Safety Assessment

To confirm the requirements of the European Cosmetic Regulation EU 1223/2009 according to Chapter III, Article 10 in the currently valid version for the following products

Sample-Cream

Bulk-Art.: 45000

Fp-Art.: FW-001 (100ml), FW-002 (50ml)

For

Jürgen Hasel

Am Eiskellerwald 11

77855 Achern
(Responsible Person)

Created by

Dr. Joachim Blank

Safety Assessor at

SiKos
Sicherheitsbewerter.de

Table of Contents

A. Safety informations for the cosmetic Product

A.1. Quantitative and qualitative composition of the product

A.1.1. Product description

Product name:	Sample-Cream
Bulk number.:	45000
Formulation number:	ER13000.19
FP-number.:	FW-001 (100ml), FW-002 (50ml)
Product type:	Gesichtscreme
Product class:	Skin care
Application area:	Gesicht
Target group (Age):	20 - 80 Jahre
Responsible person:	Hasel

A.1.2. Formulation by tradenames

Article-No.	Tradename	Percentage	INCI-Composition
999	H2O dem.	59.2	Aqua
1884	Neossance Squalane	7	Squalane
1718	Aloe Vera Saft 1:1 rekonstruiert Bio [99,5% H2O / 0,5% 1000 Aloe 200x]	5	Aloe Barbadensis Leaf Juice
1352	Cetiol® 868	4	Ethylhexyl Stearate
1370	Emulgade PL 68/50	4	Cetearyl Alcohol, Cetearyl Glucoside
1277	Glycerin 86%	4	Glycerin, Aqua
1284	NEUTRALÖL pflanzlich/	4	Caprylic/Capric Triglyceride
1060	Cosphaderm® Touch	3	Heptyl Undecylenate
1988	TEGO® Natural Betaine	3	Betaine
1773	Lanette® 16	1.5	Cetyl Alcohol
1371	Cutina PES	1	Pentaerythrityl Distearate
1319	euxyl® PE 9010	1	Phenoxyethanol, Ethylhexylglycerin, Tocopherol
1018	Lanette® O	1	Cetearyl Alcohol
1318	Zitronensäure 20%ig	0.85	Aqua, Citric Acid
1595	Cosi-Plant Hamamelis GW	0.5	Glycerin, Aqua, Hamamelis Virginiana Leaf Extract, Potassium Sorbate, Sodium Benzoate
1059	Cosphaderm® T70 non GMO	0.3	Tocopherol, Helianthus Annuus Seed Oil
1075	Cosphaderm® X 34	0.2	Xanthan Gum
1016	Eumulgin® SG	0.2	Sodium Stearoyl Glutamate
1695	2010293 Mountain Legend Woman FF Fem PCMF Öko	0.15	Parfum, Limonene, Benzyl Salicylate, Citronellol, Alpha-Isomethyl Ionone, Benzyl Benzoate, Geraniol, Butylphenyl Methylpropional, Linalool, Citral, Benzyl Cinnamate, Benzyl Alcohol, Farnesol, Eugenol, Isoeugenol
2686	ABS Willow Bark Extract Powder #10229 (Weidenrinde)	0.1	Salix Alba Bark Extract

It is possible to use alternative raw materials instead of the raw materials mentioned in the recipe. With the alternative raw materials, care must be taken to ensure that they do not fall below the NOAEL of the raw material assessed here. It is also important to ensure that the impurities/traces of the raw material specified under point 5 are not exceeded.
Raw materials from different suppliers can be listed under one raw material number. All raw materials of one raw material number correspond to the deposited specification and have the same quality.

