Cosmetic Product Safety Report

Acc to EC 1223/2009 30/11/2009

Dossier number:	1299
Product Name:	HAND WASH FUCHSIA 69
Project n°:	-
Formulation n°:	820202
Producer:	A&L JEUBIS 3800 SINT TRUIDEN Lichtenberglaan 2076 BE
Responsible person:	T-BOXX BV 5061 KN Oisterwijk Sprendlingenstraat 50 NL
Safety assessor:	Ing Patrick Gonry
Date:	27/05/2021

This document provides the necessary safety assessment of the above mentioned product and the individual ingredients as requested by EC 1223/2009.

The product is evaluated under normal circumstances and normal foreseeable use.

The toxicological assessment has been performed according to the SCCS's Notes of Guidance for the testing of Cosmetic Ingredients and their safety Evaluation - 8th Revision - December 2012

PART A Cosmetic Product Safety information

1. Quantitative and qualitative composition of the cosmetic product:

1.1 Quantitative Formulation:

See Production File

1.2 Qualitative Formulation:

Ingredient (INCI)	Source (Raw material)	CAS n°	Einecs/Elincs n°	IUPAC/Chemical Name	Function
AQUA	AQUA	7732-18-5	231-791-2	Water	SOLVENT
	EUROQUAT HCB LA				SOLVENT
	TEXAPON NSO UP				SOLVENT
CAPRIC ACID	EURAMID N2	334-48-5	206-376-4	Decanoic acid	CLEANSING
CAPRYLIC ACID	EURAMID N2	124-07-2	204-677-5	Octanoic acid	CLEANSING
COCAMIDE MIPA	EURAMID N2	68333-82-4	269-793-0/931-596-9	Amides, coco, N-(2-hydroxypropyl)	EMULSIFYING
COCAMIDOPROPYL BETAINE	EUROQUAT HCB LA	61789-40-0	263-058-8/931-296-8	1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-coco acyl derivs., hydroxides, inner salts	CLEANSING
ETHYLHEXYLGLYCERIN	NEOPRES PE9010	70445-33-9	408-080-2	1,2-Propanediol, 3-(2-ethylhexyloxy)	SKIN CONDITIONING
LAURETH-4	EURAMID N2	5274-68-0 / 9002-92-0 / 68439-50-9	226-097-1 / 500-002-6 / 500-213-3	3,6,9,12-tetraoxatetracosan-1-ol; Dodecan-1-ol, ethoxylated; Alcohols, C12-14, ethoxylated	EMULSIFYING
MARIS SAL	MARSEL 0.2-0.8			Naturally occurring substances, inorganic salts derived from sea water	SKIN CONDITIONING
PHENOXYETHANOL	NEOPRES PE9010	122-99-6	204-589-7	2-Phenoxyethanol	PRESERVATIVE
PROPYLENE GLYCOL	EURAMID N2	57-55-6	200-338-0	Propane-1,2-diol	SOLVENT
SODIUM LAURETH SULFATE	TEXAPON NSO UP	3088-31-1 / 9004-82-4 / 68891-38-3 / 1335-72-4 / 68585-34-2 / 91648-56-5	221-416-0/ - / 500-234-8 / - / 500-223-8 / 293-918-8	sodium 2-(2-dodecyloxyethoxy) ethyl sulphate	CLEANSING
SOY ACID	EURAMID N2	68308-53-2	269-657-0	Fatty acids, soya	EMOLLIENT
TOCOPHEROL	EURAMID N2	1406-66-2 / 10191-41-0 / 2074-53-5 / 59-02-9 / 148-03-8 / 119-13-1 / 54-28-4	- / 233-466-0 / 218-197-9 / 200-412-2 / 205-708-5 / 204-299-0 / 200-201-5	3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol; .alpha.-tocopherol; Vitamin E	ANTIOXIDANT

1.3 Perfume/Aroma:

Product Name + Code	Supplier	Producer	Class	IFRA	Comments
FUSCHIA BOOST MOD II 2012705		EXPRESSIONS PARFUMEES SAS	Class 9: Rinse off products with body and hand exposure.	OK	According to 49th IFRA requirements

2. Physical/Chemical characteristics and stability of the cosmetic product:

2.1 Physical/Chemical characteristics of cosmetic product:

See Specification/Technical Data Sheet of each individual raw material.

