020	0.000	0.101		
Coumarin	91-64-5	0.005	0.000	0.025		
Eugenol	97-53-0	0.002	0.000	0.010		
Limonene	5989-27-5	0.000	0.000	0.002	250	165833
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	1.1E+07
CI 15850	5858-81-1	0.000	0.000	0.000	150	2727270

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

CI 15850

5858-81-1

CI 15850 is listed as an approved colour in Annex IV of the EU's cosmetic regulations EU2009/1223 with no restrictions on its use. In the US it is known as D&C Red 6.

This pigment is often referred to as Pigment Red 57

There are no restrictions in the EU on the use of this pigment. An extensive review by the EU's scientific committee (SCCS) in 2004 found no reason to revise the advice on this pigment. They did note that there was no data on its carcinogenicity, but there is no reason to suspect that it is carcinogenic.

The NOAEL proposed by the SCCS, is a conservative one but nonetheless produces an adequate margin of safety.

SCCNFP/0795/04 Opinion of the scientific committee on cosmetic products and non-food products intended for consumers Concerning Pigment Red 57 2004

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

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 the Scientific Committee on Cosmetology (seventh series) 1986



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Coumarin

91-64-5

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.

It is a food ingredient which has a low level of toxicity. Unusually, an LD50 has been calculated for this material in female humans. This was based on work in patients with liver malfunctions treated with coumarin, and so may not be directly applicable to a healthy population, but even so indicates a very low level of toxicity.

Given its widespread consumption in food, there is no need for a margin of safety calculation to conclude that this material can be safely applied in small quantities to the skin as in this product.

Molecular Nutrition & Food Research Toxicology and risk assessment of coumarin: Focus on human data Klaus Abraham, Friederike Wöhrlin, Oliver Lindtner, Gerhard Heinemeyer and Alfonso Lampen

Hum Toxicol. 1989 Nov;8(6):501-6. The rarity of liver toxicity in patients treated with coumarin (1,2-benzopyrone). Cox D1, O'Kennedy R, Thornes RD.



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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 absorption 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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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

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



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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 safety 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 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