

Cosmetic Product Safety Report

Part B - Cosmetic product safety assessment

Gullni Sun spray SPF 50 (TBD)

Composed by **Cosmetics B.V.**, , the Netherlands

Date of issue 2024-06-25

Cosmetics B.V.



Msc. F.P.M. Ruiter

4.1. Assessment conclusion

4.1.0. Identification of the product	
Product name	: Gullni Sun spray SPF 50
Formula code	: 50062800 V1
Issue date	: 2024-06-25
4.1.1. Statement on the safety of the product	
<p>This safety assessment is executed in conformity with the criteria as stipulated in article 10 of Regulation (EC) No 1223/2009 and SCCS 11th revision of the Notes of Guidance for the safety assessment of cosmetic ingredients and/or products.</p> <p>Data used in this assessment may originate from supplier safety data sheets, toxicological profiles and technical information sheets but also form public sources.</p> <p>The sources and/or source documents are laid down and stored in the Aminchi database.</p> <p>EC and National regulations on cosmetic products in particular Regulation (EC) No 1223/2009.</p> <p>Also Recommendations from Colipa, SCCS, CIR and other public sources are evaluated.</p>	
In general	: The product does not contain substances not permitted as meant in Regulation EC No. 1907/2006 Annex XVII (CMR Cat. 1) or Regulation (EC) 1223/2009 Annex II.
Toxicological animal testing	: Neither the finished product, nor its prototypes have been tested on animals. See also V. Data on animal testing.
Toxicological tests using alternative methods	: Not applicable.
<p>Having considered the following profile:</p> <p>Product type : Cosmetics</p> <p>Application : Topical</p> <p>Usage quantity of the product : 9.0000 gram per application</p> <p>Usage frequency : 2.00 time(s) per day</p> <p>Instructions for use : Apply generously before sun exposure, using less lowers the level of protection significantly. Reapply it regularly, particularly after swimming, sweating and towelling.</p> <p>Mandatory instructions : None.</p> <p>Warnings : Avoid contact with your eyes. Overexposure to the sun is a serious health threat, even if you are using a sunscreen. Keep babies and young children out of direct sunlight.</p> <p>Mandatory warnings : None.</p> <p>Recommended warnings : None.</p>	
<p>Having regard to the physical, chemical and toxicological properties of the ingredients.</p> <p>Having regard to the phototoxic properties of the ingredients.</p> <p>Having regard to the purpose, intended application and advised use.</p> <p>Having regard to the expected exposure under normal and reasonable foreseeable conditions of use.</p> <p>Having regard to the physical, chemical and toxicological properties of the product.</p> <p>Having regard to the water quality of the manufacturing location.</p> <p>Having regard to the compliance with GMP.</p> <p>Having regard to the preservation.</p> <p>Having regard to the products stability.</p> <p>This product has a minimal eye irritation potential.</p> <p>Despite its intended leave on application eye irritation is unlikely to occur.</p> <p>This product has a minimal skin irritation potential.</p> <p>Despite its intended leave on application skin irritation is unlikely to occur.</p> <p>Dermatological testing is not required but for justification of marketing claims.</p> <p>This product has an (estimated) dermal LD50 > 5000 mg/kg.bw.</p> <p>It is considered to be non-toxic.</p> <p>This product has an (estimated) inhalation LC50 > 10000 mg/m3.</p> <p>It is considered to be non-toxic.</p> <p>This product has an (estimated) oral LD50 > 5000 mg/kg.bw.</p> <p>It is considered to be non-toxic.</p> <p>It is concluded that Gullni Sun spray SPF 50 , given the present level of knowledge, based on sufficient toxicological information, adequate Margins of Safety and/or international reviews, does not cause negative health effects to human under normal or reasonable foreseeable conditions of use.</p>	

Safety assessor : Msc. F.P.M. Ruiter

Date : 2024-06-24

Signature :



Disclaimer : The statement is preliminary. In any case of significant adverse health effects on users during use, a renewed safety assessment should take place.

Additional comments : Each and every change to the formula and/or its ingredients terminates the validity of this safety assessment.

Extra information : For supervising authorities detailed information is available at Cosmetics B.V.
In addition technical documents of substances and mixtures as well as source references of for example toxicological information are available and visible in INFO CARE's Aminchi database.