2.2 Physical/Chemical characteristics of cosmetic product:

Aspect:	Liquid	
Color:	Conform standard	
Type:	Mixture	
Smell:	Conform standard	
pH:	5.5-6.5	
Density:	1.01-1.02 g/ml	
Viscosity:	5000-10000 mPa*S	Spindle 63, RPM=10
Bacto test:	< 1000 cfu/ml	Acc.to SCCS/1501/12 Notes of Guidelines, paragraph 4-4.2 for testing of cosmetic product (edition 8th)

Conclusion: The quality of the product is controlled at each batch by the above parameters.
Product is in compliance with SCCS/1501/12 Notes of Guidelines, paragraph 4-3.3 for physical and chemical characteristic of the finished cosmetic product (edition 8th).
Product is in compliance with SCCS/1501/12 Notes of Guidelines, paragraph 4-4.2 for quantitative and qualitative microbiological limits (edition 8th) for the category 2.
Due to above reasons the product is not suspected to pose any safety risks.

To be fully in compliance with SCCS/1501/12 guideline, paragraph 4-4.2 for category 2, it is advised to do the control of the pathogens specified below:
- Pseudomonas Aeruginosa - must be absent in 0.1g (or 0.1ml) of the product
- Staphyllococus Aureus - must be absent in 0.1g (or 0.1ml) of the product
- Candida Albicans - must be absent in 0.1g (or 0.1ml) of the product

Details - see files listed below:
- Spec-D1299-HandWashFuchsia69-820202.pdf

2.3 Stability of the cosmetic product under reasonably foreseeable storage conditions:

Stability @ room T:	Stable
Stability @ 40°C:	Stable
Frigo:	

Conclusion: The stability has been investigated and has been found to be satisfactory according to "Guidelines on stabiliy testing of cosmetic products" of Colipa, March 2004,

Details - see files listed below:
- ST-ST-Pack-D1299-HandWashFuchsia69-20208.pdf

3. Microbiological quality:

3.1 Microbiological specification of the raw materials:

Raw material	Type		Value	Unit	Comments	Comments dossier
AQUA	Total Vival Count (TVC)		NR			Producer assures that the quality control of water is performed regulary acc to ISO 22716:2007
	Yeast		NR			Producer assures that the quality control of water is performed regulary acc to ISO 22716:2007
	Moulds		NR			Producer assures that the quality control of water is performed regulary acc to ISO 22716:2007
EURAMID N2	Total Vival Count (TVC)	<	100.0000	CFU/g		Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
	Yeast	<	100.0000	CFU/g		Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
	Moulds	<	100.0000	CFU/g		Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
EUROQUAT HCB LA	Total Vival Count (TVC)	<	100.0000	CFU/g		Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
	Yeast	<	100.0000	CFU/g		Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
	Moulds	<	100.0000	CFU/g		Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
FUSCHIA BOOST MOD II 2012705	Total Vival Count (TVC)		NR		Not occurring due to the nature of the product - low water activity	Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
	Yeast		NR		Not occurring due to the nature of the product - low water activity	Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
	Moulds		NR		Not occurring due to the nature of the product - low water activity	Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
MARSEL 0.2-0.8	Total Vival Count (TVC)		NR		Not occuring due to nature of product - low water activity	Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
	Yeast		NR		Not occuring due to nature of product - low water activity	Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
	Moulds		NR		Not occuring due to nature of product - low water activity	Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
NEOPRES PE9010	Total Vival Count (TVC)		NR		Not occurring due to the nature of the product - anti-microbial activity	Acc to SCCS/1501/12 Guideline, paragraph 4-4.2

	Yeast		NR		Not occurring due to the nature of the product - anti-microbial activity	Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
	Moulds		NR		Not occurring due to the nature of the product - anti-microbial activity	Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
TEXAPON NSO UP	Total Vival Count (TVC)		NR		Not occuring due to nature of product - high pH	Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
	Yeast		NR		Not occuring due to nature of product - high pH	Acc to SCCS/1501/12 Guideline, paragraph 4-4.2
	Moulds		NR		Not occuring due to nature of product - high pH	Acc to SCCS/1501/12 Guideline, paragraph 4-4.2

