



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

Product Safety Assessment

Moscow Mule

Darllly Europe Limited

Reference F4S004
Issue 1
Issue Date 29-Jun-20

Moscow Mule

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
Citral	5392-40-5	0.094
Limonene	5989-27-5	0.085
Geraniol	106-24-1	0.043
Linalool	78-70-6	0.014
Citronellol	106-22-9, 26489-010-0	0.009
Isoeugenol	97-54-1	0.000
CI 19140	1934-21-0, 12225-21-7	0.000
CI 42090	2650-18-2 / 3844-45-9 / 68921-42-6 / 155792-67-3 / 71701-18-3 / 71701-19-4	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, Citral, Limonene, Geraniol, Linalool, CI 19140, 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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Citral	5392-40-5	0.094	0.000	0.470	1400	2977.77
Limonene	5989-27-5	0.085	0.000	0.427	250	585.983
Geraniol	106-24-1	0.043	0.000	0.216	1000	4636.53
Linalool	78-70-6	0.014	0.000	0.068	500	7316.17
Citronellol	106-22-9, 26489-010-0	0.009	0.000	0.005	50	10619
Isoeugenol	97-54-1	0.000	0.000	0.000	150	1492500
CI 19140	1934-21-0, 12225-21-7	0.000	0.000	0.000	2640	4.8E+07
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

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 19140

1934-21-0, 12225-21-7

CI 19140 is the colour index number for Yellow 5. The FDA has reviewed the safety of Yellow 5 and determined that it may be safely used for coloring cosmetics and personal care products, including products intended for use on the lips, and in products intended for use in the area of the eye, when these ingredients conforms to FDA specifications. Yellow 5 is also permitted as to be used as a color in food and drugs. According to U.S. regulations, all Yellow 5 and Yellow 5 Lake that are manufactured for use in products is subject to certification by the FDA. This certification process ensures that the strict chemical and identity specifications set by FDA are met.

The Cosmetic Ingredient Review (CIR) has deferred evaluation of these ingredients because the safety has been assessed by FDA. This deferral of review is according to the provisions of the CIR Procedures.

SCCS opinion quotes an NOAEL of 2640 for oral consumption by males. To all intents and purposes this is non-toxic, as the margin of safety calculation indicates.

SCCNFP/0786/04 Opinion of the Scientific Committee on Cosmetic Products and Non Food Products Intended for Consumers concerning
Acid Yellow 23 2004

Code of Federal Regulations § 74.1705 and § 74.2705 Color Additives Approved for Use in Drugs Part 73, Subpart B: Color additives exempt from batch certification, Part 74, Subpart B: Color additives subject to batch certification. Color Additives Approved for Use in Cosmetics Part 73, Subpart C: Color additives exempt from batch certification Part 74, Subpart C: Color additives subject to batch certification



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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 the Scientific Committee on Cosmetology (seventh series) 1986



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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 occurring 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 strongly 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%
Hydroalcohols for Shaved Skin 0.2%
Hydroalcohols 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. Sipes, H. Tagami

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. Sipes, H. Tagami



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Isoeugenol

97-54-1

Isoeugenol is a pale yellow liquid which smells something like carnation.

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 in this product is well below the IFRA guideline limit for this category of product. The NOAEL is derived from a nutritional study in rats and so is questionable as to its relevance to a product used on the skin which would be a much lower hazard. But the MoS calculation even using this very conservative data is still perfectly acceptable.

IFRA Standard

EFSA Journal 2012;10(1):2532 EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP); Scientific Opinion on the safety and efficacy of propenylhydroxybenzenes (chemical group 17) when used as flavourings for all animal species.

EFSA Journal 2012;10(1):2532
Suggested citation: EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP); Scientific Opinion on the safety and efficacy of propenylhydroxybenzenes (chemical group 17) when used as flavourings for all animal species. EFSA Journal 2012;10(1):2532. [15 pp.] doi:10.2903/j.efsa.2012.2532. Available online: www.efsa.europa.eu/efsajournal
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SCIENTIFIC OPINION
Scientific Opinion on the safety and efficacy of propenylhydroxybenzenes (chemical group 17) when used as flavourings for all animal species1
EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) (www.efsa.europa.eu/efsajournal)

Scientific Opinion on the safety and efficacy of propenylhydroxybenzenes (chemical group 17) when used as flavourings for all animal species1
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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 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 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

A handwritten signature in blue 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