4.2. Labelled warnings and instructions of use

4.2.0. Identification of the product

Product name	: Gullni Sun spray SPF 50
Formula code	: 50062800 V1
Issue date	: 2024-06-25

4.2.1. Label

On the basis of article 19 of Regulation (EC) No. 1223/2009 the label shall carry the following elements:

Product name	: Gullni Sun spray SPF 50
Responsible person	: Cosmetics B.V. the Netherlands
File owner	:
Instructions for use	: Apply generously before sun exposure, using less lowers the level of protection significantly. Reapply it regularly, particularly after swimming, sweating and towelling.
Mandatory instructions	: None.
Warnings	: Avoid contact with your eyes. Overexposure to the sun is a serious health threat, even if you are using a sunscreen. Keep babies and young children out of direct sunlight.
Mandatory warnings	: None.
Recommended warnings	: None.
Product use	: Sunscreen lotion
Contents	: 1000000 ml
Batch code	: Mandatory
Durability indication	:  12 M
Ingredient declaration	: See 'INCI declaration' The ingredient declaration is to start with the wording 'Ingredients:'. Ingredients present in quantities of more than 1% need to be mentioned in descending order. Ingredients present in concentrations of less than 1% can be mentioned in random order.

Inci declaration

AQUA DIBUTYL ADIPATE DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE GLYCERIN C12-15 ALKYL BENZOATE ETHYLHEXYL SALICYLATE ETHYLHEXYL TRIAZONE COPERNICIA CERIFERA CERA BIS-DIGLYCERYL POLYACYLADIPATE-2 BIS-ETHYLHEXYLOXYPHENOL METHOXYPHENYL TRIAZINE PHENYLBENZIMIDAZOLE SULFONIC ACID POTASSIUM CETYL PHOSPHATE MICROCRYSTALLINE CELLULOSE SODIUM STEAROYL GLUTAMATE HYDROGENATED PALM GLYCERIDES CETEARYL ALCOHOL HYDROXYACETOPHENONE POTASSIUM HYDROXIDE PARFUM DECYLENE GLYCOL CAPRYLYL GLYCOL TOCOPHERYL ACETATE INULIN LAURYL CARBAMATE TETRASODIUM IMINODISUCCINATE CELLULOSE GUM ORYZA SATIVA BRAN CERA

CAPRYLHYDROXAMIC ACID
DIUTAN GUM
TOCOPHEROL
HELIANTHUS ANNUUS SEED OIL
SODIUM CHLORIDE
TETRAMETHYL ACETYLOCTAHYDRONAPHTHALENES
LINALYL ACETATE
VANILLIN

Artwork and product photo

4.3. Reasoning

4.3.0. Identification of the product	
Product name	: Gullni Sun spray SPF 50
Formula code	: 50062800 V1
Issue date	: 2024-06-25
<p>The following endpoints have been assessed in accordance with the notes of guidance of the SCCS and the requirements laid down in the Cosmetics Regulation: acute and sub-chronic toxicity for the relevant routes of exposure, phototoxicity, teratogenicity, mutagenicity and carcinogenicity, skin and inhalation sensitisation where applicable and skin and eye irritation.</p> <p>The evaluation is based on normal or reasonably foreseeable conditions of use. Misuse or use other than intended by for example deliberately swallowing or inhaling is not the primary subject to this assessment.</p> <p>The user group consists of adults and children. Without special health or age characteristics.</p>	
4.3.1. Safety evaluation of substances and/or mixtures	
Initial hazard review	: See table 'Initial hazard assessment' for the presence of hazardous substances and restrictions in the Annex of regulation (EC) No 1223/2009.
Assessment	: The product does not contain raw materials, which are not permitted in the sense of Regulation (EC) No 1223/2009. The product does not contain ingredients, which are not permitted in the sense of Regulation (EC) No 1223/2009.
4.3.2. Safety evaluation of the cosmetic product	
User group	: Adults and children
Packaging	: IBC
Application	: Sunscreen lotion
Instructions for use	: Apply generously before sun exposure, using less lowers the level of protection significantly. Reapply it regularly, particularly after swimming, sweating and towelling.
Mandatory instructions	: None.
Warnings	: Avoid contact with your eyes. Overexposure to the sun is a serious health threat, even if you are using a sunscreen. Keep babies and young children out of direct sunlight.
Mandatory warnings	: None.
Recommended warnings	: None.
Assessment	: The packaging provides no reason for special hazards or deviating use. The conclusions of the safety of the individual chemicals are given in the tables of 4.3.2.. This data represents the most likely route(s) of exposure.
Usage quantity of the product	: 9.0000 gram per application
Usage frequency	: 2.00 time(s) per day
Retention factor	: 1.00
Exposed skin surface	: 17500.00 cm2
Body weight	: 60.00 kg
Systemic exposure dose (SED)	: The SED is calculated as follows: <div>$SED = (A \text{ (mg/day)} * C \text{ (\%)} / 100 * DAp \text{ (\%)} / 100) / BW \text{ (kg)}$<p>A = Estimated daily exposure to a cosmetic product C = Concentration of substance in the product DAp = Dermal absorption BW = Body weight</p><p>The SED is calculated according to the SCCS's Notes of Guidance, 9th revision, 2015.</p><p>For specific baby products the body weight is 6,2 kg* otherwise 60 kg is used.</p><p>* H.J. Bremmer, L.C.H. Prud'Homme de Lodder, J.G.M. van Engelen, Cosmetics Fact Sheet, RIVM, 2006</p></div>