Raw material	**Pathogen**	**Result**	**Comments**
AQUA	Pathogens	NR	Producer assures that the quality control of water is performed regulary acc to ISO 22716:2007
EURAMID N2	Pathogens	OK	Absent - supplier statement
EUROQUAT HCB LA	Pathogens	OK	Challange test proves inhibition of growth of specified pathogenic micro-organism
FUSCHIA BOOST MOD II 2012705	Pathogens	NR	Not occurring due to the nature of the product - low water activity
MARSEL 0.2-0.8	Pathogens	NR	Not occuring due to nature of product - low water activity
NEOPRES PE9010	Pathogens	NR	Not occurring due to the nature of the product - anti-microbial activity
TEXAPON NSO UP	Pathogens	NR	Not occuring due to nature of product - high pH

NR = not relevant because of type of product: oil, wax preservative
NI = no information, but because of type of product impossible to occur (oil, wax, preservative etc)

Conclusion: The microbiological purity of each raw material is guaranteed.

3.2 Results of preservation challenge test:

CT n°: 734-ref

Test type

Ph EUR + Escherichia Coli

Pathogen	Results	Comments
Staphylococcus Aureus	Passed	Acc to test procedures without any remarks
Escherichia Coli	Passed	Acc to test procedures without any remarks
Pseudomonas Aeroginosa	Passed	Acc to test procedures without any remarks
Aspergillus Niger	Passed	Acc to test procedures without any remarks
Candida Albicans	Passed	Acc to test procedures without any remarks

Conclusion: The challenge test base on the similar formulation was used as reference (D1294)- it supports the safety of the product against microbiological contamination during application.
It is acc to SCCS/1501/12 Notes of Guidelines, paragraph 4-4.3 for testing of cosmetic product (edition 8th).

Details - see files listed below:

- CT734-D1294-HandWashOrange77-820221-ref.pdf

4. Impurities, traces, information about packaging material:

4.1 The purity of the raw materials:

Heavy metals content:

Raw material	Type	Content (ppm):	Comments:
EURAMID N2	As	< 0,5000	
	Cd	< 0,5000	
	Cr	< 0,5000	
	Ni	< 0,5000	
	Pb	< 0,5000	
	Hg	< 0,0500	
	Co	< 0,5000	
	Sb	< 0,5000	
EUROQUAT HCB LA	Pb	< 0,0500	
	Cd	< 0,0500	
	Zn	< 1,0000	
	As	< 0,1000	
	Cr	< 0,0500	
	Cu	< 0,5000	
	Ni	< 0,0500	
	Fe	< 1,0000	
MARSEL 0.2-0.8	As	< 0,5000	
	Cd	< 0,5000	
	Cu	< 0,5000	
	Hg	< 0,5000	
	Pb	< 0,5000	
NEOPRES PE9010	Total	< 20,0000	
TEXAPON NSO UP	As	= 1,0000	According to German Federal Health Gazette 28, 216 (1985) and supplements (1992)
	Sb	= 5,0000	According to German Federal Health Gazette 28, 216 (1985) and supplements (1992)
	Pb	= 10,0000	According to German Federal Health Gazette 28, 216 (1985) and supplements (1992)
	Cd	= 2,0000	According to German Federal Health Gazette 28, 216 (1985) and supplements (1992)
	Hg	= 1,0000	According to German Federal Health Gazette 28, 216 (1985) and supplements (1992)
	Ni	= 2,0000	According to German Federal Health Gazette 28, 216 (1985) and supplements (1992)

DL = Detection limit

Pesticides content:

Raw material	Pesticide	Result	Comments
AQUA	Pesticides	NR	Producer assures that the quality control of water is performed regulary acc to ISO 22716:2007
EURAMID N2	Pesticides	OK	Absent - statement of a supplier
EUROQUAT HCB LA	Pesticides	OK	Not expected to be present - statement of a supplier.
MARSEL 0.2-0.8	Pesticides	NR	Due to nature of the product - mineral
NEOPRES PE9010	Pesticides	NR	Not occuring due to the nature of the product - synthetic
TEXAPON NSO UP	Pesticides	OK	According to Ph Eur, Section 2.8.13 - "Pesticide residues"

Residual solvents:

Not present in any raw material.

