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SAFETY ASSESSMENT/ COSMETIC PRODUCT SAFETY REPORT

Product Name: Nilaqua Foaming Hand Soap - Wild Meadow
Formula code: NC1M
On behalf of: Waterless Limited, Unit 1, Viking Way Swansea, SA1 7DA
our ref: B2562

PART A, SAFETY REPORT

This Safety Report/Assessment is conducted to (EC) No.1223-2009 and UK Cosmetic Regulations.
Assessment is made for compliance to US Cosmetic Regulations.

The Assessment is conducted in accordance with the principles of Good Laboratory Practice referred to in Article 1 of Council Directive 2004/10/EC on the applications of the principles of good laboratory practice and the verification of their application for tests on chemical substances.

This assessment takes account of:

1. the general toxicological profile of each ingredient used:
2. the chemical structure of each ingredient:
3. the level of exposure of each ingredient;
4. the specific exposure characteristics of the areas on which the cosmetic product will be applied;
5. the specific exposure characteristics of the class of individuals for whom the cosmetic product is intended.

REVIEW OF INGREDIENTS

All of the ingredients have a history of use in cosmetic and toiletry products. Ingredients that are:

- Prohibited under EU / UK/USA Cosmetics Regulations
- Restricted when used beyond the allowed authorised conditions
- With toxicological data incompatible with the intended concentration and use
- Which have insufficient toxicological data nor safety in use experience

- Which are not properly characterised with regard to purity and analytical composition
- ……..are excluded.

ASSESSMENT

Assessment is based on ingredient safety review and information on the final formulation, including the intended and reasonably foreseeable use, the physico-chemical and microbiological specifications of the raw materials and the finished product, stability and a history and record of any reported undesirable effects linked to the use of the product.

DESCRIPTION OF THE PRODUCT

Cleansing solution

DESCRIPTION OF INTENDED AND REASONABLY FORESEEABLE USE

The product is for use on adults and may be typically used up to 1x or more times daily or as required.

QUANTITATIVE COMPOSITION OF THE PRODUCT

Ingredients are listed below.
CAS numbers are reported in Raw materials safety reviews
Functions are as reported in CosIng:
https://ec.europa.eu/growth/sectors/cosmetics/cosing_en

INCI (EU)	
Aqua	]75%-100%]
TEA-Lauryl Sulfate	]1%-5%]
Propylene Glycol	]0,1%-1%]
Benzyl Alcohol	]0,1%-1%]
Cocamidopropyl Betaine	]0,1%-1%]
Parfum	]0,1%-1%]
Dehydroacetic Acid	[0%-0,1%]
Benzoic Acid	[0%-0,1%]
Disodium EDTA	[0%-0,1%]
Sorbic Acid	[0%-0,1%]
Sodium Benzoate	[0%-0,1%]
Potassium Sorbate	[0%-0,1%]
Tocopherol	[0%-0,1%]

"Additional labeling requirements" As per article 19, paragraph 1, point g of regulation (EC) No 1223/2009.

INCI (EU)
Coumarin
Benzyl Salicylate
Linalool
Hexyl Cinnamal
Benzyl Alcohol
Alpha-Isomethyl Ionone
Limonene

The above ingredients have been reviewed for potential to be skin irritants, sensitisers or photo-sensitisers.

Where data is available for systemic and sub-chronic toxicity this has been taken into account.
A review of the literature and of the structural chemistry has been made for each ingredient to estimate the likely potential for genotoxicity, reproductive effects and carcinogenicity.
No animal testing has been conducted on this formulation. All safety data is taken from existing published sources.

MARGINS OF SAFETY

Based on the available toxicological literature or on “read-across” data Margins of Safety have been calculated for both topical and systemic effects. The procedure is as described in: THE SCCS NOTES OF GUIDANCE, FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION, 12th REVISION, 2023.
Dermal Absorption reported as a % of the substance applied:

The calculation of the SED is as follows:

$$SED = \frac{\mathbf{A}\ (g/day) \times 1000 mg/g \times \mathbf{C}\ (\%)/100 \times \mathbf{DAp}\ (\%)/100}{60\ kg}$$

SED (mg/kg bw/day) = Systemic Exposure Dosage
A (g/day) = Amount of the cosmetic product applied daily:
see the daily exposure values for different cosmetic product types
C (%) = the Concentration of the ingredient under study in the finished cosmetic product on the application site
DAp (%) = Dermal Absorption expressed as a percentage
of the test dose assumed to be applied in real life conditions
60 kg = Adult body weight

The calculation of Margin of Safety (MOS): $\frac{\mathbf{NOAEL}}{\mathbf{SED}}$
NOAEL data is derived from published literature where available.

Estimated Daily Exposure Levels:
Data for Estimated daily exposure levels is taken from the current Colipa data as presented in THE SCCS NOTES OF GUIDANCE, FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION, 11th REVISION, 2023. .

Table 3: Estimated daily exposure levels for different cosmetic product types according to Colipa data [SCCNFP/0321/02; Hall et al. 2007, 2011].

Product type	Estimated daily amount applied	Relative amount applied (mg/kg bw/day	Retention factor 1	Calculated daily exposure (g/day)	Calculated relative daily exposure (mg/kg bw/day)
Hand wash soap 2	20g	-	0.01	0.20-3	3.33

1 The retention factor was introduced by the SCCNFP to take into account rinsing off and dilution of finished products by application on wet skin or hair (e.g. shower gels, shampoos, …) [SCCNFP/0321/00]
2 Product types not covered by the Colipa studies: existing daily application amounts are divided by the adult body weight of 60 kg.