Margin of safety calculation : The Margin of Safety (MoS) is calculated as follows:

$$\text{MoS} = \text{NOAEL} / \text{SED}$$

In case of a 28 days NOAEL an extra factor 3 is applied.

Margins of safety : See part A table 3.8.4. 'Toxicological Evaluation - Margins of Safety'.

MoS discussion : Safety motivation(s) for substances for which MoS calculations for one or more toxicological endpoints are indecisive and for which expert reviews by e.g. SCCS, CIR, ECHA/IFRA miss:

DIBUTYL ADIPATE

Item(s) for review: chronic toxicity and reprotoxicity

The relevant NOAELs for all three routes are > 1000 mg/kg.bw/d, the highest tested doses. The real NOAELs will be (much) higher. Testing with higher doses is not required. Following the OECD approach the top dose need not exceed 1000 mg/kg.bw for low toxic substances. The use of dibutyl adipate can be considered safe.

Supportive evidence: CIR reported dibutyl adipate as safe up to 8%, the highest dose seen in the market.

DECYLENE GLYCOL

Conclusion: The CIR Expert Panel concluded decylene glycol is safe in the present practices of use and concentrations described. According to CIR the expectation is that 1,2-Glycols will be used in product categories and at concentrations comparable to others in the group. Reported concentrations for leave-on applications are 5 – 10% (source: IJT 31(Suppl. 2):147-168, 2012). Decylene glycol is used in a concentration of 0,25% in this product, so below the reported concentrations. It is therefore considered as being safe.

DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE

According to Annex VI DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE is allowed in this concentration.

ETHYLHEXYL SALICYLATE

According to Annex VI ETHYLHEXYL SALICYLATE is allowed in this concentration.

ETHYLHEXYL TRIAZONE

According to Annex VI ETHYLHEXYL TRIAZONE is allowed in this concentration.

BIS-ETHYLHEXYLOXYPHENOL METHOXYPHENYL TRIAZINE

According to Annex VI BIS-ETHYLHEXYLOXYPHENOL METHOXYPHENYL TRIAZINE is allowed in this concentration.

PHENYLBENZIMIDAZOLE SULFONIC ACID

According to Annex VI PHENYLBENZIMIDAZOLE SULFONIC ACID is allowed in this concentration.

POTASSIUM HYDROXIDE

The concentration, the use of POTASSIUM HYDROXIDE complies with the restrictions of Annex III 15a (d) Other uses as pH adjuster, pH < 11.

TOLUENE

TOLUENE is present as contaminant.

Phenol

Phenol is listed in Annex II. Phenol is present as contaminant in a technically acceptable concentration which is considered safe for use. As such it meets the criteria of the Cosmetic Regulation.

METHYLPARABEN

According to Annex V METHYLPARABEN is allowed in this concentration.