Residual monomers:

Not present in any raw material.

Residual reactants:

Raw material	Impurity	Result	Content (ppm):	Comments:
EUROQUAT HCB LA	Dimethylaminopropylamine		<= 10,0000	
	Monochloracetic acid		<= 5,0000	

DL = Detection limit"

Policyclic Aromatic Hydrocarbons:

Not present in any raw material.

Other impurities:

Raw material	Impurity	Result	Content (ppm):	Comments:
EURAMID N2	DIPA		< 200,0000	
	MIPA		< 7000,0000	
EUROQUAT HCB LA	Amido-amine		< 3000,0000	
	Glycerine		< 20000,0000	
	Glycolic Acid		<= 4000,0000	
	Sodium Chloride		<= 50000,0000	
	Sodium glycolate		< 5000,0000	
NEOPRES PE9010	Ethylene glycol		< 18,0000	
TEXAPON NSO UP	SO4--		<= 5000,0000	

DL = Detection limit"

4.2 Prohibited impurities and CMR ingredients:

Prohibited impurities:

Not present in any raw material.

CMR impurities:

Raw material	Impurity	Result	Content (ppm):	Comments:
EURAMID N2	1.4-Dioxane		<= 2,0000	Unavoidable due to the type of the production process.
	Ethylene Oxide		<= 1,0000	Unavoidable due to the type of the production process.
	Nitrosamine		<= 0,0250	Unavoidable due to the type of the production process (< 25 ppb ATNC (25 ppb = LoD)).
EUROQUAT HCB LA	Nitrosamine		< 0,0150	Unavoidable due to the type of the production process.
	Formaldehyde		<= 5,0000	Unavoidable due to the type of the production process.
NEOPRES PE9010	1.4-Dioxane		< 1,8000	Unavoidable due to type of production process
	Ethylene Oxide		< 0,9000	Unavoidable due to type of production process
	Phenol		<= 10,0000	Residual reactant - unavoidable due to type of production process
TEXAPON NSO UP	1.4-Dioxane		< 10,0000	Unavoidable due to type of production process
	Ethylene Oxide		< 1,0000	Unavoidable due to type of production process

DL = Detection limit"

Conclusion: The chemical purity is guaranteed for each individual raw material.

4.3 Packaging information:

Type	Material	Impurity	Volume
Pump Bottle	HDPE + PP	Meet requirements of purity given by EU Food regulation	250ml

Stability with a product:

Type	Volume	Comments	Stability
Pump Bottle	250ml		Performed

5. Normal and reasonably foreseeable use:

The labelling and packaging assures that the consumer will use the product only for the intended purpose.

6. Exposure to the cosmetic product:

Site of application:	Hand
Surface area of application (cm2):	860,00
Amount of product applied (g):	20,0000
Duration of use (min):	1.0000 Minute
Frequency of use:	10,0000
Normal/reasonably foreseeable exposure route:	area hands
Targeted population:	Adults

Calculation of primary exposure - see "Toxicological Summary"
Calculation of secondary exposure - see "Toxicological Summary"

7. Exposure to the substances:

See Toxicological information of each individual ingredient.

8. Toxicological profile of the substances:

Ingredient (INCI)	Type	Value	Comments
CAPRIC ACID	Acute toxicity	LD50 > 2000.0000 mg/kg	Rat/Dermal
	Acute toxicity	LD50 > 2000.0000 mg/kg	Rat/Oral
	Skin Irritation	Not Irritant	Whittle, E. et al. Toxicology in Vitro 10: 95 - 100 1996
	Eye irritation	Irritant @ 70%	Study 2011
	Skin sensitization	Not Sensitizing	Study 1965 and 1981
	MUTAGENICITY	Not Mutagenic	Zeiger, E. et al. 1988 Environ Molec Mutagen 11(12):1-158
CAPRYLIC ACID	Acute toxicity	LD50 > 2000.0000 mg/kg	Rat/Oral
	Skin Irritation	Irritant	Study 1984
	Eye irritation	Severe Irritant @ 70%	Study 2011
	Skin sensitization	Not Sensitizing @ 10%	Basketter, D.A. et al. 1988 Food and Chemical Toxicology 36 (4):327 - 33