Article-No.	Tradename	Supplier
1773	Lanette® 16	BTC Europe GmbH
1773	Vegarol 1698	VVF Limited
1773	Kalcol 6870 P	Kao Chemicals Europe. S.L
1060		Cosphatec GmbH

Article-No.	Tradename	Supplier
1060	Heptyl Undecylenate	ACME SYNTHETIC CHEMICALS.
1059	Cosphaderm® T-70 NON GMO	Cosphatec GmbH
1059	dermofeel Toco 70 non GMO	Evonik Dr. Straetmans GmbH
1018	Lanette® O	BTC Europe GmbH
1018	Palmerol 6850	Biesterfeld Spezialchemie GmbH
1018	ECOROL 68/50P (Ph.Eur.)	Ecogreen Oleochemicals
1277	Glycerin 85% pflanzlich Ph. Eur. 10.0	Gustav Heess
1277	Glycerin 86,5% PHEUR, pflanzlich, kosher	A. + E. Fischer Chemie
1277	Glyzerin 86,5 % HP (pflanzlich)	Julius Hoesch GmbH & Co. KG
1277	Glycamed®86.5 %	Glacon Chemie
1319	euxyl® PE 9010	Julius Hoesch GmbH & Co. KG
1319	COSIGARD LIQUID PEHG	Cosnaderm Chemische Rohstoffe GmbH

A.1.3. Formulation by INCI

Percentage	Inci/Ctfa-Name	Function	CAS-Number	EINECS-Number
60.5744	Aqua	Solvent	7732-18-5	231-791-2
7	Squalane	Emollient	111-01-3	203-825-6
5	Aloe Barbadensis Leaf Juice	Skin Conditioning	85507-69-3 / 94349-62-9	287-390-8 / 305-181-2
4	Caprylic/Capric Triglyceride	Skin Conditioning	73398-61-5 / 65381-09-1	277-452-2 / 265-724-3
4	Ethylhexyl Stearate	Emollient	22047-49-0	244-754-0
3.7641	Glycerin	Humectant	56-81-5	200-289-5
3	Betaine	Hair Conditioning	107-43-7	203-490-6
3	Cetearyl Alcohol	Emollient Emulsifying	67762-27-0 / 8005-44-5	267-008-6 / -
3	Heptyl Undecylenate	Emollient	68141-27-5	268-850-7
2	Cetearyl Glucoside	Emulsifying	246159-33-1	
1.5	Cetyl Alcohol	Viscosity Controlling	36653-82-4	253-149-0
1	Pentaerythrityl Distearate	Emulsifying	13081-97-5	235-991-0
0.9	Phenoxyethanol	Preservative	122-99-6	204-589-7
0.21009	Tocopherol	Antioxidant	54-28-4 (gamma)/ 16698-35-4(beta) / 10191-41-0(DL) / 119-13-1 / 1406-18-4 / 1406-66-2 / 2074-53-5 (DL) / 59-02-9 (D)/7616-22-0	200-201-5 / 240-747-1 / 233-466-0 / 204-299-0 /215-798-8 / - / 218-197-9 / 200-412-2 / -
0.2	Sodium Stearoyl Glutamate	Emulsifying	38517-23-6 / 79811-24-8	253-980-9
0.2	Xanthan Gum	Binding	11138-66-2	234-394-2
0.17	Citric Acid	Buffering	77-92-9 / 5949-29-1	201-069-1

Percentage	Inci/Ctfa-Name	Function	CAS-Number	EINECS-Number
0.15	Parfum	Perfuming		
0.1	Salix Alba Bark Extract	Skin Conditioning	84082-82-6	282-029-0
0.09991	Ethylhexylglycerin	Deodorant	70445-33-9	408-080-2
0.09	Helianthus Annuus Seed Oil	Emollient	8001-21-6	232-273-9
0.0375	Hamamelis Virginiana Leaf Extract	Skin Conditioning	84696-19-5	283-637-9
0.004404	Limonene	Perfuming	138-86-3	205-341-0/931-893-3
0.0035985	Benzyl Salicylate	Perfuming	118-58-1	204-262-9
0.002	Potassium Sorbate	Preservative	24634-61-5 / 590-00-1	246-376-1 / -
0.002	Sodium Benzoate	Preservative	532-32-1	208-534-8