4.3. Reasoning

4.3.0. Identification of the product

Product name	: Gullni Sun spray SPF 50
Formula code	: 50062800 V1
Issue date	: 2024-06-25

4.3.1. Initial hazard assessment

INCI name	H-Statements	Annex EC No. 1223/2009	Limitations in cosmetics	Warnings on cosmetics
AQUA	----	----		
DIBUTYL ADIPATE	----	----		
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE	----	VI/28	max. 10%.	
GLYCERIN	----	----		
C12-15 ALKYL BENZOATE	----	----		
ETHYLHEXYL SALICYLATE	H410	VI/20	max. 5%.	
ETHYLHEXYL TRIAZONE	H413	VI/15	max. 5%.	
COPERNICIA CERIFERA CERA	----	----		
BIS-DIGLYCERYL POLYACYLADIPATE-2	----	----		
BIS-ETHYLHEXYLOXYPHENOL	----	VI/25	max. 10%.	
METHOXYPHENYL TRIAZINE	----	----		
PHENYLBENZIMIDAZOLE SULFONIC ACID	----	VI/6	max. 8%.	
POTASSIUM CETYL PHOSPHATE	H318	----		
MICROCRYSTALLINE CELLULOSE	----	----		
SODIUM STEAROYL GLUTAMATE	H319; H412	----		
HYDROGENATED PALM GLYCERIDES	----	----		
CETEARYL ALCOHOL	----	----		
HYDROXYACETOPHENONE	H319; H412	----		
POTASSIUM HYDROXIDE	H290; H302; H314; H318	III/15a; III/15d	15a: (a) max. 5% in nail cuticle solvent (b) Hair straightener 1. General use max 2%, 2. Professional use max 4,5% (c) pH adjuster - depilatories up to pH 12,7 (d) Other uses as pH adjuster up to pH 11. 15d: Callosity softener/remover max 1,5%.	15a: (a)(b 1.) Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children. (b 2.) For professional use only. Avoid contact with eyes. Can cause blindness. (c) Keep out of reach of children. Avoid contact with eyes. 15d:
CAPRYLYL GLYCOL	H319	----		
DECYLENE GLYCOL	H318	----		
TOCOPHERYL ACETATE	----	----		
INULIN LAURYL CARBAMATE	----	----		
TETRASODIUM IMINODISUCCINATE	----	----		
CELLULOSE GUM	----	----		
ORYZA SATIVA BRAN CERA	----	----		

INCI name	H-Statements	Annex EC No. 1223/2009	Limitations in cosmetics	Warnings on cosmetics
CAPRYLHYDROXAMIC ACID	H315; H319; H335	----		
DIUTAN GUM	----	----		
TOCOPHEROL	----	----		
TETRAHYDROLINALOOL	H315; H317; H319	----		
HELIANTHUS ANNUUS SEED OIL	----	----		
TETRAMETHYL ACETYLOCTAHYDRONAPHTHALENES	H315; H317; H410	----		
DISODIUM L-ASPARTATE	----	----		
REACTION MASS OF 2-METHYLBUTYL SALICYLATE AND PENTYL SALICYLATE	H302; H400; H410	----		
DISODIUM FUMARATE	----	----		
CYCLAMEN ALDEHYDE	H315; H317; H412	----		
ETHYL LINALOOL	H315; H317; H319	----		
TETRAHYDRO-METHYL-METHYLPROPYL)- PYRAN-4-OL	H319	----		
PHENETHYL ACETATE	H318	----		
HEXYL BENZOATE	H400; H410	----		
cis-3-HEXENYL SALICYLATE	H400	----		
HEXYL SALICYLATE	H315; H317; H400; H410	----		
BENZYL ACETATE	H412	----		
PENTADECALACTONE	H317; H411	----		
SODIUM CHLORIDE	----	----		
METHYL ALCOHOL	H225; H301; H311; H331; H370	III/52	Denaturant for ethanol and isopropyl alcohol. Max. 5% calculated as a % of ethanol and isopropyl alcohol.	
FATTY ACIDS, C8-18	H314; H318	----		
LINALYL ACETATE	H315; H317; H319	III/337		
DIHEXYL PHTHALATE	H360FD	II/1559		
VANILLIN	H319	III/346		
TOLUENE	H225; H304; H315; H336; H361d; H373	III/185	Max. 25% in nail products..	Keep out of reach of children. To be used by adults only..
METHYL-BENZODIOXEPINONE	H314; H318; H336; EUH071	----		
METHYL DIHYDROXY-DIMETHYLBENZOATE	H317	----		
CIS-3-HEXENYL BENZOATE	H317; H411	----		
5,5,6-TRIMETHYLBICYCLOHEPT-2- YLCYCLOHEXANOL	H319; H411	----		
ETHYLHEXANOL	H315; H319; H332; H335	----		
JUNIPERUS VIRGINIANA OIL	H304; H400; H410	III/358		
HEXAN-1-OL	H302	----		
ISOBUTYL ACETATE	H225; H336; EUH066	----		
TOCOPHEROL	H317	----		
ISOOCTANOL	H302; H315; H319	----		
ETHYL ACETATE	H225; H319; H336; EUH066	----		