	MUTAGENICITY	Not Mutagenic	Study 2010
COCAMIDE MIPA	Acute toxicity	LD50 > 5000.0000 mg/kg	RAT/ORAL
	Skin Irritation	IRRITANT	
	Eye irritation	IRRITANT	
COCAMIDOPROPYL BETAINE	Acute toxicity	LD50 > 2000.0000 mg/kg	RAT/DERMAL
	Acute toxicity	LD50 > 4900.0000 mg/kg	RAT/ORAL
	Acute toxicity	LD50 = 4910.0000 mg/kg	Mouse/Oral
	Skin Irritation	IRRITANT	at 30%
	Skin Irritation	SLIGHTLY IRRITANT	at 10%
	Eye irritation	IRRITANT	at 30%
	Eye irritation	SLIGHTLY IRRITANT	at 10%
	Skin sensitization	NOT SENSITIZING	3%
	Photo toxicity	NOT PHOTOTOXIC	
	MUTAGENICITY	Not Mutagenic	
	ALLERGY	Have been reported	
ETHYLHEXYLGLYCERIN	Acute toxicity	LD50 > 2000.0000 mg/kg	Rat/Dermal
	Acute toxicity	LD50 > 2000.0000 mg/kg	Rat/Oral
	Skin Irritation	Not Irritant	0.995% Human
	Skin Irritation	SLIGHTLY IRRITANT	100%
	Eye irritation	IRRITANT	100%
	Eye irritation	NOT IRRITANT	@ 5%
	Skin sensitization	NOT SENSITIZING	
	Photo toxicity	NOT PHOTOTOXIC	
	LC50	3.07 mg/L	CIR
	MUTAGENICITY	Not Mutagenic	In-Vivo
	MUTAGENICITY	Not Mutagenic	Mouse lymphoma
	MUTAGENICITY	Not Mutagenic	Salmonella typhimurium
	NOAEL - DEVELOP TOXICITY	50 mg/kg/d	CIR
	NOAEL - REPROD TOXICITY	800 mg/kg/d	CIR
	PHOTO SENSIBILISATION	Not Photo Sensibilizing	CIR
LAURETH-4	Acute toxicity	LD50 > 2000.0000 mg/kg	RAT/DERMAL
	Acute toxicity	LD50 = 3300.0000 mg/kg	RABBIT/DERMAL
	Acute toxicity	LD50 > 5000.0000 mg/kg	RAT/ORAL
	Skin Irritation	SLIGHTLY IRRITANT	
	Eye irritation	IRRITANT	100%
	Eye irritation	NOT IRRITANT	<1%
	Eye irritation	SLIGHTLY IRRITANT	10%
	Skin sensitization	NOT SENSITIZING	
	Photo toxicity	NOT PHOTOTOXIC	<6%
	PHOTOSENSIBILISATION	NON PHOTOSENSIBILIZING	1.8%
	REPRODUCTIVE TOXICITY	NO REPRODUCTIVE TOXICITY	
	TERATOGENICITY	NOT TERATOGENIC	
	LC50	>100 mg/m3	