A.1.4. Inci-declaration on packaging

Ingredients: Aqua, Squalane, Aloe Barbadensis Leaf Juice, Caprylic/Capric Triglyceride, Ethylhexyl Stearate, Glycerin, Betaine, Cetearyl Alcohol, Heptyl Undecylenate, Cetearyl Glucoside, Cetyl Alcohol, Pentaerythrityl Distearate, Phenoxyethanol, Tocopherol, Sodium Stearoyl Glutamate, Xanthan Gum, Citric Acid, Parfum, Salix Alba Bark Extract, Ethylhexylglycerin, Helianthus Annuus Seed Oil, Hamamelis Virginiana Leaf Extract, Limonene, Benzyl Salicylate, Potassium Sorbate, Sodium Benzoate

The INCI's beginning from the ingredient Phenoxyethanol are less than 1 percent, and can therefore be freely chosen in order for marketing reasons.

A.2. Information on fragrances/flavours

Name	Concentration	Code-number	Supplier
2010293 Mountain Legend Woman FF Fem PCMF Öko	0.15 %	2010293	Firma Düllberg GmbH & Co KG Obenhauptstrasse 3 22335 Hamburg

A.2.1. Physical/chemical properties and stability of the cosmetic product

A.2.2. Product specification

A.2.3. Stability of the cosmetic products

A.3. Mikrobiological quality

A.3.1. Preservative stress test (Challenge test)

A.3.2. Production controls

For cosmetics that come into contact with the skin, the product is classified in category 2 - other products - according to the SCCS guideline in the current version in accordance with EN ISO 17516:2014. Therefore, the following microbiological limit values must be observed:

< 1000 CFU/g or ml (aerobic mesophilic microorganisms, total microbial count)
Escherichia coli: not detectable
Pseudomonas aeroginosa: not detectable
Staphylococcus aureus: not detectable
Candida albicans: not detectable

For each production batch, the parameters listed below are checked with the specification limits mentioned. For the total microbial count , a limit value lower by a factor of 10 as defined by the SCCS was chosen.
The total bacterial count of the process water used is monitored by the manufacturer in the course of hygiene monitoring. Likewise, the total bacterial count of the used, microbiologically susceptible raw materials is regularly examined and corresponds to the specified limit values.

All records are documented and archived by the manufacturer.

A.4. Impurities, traces, information on packaging material

A.4.1. Raw materials

The individual specifications with data on impurities, residual solvents, heavy metals etc. of the raw materials used are contained in the PIF. The maximum possible inputs of contaminants into the cosmetic product through the raw materials are listed below.

Impurity	Raw Material	Content	Max. content in cosmetic product
Anthraquinones (measured as Aloin) [ppm]	Aloe Vera Saft 1:1 rekonstruiert Bio [99,5% H2O / 0,5% 1000 Aloe 200x]	0.005	**0.005**
Antimony [ppm]	Eumulgin® SG	0.01	
	Emulgade PL 68/50	0.2	
	Cutina PES	0.05	
	Lanette® 16	0.075	
	Cetiol® 868	0.2	
	Lanette® O	0.05	
	TEGO® Natural Betaine	0.03	**0.615**
Arsenic [ppm]	Eumulgin® SG	0.002	
	Emulgade PL 68/50	0.04	
	Cutina PES	0.01	
	Lanette® 16	0.015	
	Cosphaderm® Touch	0.03	
	Cetiol® 868	0.04	
	Cosphaderm® T70 non GMO	0.003	
	Neossance Squalane	0.07	
	Lanette® O	0.01	
	Aloe Vera Saft 1:1 rekonstruiert Bio [99,5% H2O / 0,5% 1000 Aloe 200x]	0.000125	
	TEGO® Natural Betaine	0.03	
	Glycerin 99 % pflanzlich PH.Eur	0.1032	
	Cosphaderm® X 34	0.004	
	Zitronensäure monohydrat E330	0.0017	**0.359025**
Benzo(a)pyrene [ppb]	Emulgade PL 68/50	0.08	
	Cutina PES	0.02	
	Lanette® 16	0.03	
	Cetiol® 868	0.08	
	Cosphaderm® T70 non GMO	0.006	**0.216**