INCI name	H-Statements	Annex EC No. 1223/2009	Limitations in cosmetics	Warnings on cosmetics
HYDROXYLAMINE HCl	H290; H302; H315; H317; H319; H373; H400	II/1506		
PHENOL	H301; H311; H314; H331; H341; H373; H318	II/1175		
METHYLPARABEN	H412	V/12	Max. 0,4 % (as acid) for single ester, max. 0,8 % (as acid) for mixtures of esters.	
BETA-CARYOPHYLLENE	H304; H317	III/332		
PINENE	H226; H302; H304; H315; H317; H400; H410	III/371	Peroxide value less than 10 mmol/L. This limit applies to the substance and not to the finished cosmetic product.	

4.3. Reasoning

4.3.0. Identification of the product

Product name	: Gullni Sun spray SPF 50
Formula code	: 50062800 V1
Issue date	: 2024-06-25

4.3.2. Safety assessment

The table(s) below present an overview of margins of safety and qualitative conclusions for each substance for the most relevant route(s) of exposure. Where the MoS is calculated with LD50's or NO(A)EL's measured as more (">") than a specific value, or where it is obtained with route-to-route extrapolations, or where the MoS is obtained from using a read across value, the resulting MoS is represented as > 100 or > 1000. Otherwise a numerical MoS is shown.
In case no value has been found for LD50, LC50 or NOAEL, this will be displayed as LD50 na / LC50 na / NO(A EL na. 'na' means not available, no data found.
The key conclusion is based on the primary route of exposure.

4.3.2. Primary route of exposure - Dermal

INCI name	Within Annex	Acute dermal toxicity	(Sub)Chronic dermal toxicity	Skin sensitisation	Mutagenicity	Carcinogenicity	Reprotoxicity (fertility)	Reprotoxicity (development)	Aminchi Expertise	Assessment	Conclusion
AQUA		1248	> 1000	No evidence	Not mutagenic	No evidence	No evidence	No evidence			Safe
DIBUTYL ADIPATE		1281	11	No evidence	Negative	NOEL na	33	36	No	Reviewed	Safe
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE	Yes	> 1000	> 1000	NOEL missing	Not mutagenic	NOEL na	> 1000	> 1000			Safe
GLYCERIN		1903	> 100	No evidence	Negative	> 100	51	33	CIR		Safe
C12-15 ALKYL BENZOATE		267	> 100	No evidence	Negative	NOEL na	> 100	> 100	CIR		Safe
ETHYLHEXYL SALICYLATE	Yes	673	> 100	No evidence	Not mutagenic	> 1000	74	> 100			Safe
ETHYLHEXYL TRIAZONE	Yes	381	> 1000	No evidence	Negative	NOEL na	> 1000	NOAEL na			Safe
COPERNICIA CERIFERA CERA		> 100	> 1000	No evidence	Negative	No evidence	No evidence	No evidence			Safe
BIS-DIGLYCERYL POLYACYLADIPATE-2		667	> 100	No evidence	Negative	NOEL na	NOAEL na	No evidence	CIR		Safe
BIS-ETHYLHEXYLOXYPHENOL	Yes	673	> 1000	No evidence	Negative	NOEL na	> 1000	No evidence			Safe
METHOXYPHENYL TRIAZINE											
POTASSIUM CETYL PHOSPHATE		> 1000	> 100	No evidence	Negative	NOEL na	NOAEL na	NOAEL na	CIR		Safe
PHENYLBENZIMIDAZOLE SULFONIC ACID	Yes	1684	> 100	No evidence	Negative	NOEL na	NOAEL na	> 100			Safe
POTASSIUM CETYL PHOSPHATE		1185	> 1000	No evidence	Negative	NOEL na	NOAEL na	NOAEL na	CIR		Safe
MICROCRYSTALLINE CELLULOSE		1565	NOAEL na	No evidence	Not mutagenic	No evidence	NOAEL na	NOAEL na	CIR		Safe
SODIUM STEAROYL GLUTAMATE		> 1000	> 100	No evidence	Negative	No evidence	No evidence	NOAEL na	NICNAS		Safe
HYDROGENATED PALM GLYCERIDES		> 1000	> 100	No evidence	Negative	NOEL na	> 100	> 100	No concern		Safe
CETEARYL ALCOHOL		8889	> 1000	No evidence	Negative	No evidence	No evidence	> 1000			Safe
HYDROXYACETOPHENONE		2673	> 100	No evidence	Negative	NOEL na	> 100	NOAEL na	No concern		Safe
POTASSIUM HYDROXIDE	Yes	> 100	NOAEL na	No evidence	Negative	No evidence	No evidence	No evidence			Safe