	MUTAGENICITY	NOT MUTAGENIC	
	DNEL	294 mg/m3	
MARIS SAL	Acute toxicity	LD50 > 10000.0000 mg/kg	RABBIT/DERMAL
	Acute toxicity	LD50 = 3550.0000 mg/kg	RAT/ORAL
	Skin Irritation	SLIGHTLY IRRITANT	10%
	Eye irritation	SLIGHTLY IRRITANT	0.9%
	Skin sensitization	NOT SENSITIZING	
	Photo toxicity	NOT PHOTOTOXIC	
	TERATOGENICITY	TERATOGENIC	13400 mg/kg/d Rat
	TERATOGENICITY.	TERATOGENIC	1900 mg/kg/d Mouse
	LC50	42 mg/l	
	LETHAL DOSE	3g/kg	Human
	MUTAGENICITY	NOT MUTAGENIC	
	CARCENOGENICITY		Stomach Cancer is assaciated with high dosage
	DEVELOPMENT TOXICITY	DEVELOPMENT TOXIC	10000mg/kg/d
	DNEL	2068.62 mg/m3	
PHENOXYETHANOL	Acute toxicity	LD50 = 1200.0000 mg/kg	RAT/ORAL
	Acute toxicity	LD50 > 5000.0000 mg/kg	RABBIT/DERMAL
	Skin Irritation	NOT IRRITANT	
	Eye irritation	IRRITANT	
	Skin sensitization	NOT SENSITIZING	
	Photo toxicity	NOT PHOTOTOXIC	
	REPRODUCTIVE TOXICITY	REPRODUCTIVE TOXICITY	@3700mg/kg/d
	TERATOGENICITY	NOT TERATOGENIC	@1.000mg/kg/d
	MUTAGENICITY	NOT MUTAGENIC	
	NOAEL	200mg/kg/d	Based on weight loss
	DEVELOPMENT TOXICITY	DEVELOPMENT TOXIC	@ 3700mg/kg/d
PROPYLENE GLYCOL	Acute toxicity	LD50 > 2000.0000 mg/kg	Rabbit/Dermal
	Acute toxicity	LD50 >= 22000.0000 mg/kg	Rat/Oral
	Skin Irritation	NOT IRRITANT	Study 1984
	Eye irritation	Not Irritant	Jacobs GA, J.Am Coll. Toxicol, 11, 739 1988
	Skin sensitization	Not Sensitizing at 100%	Basketter DA et al, Food and Chemical Toxicology, 36, 327-333, 1998
	TERATOGENICITY	Not Teratogenic	
	BIO ACCUMULATION	No Bio accumulation	ECHA
	LC50	317042mg/m3 Air 2h	Konradova V, Folia Morphologica26, 28-34, 1978
	MUTAGENICITY	Not Mutagenic	Ames, (Ishidate et al., 1994, Pfeiffer et al. 1980)
	MUTAGENICITY	Not Mutagenic	Human embryonic lung culture (Litton Bionetics 1974, Huntingdon Research 1990)
	MUTAGENICITY	Not Mutagenic	In-Vivo, Study 1974
	NOAEC	2200 mg/m3/d for male	Suber et al., Fd Chem Toxicol, 27, 573-583, 1989
	NOAEL - REPROD TOXICITY	10100 mg/kg/d	Morrissey RE, Fundamental and Applied Toxicology, 13, 747-777, 1989
	NOAEL - TERATOGENICITY	520 mg/kg/d	Study 1993
SODIUM LAURETH SULFATE	Acute toxicity	LD50 > 15000.0000 mg/kg	Hamster/Oral