It was concluded that all ingredients, when considered both individually and in combination have an adequate Margin of Safety, ie > 100.

PHYSICAL/CHEMICAL CHARACTERISTICS

The raw material Specifications and the Finished Product Specification are to be provided. All Specifications meet good standards for safe use of this product.
See Appendix

RAW MATERIAL QUALITY/ PURITY

All raw materials are to be from reputable sources of supply and must meet current standards of purity and quality.

The Molecular formulae for defined chemical substances are as recorded in the current Edition of ICID.
Manufacturers Material data sheets/ Certificates are Appended

The raw materials meet current good standards for quality and purity.
Manufacturers Material data sheets/ Certificates are presented in Appendix.

GOOD MANUFACTURING PRACTICE

The product is to be manufactured to adequate standards of Good Manufacturing Practice and there to be are adequate controls in regards to Microbial quality.

STABILITY

The product is deemed stable under normal and foreseeable conditions of use. Stability data is summarised in Appendix.

MICROBIAL QUALITY

INGREDIENTS

It is a requirement that all raw materials/ ingredients meet a microbial quality of < 1000 cfu/ gram products

FINSHED PRODUCT

It is a requirement that the Finished Product meets a microbial quality of < 1000 cfu/ gram and zero harmfuls.

CHALLENGE TEST DATA

The product must pass a Microbial Challenge test.

PACKAGING

The packaging materials are to meet acceptable standard of purity. Consideration has been given to interaction between the product and the packaging. It is considered there is no adverse interaction between product and packaging as regards safety to the consumer.

FINISHED PRODUCT SAFETY

The above formulation is based on known ingredients with history of safe use in cosmetic products.
The product is considered to be protected from microbial growth.
It is noted that all ingredients are used within limits as specified in the Cosmetics Regulations.
The microbial content (Total Viable Count) at time of manufacture must be within recognised limits (nmt 1000cfu and zero harmfuls /gm).

This Safety Assessment has taken account of:

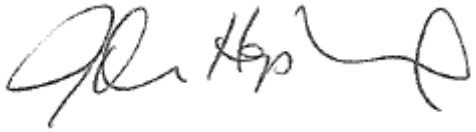
1. The Quantitative/Qualitative composition of the product,
2. The intended and reasonably foreseeable use of the product,
3. Margins of Safety for all ingredients considered both individually and in combination.
4. Standards of good manufacturing practice
5. A consideration of potential interactions of substances in the formulation.
6. A consideration of the stability of the formulation.

It is a requirement that all raw materials meet EU/ UK standards for purity and regulatory compliance.
It is noted that all ingredients are used within limits as specified in the Cosmetics Regulations.

PART A SAFETY SUMMARY

In reviewing the safety and toxicity profile of the ingredients used and their history of safe use, it is concluded that there are no likely safety hazards from normal use of this product and when used as directed or from foreseeable conditions of misuse.
The product is considered safe for sale in UK, USA and in EU Countries.

Dated: December 19th 2023



Dr. JOHN HOPKINS BSc. PhD. MRSB. C Biol.
Safety Assessor

PART B

SAFETY ASSESSMENT SUMMARY
According to EC1223-2009.

SUMMARY

Reasoning:
This Assessment has considered the safety and toxicological profile of all raw materials and any trace components present. Consideration has been given to parameters of weight of evidence (particularly for long established materials) and also published toxicity data for NOAEL's allowing calculations of Margins of Safety, based on established use of the product. Margins of Safety have been calculated to confirm safety from a systemic aspect.

Assessment for local effects, including skin and eye irritation, dermal sensitization and photoallergenicity was evaluated based on established safe use for dermal safety, derived from manufacturers data, and data published by CIR and also in the public domain.

Assessment for systemic effects including target organ toxicity, effects on maternal and reproductive toxicity and a review of genotoxic and carcinogenic safety was evaluated based on established safe and from manufacturers data, and data published by CIR and also in the public domain.

Established use and consumer exposure is derived from data produced by SCCS in Notes of Guidance.

The above formulation is based on known ingredients with history of safe use in cosmetic products.
The Assessment has considered the safety of the individual ingredients both separately and in combination to produce the final formulation.

A review of the data relating to raw material purity indicates that all materials and packaging have a satisfactory physical and chemical profile. There are no unacceptable levels of prohibited substances or impurities.

The product is deemed to have adequate stability.
The product is considered to be adequately preserved.
The finished product specification is considered to meet current standards for Microbial quality.
This Safety Assessment has taken account of:

1. The Quantitative/Qualitative composition of the product,
2. The intended and reasonably foreseeable use of the product,
3. Margins of Safety for all ingredients considered both individually and in combination.
4. Standards of good manufacturing practice

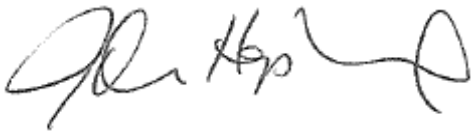
5. A consideration of potential interactions of substances in the formulation.
6. A consideration of the stability of the formulation.

Conclusion

In reviewing the safety and toxicity profile of the ingredients and their history of safe use, raw material standards and labelling, it is concluded that there are no likely safety hazards from normal use of this product and when used as directed or from foreseeable conditions of misuse.

The product is considered safe for sale in UK and in EU Countries.

Dated: December 19th 2023



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This Safety Report is valid according to current Regulatory requirements. Changes in Regulations may require a review of this Report