INCI name	Within Annex	Acute dermal toxicity	(Sub)Chronic dermal toxicity	Skin sensitisation	Mutagenicity	Carcinogenicity	Reprotoxicity (fertility)	Reprotoxicity (development)	Aminchi Expertise	Assessment	Conclusion
CAPRYLYL GLYCOL	Yes	> 1000	> 100	No evidence	Negative	NOEL na	> 1000	> 1000	CIR	Reviewed	Safe
DECYLENE GLYCOL		5387	56	No evidence	Negative	NOEL na	> 1000	NOAEL na	No		Safe
TOCOPHERYL ACETATE		10101	> 1000	No evidence	Not mutagenic	No evidence	No evidence	No evidence			Safe
INULIN LAURYL CARBAMATE		> 1000	NOAEL na	No evidence	Not mutagenic	NOEL na	NOAEL na	NOAEL na	TTC		Safe
TETRASODIUM IMINODISUCCINATE		8658	> 100	No evidence	Negative	NOEL na	> 100	> 1000	No concern		Safe
CELLULOSE GUM		8865	> 1000	No evidence	Not mutagenic	No evidence	No evidence	No evidence			Safe
ORYZA SATIVA BRAN CERA		> 1000	> 1000	No evidence	Negative	NOEL na	> 1000	> 1000	No concern		Safe
CAPRYLHYDROXAMIC ACID		> 1000	> 100	No evidence	Not mutagenic	NOEL na	NOAEL na	No evidence	No concern		Safe
DIUTAN GUM		15326	NOAEL na	No evidence	Negative	NOEL na	No evidence	No evidence	TTC		Safe
TOCOPHEROL		> 1000	> 1000	No evidence	Not mutagenic	No evidence	No evidence	> 1000			Safe
TETRAHYDROLINALOOL		63492	> 1000	Review	Negative	NOEL na	> 1000	> 1000	IFRA/EFFA CIR		Safe
HELIANTHUS ANNUUS SEED OIL		> 1000	> 1000	No evidence	Not mutagenic	No evidence	> 1000	NOAEL na			Safe
TETRAMETHYL ACETYLOCTAHYDRONAPHTHALENES		111111	> 1000	Review	Negative	NOEL na	> 1000	> 1000	IFRA/EFFA		Safe
disodium L-aspartate		> 1000	> 1000	No evidence	na	NOEL na	NOAEL na	NOAEL na	CIR		Safe
Reaction mass of 2-methylbutyl salicylate and pentyl salicylate		> 1000	> 1000	No evidence	Negative	NOEL na	> 1000	> 1000	IFRA/EFFA		Safe
DISODIUM FUMARATE		> 1000	NOAEL na	No evidence	Not mutagenic	NOEL na	NOAEL na	NOAEL na	CIR		Safe
CYCLAMEN ALDEHYDE		370370	> 1000	> 1000	Negative	NOEL na	> 100	NOAEL na	IFRA/EFFA IFRA/EFFA		Safe
ETHYL LINALOOL		370370	> 1000	No evidence	Not mutagenic	NOEL na	NOAEL na	NOAEL na			Safe
TETRAHYDRO-METHYL-METHYLPROPYL)-PYRAN-4-OL		148148	37037	No evidence	Negative	NOEL na	> 1000	> 1000	IFRA/EFFA		Safe
PHENETHYL ACETATE		460000	> 1000	No evidence	Negative	> 1000	> 1000	> 1000	IFRA/EFFA		Safe
HEXYL BENZOATE		1524444	NOAEL na	NOEL missing	Negative	NOEL na	NOAEL na	NOAEL na			Safe
cis-3-HEXENYL SALICYLATE	Yes	148148	> 1000	No evidence	Negative	NOEL na	> 1000	> 1000	IFRA/EFFA		Safe
HEXYL SALICYLATE		370370	> 1000	> 1000	Negative	NOEL na	No evidence	No evidence	IFRA/EFFA		Safe
BENZYL ACETATE		370370	> 1000	No evidence	Negative	> 1000	NOAEL na	> 1000	IFRA/EFFA		Safe
PENTADECALACTONE		370370	> 1000	No evidence	Negative	NOEL na	> 1000	> 1000	IFRA/EFFA		Safe
SODIUM CHLORIDE		888889	> 1000	No evidence	Negative	No evidence	No evidence	No evidence			Safe
METHYL ALCOHOL		> 1000	> 1000	No evidence	Negative	> 1000	> 1000	NOAEL na			Safe
Fatty acids, C8-18, potassium salts		> 1000							TTC		Safe
Fatty acids, C8-18		> 1000	> 1000	No evidence	Negative	NOEL na	> 1000	> 1000	TTC		Safe
LINALYL ACETATE		> 1000	18519	Review	Not mutagenic	NOEL na	NOAEL na	> 1000	IFRA/EFFA		Safe
Dihexyl phthalate		No	3809524	NOEL missing	na	NOEL na	> 1000	> 1000	TTC		Safe
VANILLIN	Yes	1113333	> 1000	No evidence	Negative	No evidence	NOAEL na	> 1000	IFRA/EFFA		Safe
TOLUENE		3580362	> 1000	No evidence	Negative	NOEL na	NOAEL na	NOAEL na			Safe
METHYL-BENZODIOXEPINONE		> 1000							IFRA/EFFA		Safe
METHYL DIHYDROXY-DIMETHYLBENZOATE		2020202	> 1000	> 300	Negative	No evidence	> 1000	> 1000			Safe
CIS-3-HEXENYL BENZOATE		> 1000	NOAEL na	> 300	Negative	NOEL na	NOAEL na	NOAEL na	IFRA/EFFA		Safe
5,5,6-TRIMETHYLBICYCLOHEPT-2-YLCYCLOHEXANOL		2020202	> 1000	No evidence	Negative		> 1000	> 1000	IFRA/EFFA		Safe