	Acute toxicity	LD50 >= 1820.0000 mg/kg	Rat/Oral
	Acute toxicity	LD50 > 2000.0000 mg/kg	Rat/Dermal
	Acute toxicity	LD50 > 3658.3300 mg/kg	Rabbit/Dermal
	Acute toxicity	LD50 = 500.0000 mg/kg	Rabbit/Dermal
	Skin Irritation	Irritant	PII = 4 (HERA)
	Skin Irritation	Slightly Irritant	at 1 and 5% J. Soc. Cosmet Chem 23 371-381(1972)
	Eye irritation	Irritant	J. Soc Cosmet Chem, 44 153-164 (1993)
	Skin sensitization	Sensitizing	Human
	Skin sensitization	Sensitizing	Journal of Investigative Dermatology 1969 vol. 52, No. 3
	Skin sensitization	Sensitizing	Mouse
	TOXICOKINECTICS	Metabolism	Metabolized
	TOXICOKINECTIS	Absorption	The dermal absorption of the chemical is relatively poor as can be expected from ionic molecule
	TOXICOKINETICS	Distribution	Distributed into the liver
	TOXICOKINETICS	Excretion	Through urine, faeces, expired air
	LOAEL	250 mg/kg/d	Food Cosmetic. Toxicology. Vol. 5, pp, 763-769 1967
	LOAEL DEVELOPMENT TOXICITY	714 mg/kg/d	SSS QSAR Team, QSAR Toolbox version 3.1 (2013)
	MUTAGENICITY	Not Mutagenic	
	NOAEL - MATERNAL TOXICITY	907 mg/kg/d	SSS QSAR Team, QSAR Toolbox version 3.1 (2013)
	REPRODUCTIVE TOXICITY	NO REPRODUCTIVE TOXICITY	@ 120 mg/kg/d
	REPRODUCTIVE TOXICITY	REPRODUCTIVE TOXICITY	@ 474.25 mg/kg/d
	Skin Irritation	Not Irritant	
	Skin Irritation	Not Irritant	Compostition
SOY ACID	Eye irritation	Not Irritant	
	Eye irritation	Not Irritant	Based on composition
	Skin sensitization	Not Sensitizing	
	Skin sensitization	Not Sensitizing	Based on composition
TOCOPHEROL	Acute toxicity	LD50 > 3000.0000 mg/kg	RABBIT/DERMAL
	Acute toxicity	LD50 > 4000.0000 mg/kg	RAT/ORAL
	Skin Irritation	NOT IRRITANT	
	Eye irritation	NOT IRRITANT	
	Skin sensitization	NOT SENSITIZING	
	Photo toxicity	NOT PHOTOTOXIC	
	CARCENOGENICITY	NON CARCENOGENIC	

8.1 Calculation of Margin of safety (MoS):

See "Toxicological Summary".

9. Undesirable effects and serious undesirable effects:

9.1 Following undesirable effects have been observed:

None

9.2 Following serious undesirable effects have been observed:

None

10. Information on the cosmetic product:

10.1 Claims:

Conclusion: There are no claims which needs to be substantiated according to the EU 655/2013.

PART B Cosmetic Product Safety assessment

1. Assessment conclusion:

1.1 Product presentation:

The product presentation and in particular its form, odour, colour, appearance, packaging, label design, size do not endanger consumer's health and safety due to confusion with foodstuff. The product does not appear other than it is. The product is therefore in compliance with Council Dir 87/357/EEC of 25 June 1987.

1.2 Labelling:

The labelling of the product is in compliance with Chapter VI Article 19:

Nomenclature	OK	In compliance to Art. 19.6
Language	OK	OK for FR,NL,DE,BE
Non prepacked product	NR	
Impossibility to label because of type	NR	
Impossibility to label because of size	NR	
List of ingredients	OK	In compliance to Art. 19.1g
Function of the product	OK	In compliance to Art. 19.1f
Batchn°	OK	We have no possibility to control this point so we assume that batch nr is always placed on the design of the package and design of the box (if applicable).
Particular precautions	NR	
Minimum durability date	OK	In compliance to Art. 19.1c
Nominal content	OK	In compliance to Art. 19.1b
Address	OK	In compliance to Art. 19.1a

NOK - Not OK
NR - Not relevant

1.3 Instructions for use and disposal:

OK - Instruction for use is obvious for the type of the product and it does not have to be specified on the product

1.4 Other indication:

NR

2. Labelled warnings and instructions of use:

NR

3. Reasoning:

3.1 Scientific Reasoning:

The product is found to be safe for cosmetic application because:
The MoS of each individual ingredient was found to be significantly higher than 100. For ingredients where no data on penetration was available 100% penetration was assumed, which is clearly an overestimation.
All ingredients are commonly used in cosmetics and contain all the necessary toxicological, chemical and physical information.

The concentration of impurities in the raw material are below detection limit or are present in a safe concentration.

The microbiological purity for each individual raw material is assured by the supplier or is not relevant due to the nature of a product.

The quality of water used for the production is controlled by the internal method described in the producer statement.