INCI name	Within Annex	Acute dermal toxicity	(Sub)Chronic dermal toxicity	Skin sensitisation	Mutagenicity	Carcinogenicity	Reprotoxicity (fertility)	Reprotoxicity (development)	Aminchi Expertise	Assessment	Conclusion
ETHYLHEXANOL		1955034	> 1000	No evidence	Negative na	> 1000	NOAEL na	> 1000	TTC		Safe
JUNIPERUS VIRGINIANA OIL		4444444							IFRA/EFFA		Safe
Hexan-1-ol		2219048	> 1000	No evidence	Negative	No evidence	> 1000	No evidence			Safe
ISOBUTYL ACETATE		6400000	> 1000	No evidence	Negative	NOEL na	NOAEL na	NOAEL na	TTC		Safe
TOCOPHEROL		26666667	> 1000	No evidence	Not mutagenic	No evidence	No evidence	No evidence			Safe
ISOOCTANOL		6746988	> 1000	No evidence	Not mutagenic	NOEL na	NOAEL na	> 1000	TTC		Safe
ETHYL ACETATE		120000000	> 1000	No evidence	Negative	NOEL na	NOAEL na	NOAEL na	CIR		Safe
HYDROXYLAMINE HCl	No	> 1000	> 1000	Review	Negative	NOEL na	NOAEL na	> 1000	DST		Safe
Phenol	Yes	8835341	870147	No evidence	na	> 1000	NOAEL na	> 1000			Safe
METHYLPARABEN	Yes	> 1000	> 1000	No evidence	Negative	No evidence	NOAEL na	> 1000			Safe
BETA-CARYOPHYLLENE		> 1000	NOAEL na	No evidence	Negative	NOEL na	> 1000	NOAEL na	IFRA/EFFA		Safe
PINENE		> 1000	> 1000	Review	Not mutagenic	NOEL na	> 1000	NOAEL na	IFRA/EFFA		Safe

Simultaneously a MoS > 1000 indicates that a fluctuation in the concentration, or exposure due to another foreseeable use with a higher SED will still result in safe use.

Aminchi requires a conclusion "safe" on each toxicological endpoint. Aminchi's safety assessment algorithm does not declare a substance safe based on the lowest NO(A)EL if any of the endpoints is not addressed either quantitative or qualitative.

The algorithm first of all compares the presence and concentration of a substance with any of the requirements of the annexes of the cosmetics regulation.

The next decision criterion is a "safe" on all toxicological endpoints. If any of the endpoints is non-decisive, usually because any of the endpoint values miss, than Aminchi uses a series of criteria. The criterion to identify safe use is given in the column Aminchi expertise.

If, after Aminchi's automated safety assessment one or more substances are still not safe, the safety assessor has the option of a manual justification for safe use. His/her justifications are listed in section 4.1.1. Whether such evaluation took place is indicated by the mark "Reviewed" in the column assessment.

A detailed protocol of the Aminchi algorithm is available in the software.

Explanation of terms used in the column Aminchi expertise:

IFRA/EFFA : Chemical present as ingredient in a perfume composition or as constituent of an essential oil, for which a valid IFRA Certificate is available. Substances whose use is covered by a valid IFRA certificate are considered safe to use.

CIR : Chemical present in a concentration regarded as 'safe as used' by CIR (Cosmetic Ingredient Review expert panel)

ADI : Chemical present in a concentration below 10% of ADI (Acceptable Daily Intake)

TTC : Chemical present in a concentration below the TTC (Toxicological Threshold Concentration)

IKW : The concentration of 1,4-dioxane or ethylene oxide is below the maximum allowed concentration of 10 resp. 1 ppm as established by IKW (Industrieverband Koerperpflege- und Waschmittel e. V.)

4.4.1. Safety assessor

Name : Msc. F.P.M. Ruiter

Position :

Company name : Cosmetics B.V.

Address :

the Netherlands

Telephone :

Website :

4.4.2. Qualification

Training and Education : University education, University of Amsterdam, March 1994, Specialisation Environmental Chemistry
Cosmetics Legislation, September 2019, NCV
Safety Assessment of Cosmetics in the EU, Free University of Brussels, training course, 2021

Memberships : NCV (Dutch Cosmetics Association)
NVCC (Dutch Association for Cosmetic Chemists)
KNCV (Royal Dutch Chemistry Association)

Other : Position: Quality Manager
Member of the NCV task force GMP for Cosmetics

4.4.3. For approval

Conclusion : It is concluded that the product, given the present level of knowledge and our company's expert review, is unlikely to cause negative health effects to human under normal or reasonable foreseeable conditions of use.

Issue date : 2024-06-24

Signature :





Faculteit der Scheikunde

De examencommissie voor de opleidingen scheikunde, farmacochemie en milieuwetenschappen/scheikunde verklaart dat

Franciscus Petrus Maria Ruiter

geboren op 5 maart 1969 te Avenhorn

het afsluitend examen, verbonden aan de opleiding scheikunde, met goed gevolg heeft afgelegd en bevoegd is tot het uitoefenen van alle aan het bezit van dit getuigschrift bij de wet verbonden rechten.

Amsterdam, 23 maart 1994.

voorzitter

secretaris

geëxamineerde

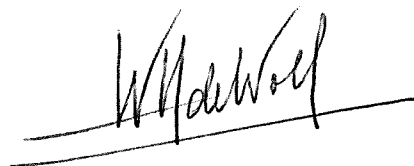
vrije Universiteit amsterdam

Het afsluitend examen heeft de volgende onderdelen omvat:

- . instroomprogramma
- . basiscursussen
- . programma in de afstudeerrichting MILIEUCHEMIE



voorzitter van de examencommissie



secretaris van de examencommissie



European Credit Transfer and Accumulation System ECTS: 6 credit points
ERT-accredited course: taken into consideration for the recognition as European Recognised Toxicologist

CERTIFICATE

The Undersigned declare that

Frank RUITER

has followed the lessons and has successfully passed the exam of the

“Online Safety Assessment of Cosmetics in the EU – Training Course 2021”

organized by the Vrije Universiteit Brussel

Brussels, April 15th 2021



Em. Prof. Dr. Pharm. V. Rogiers
Course organizer



Prof. Dr. Caroline Pauwels
Rector of Vrije Universiteit Brussel