The challenge test and the microbial control on each batch assure a microbial security
For the particular category, the product is in compliance with :
- SCCS/1501/12 Notes of Guidelines, paragraph 4-4.2 and 4-4.3 for quantitative and qualitative microbiological limits (edition 8th)
- ISO-17516-2014, paragraph 4
The stability of the product is guaranteed by a stability assessment - it is according to "Guidelines on stabiliy testing of cosmetic products" of Colipa, March 2004.
Product is in compliance with SCCS/1501/12 Notes of Guideline, paragraph 4-3.3.
The interaction of the product with the packaging has been studied and was found to be neglect able. Therefore we can assume that the product will remain stable in the packaging.
The quality of the product is is controlled at each batch.
Product is in compliance with SCCS/1501/12 Notes of Guidelines, paragraph 4-3.3 for physical and chemical characteristicd of the finished cosmetic product (edition 8th).
The labelling is correct and informs the consumer correctly according to the EC 1223/2009.

The product presentation and in particular its form, odour, colour, appearance, packaging, label design, size do not endanger consumer's health and safety due to confusion with foodstuff. The product does not appear other than it is. The product is therefore in compliance with Council Dir 87/357/EEC of 25 June 1987.
There are no claims which needs to be substantiated according to the directive 655/2013.

The production and the storage of the product, its quality control and storage of raw materials are done according to the Good Manufacturing Practice guidelines described by the norm ISO 22716:2007(E).
Alle the restriction specified in Annexes II+III+IV+V have been taken into account while evaluation the product.

No secondary MOS calculation has been performed because all ingredients are not volatile and are not atomized.

To be fully in compliance with SCCS/1501/12 guideline, paragraph 4-4.2 for category 2, it is advised to do the control of the pathogens specified below:
- Candida Albicans - must be absent in 0.1g (or 0.1ml) of the product
- Pseudomonas Aeruginosa - must be absent in 0.1g (or 0.1ml) of the product
- Staphyllococus Aureus - must be absent in 0.1g (or 0.1ml) of the product

3.2 Use for children under 3 year:

The product is not assessed for this purpose. It is therefore not recommended to be used by children under 3 years.

3.3 External intimate hygiene:

The product is not assessed for this purpose. It is therefore not recommended to be used for external intimate hygiene.

3.4 Possible interaction of substances:

None of the substances from the formulations are able to interact with each other.

3.5 Possible alteration or reaction under certain circumstances:

None of the substances from the formulations can show an alteration or reaction under certain circumstances.

3.6 Toxicological consideration and non consideration:

The following raw materials have been considered / not considered:

Raw material	Considered	Non considered	Reason
AQUA		X	Neutral product in toxicological aspect
EURAMID N2	X		
EUROQUAT HCB LA	X		
FUSCHIA BOOST MOD II 2012705		X	Regulated by IFRA
MARSEL 0.2-0.8	X		
NEOPRES PE9010	X		
TEXAPON NSO UP	X		

3.7 Impact of stability:

Group	Impact	Comments
Preservative	OK	The product contains sufficient preservative system as proven by the results of the challange test.
Stabilizer	OK	The product contains sufficient stabilizer as proven by the results of the stability test.
Antioxidant	OK	The product contains sufficient antioxidant as proven by the results of the stability test.
Emulsifier	OK	The product contains sufficient emulsifier as proven by the results of the stability test.

Conclusion: All the ingredients needed to assure full stability of the product are present in the formulation.

4. Conclusion:

Conclusion: Based on the assessment performed in part A and the reasoning it can be concluded that the above product is safe to be used as a cosmetic product for its intended use. The product is in compliance with EC/1223/2009 with some minor remarks: see reasoning.

Safety assessor credentials:

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Poland

Proof of qualification: **Chemical Engineer Degree - 1991 - University Ghent, Belgium**
Safety Engineer at Indaver Chemical plant: 1991-1998
Parfumerie and Cosmetic - 1997 - Elishout - Anderlecht, Belgium
Dermato cosmetic science 1998 - University Brussel, Belgium

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Date: 27/05/2021
Dossier validity: Permanent

Disclaimer:
The above conclusion is valid until:
1) An amendment or change in cosmetic law occurs
2) The formulation is changed: any of the raw materials are omitted, added or changed.
3) Change of responsible person
4) Change of producer
5) Change of label
6) The safety assessor is not informed about undesirable effects and serious undesirable effects.

Attachments:
1. Declaration concerning Safety (MOS calculation)
2. Diploma of Safety Assessor
3. List of the documents used to evaluate the safety of above product