Impurity	Raw Material	Content	Max. content in cosmetic product
Cadmium [ppm]	Eumulgin® SG	0.004	
	Emulgade PL 68/50	0.08	
	Cutina PES	0.02	
	Lanette® 16	0.03	
	Cosphaderm® Touch	0.03	
	Cetiol® 868	0.08	
	Cosphaderm® T70 non GMO	0.003	
	Lanette® O	0.02	
	Aloe Vera Saft 1:1 rekonstruiert Bio [99,5% H2O / 0,5% 1000 Aloe	0.000025	
	200x]	0.03	
	TEGO® Natural Betaine	0.0344	
	Glycerin 99 % pflanzlich PH.Eur	0.002	
	Cosphaderm® X 34		**0.333425**
Chromium [ppm]	TEGO® Natural Betaine	0.03	**0.03**
Cobalt [ppm]	TEGO® Natural Betaine	0.03	**0.03**
Heavy Metals [ppm]	Eumulgin® SG	0.02	
	Emulgade PL 68/50	0.4	
	Cutina PES	0.1	
	Cosphaderm® Touch	0.3	
	Cetiol® 868	0.4	
	NEUTRALÖL pflanzlich/	0.8	
	Neossance Squalane	0.7	
	Lanette® O	0.1	
	Aloe Vera Saft 1:1 rekonstruiert Bio [99,5% H2O / 0,5% 1000 Aloe	0.005	
	200x]	0.6	
	TEGO® Natural Betaine	0.172	
	Glycerin 99 % pflanzlich PH.Eur	0.2	
	euxyl® PE 9010	0.04	
	Cosphaderm® X 34	0.0085	
	Zitronensäure monohydrat E330		**3.8455**
Isopropanol [ppm]	Cosphaderm® X 34	1	**1**

Impurity	Raw Material	Content	Max. content in cosmetic product
Lead [ppm]	Eumulgin® SG	0.004	
	Emulgade PL 68/50	0.08	
	Cutina PES	0.1	
	Cosphaderm® Touch	0.03	
	Cetiol® 868	0.4	
	Cosphaderm® T70 non GMO	0.0003	
	Neossance Squalane	0.035	
	Lanette® O	0.1	
	Aloe Vera Saft 1:1 rekonstruiert Bio [99,5% H2O / 0,5% 1000 Aloe 200x]	0.00025	
	TEGO® Natural Betaine	0.03	
	Glycerin 99 % pflanzlich PH.Eur	0.0688	
	Cosphaderm® X 34	0.004	
	Zitronensäure monohydrat E330	0.00085	**0.8532**
Mercury [ppm]	Eumulgin® SG	0.002	
	Emulgade PL 68/50	0.04	
	Cutina PES	0.01	
	Lanette® 16	0.015	
	Cosphaderm® Touch	0.03	
	Cetiol® 868	0.04	
	Cosphaderm® T70 non GMO	0.0003	
	Neossance Squalane	0.0035	
	Lanette® O	0.01	
	Aloe Vera Saft 1:1 rekonstruiert Bio [99,5% H2O / 0,5% 1000 Aloe 200x]	0.000125	
	TEGO® Natural Betaine	0.03	
	Glycerin 99 % pflanzlich PH.Eur	0.0344	
	Cosphaderm® X 34	0.002	
	Zitronensäure monohydrat E330	0.0017	**0.219025**
Nickel [ppm]	Eumulgin® SG	0.004	
	Emulgade PL 68/50	0.08	
	Cutina PES	0.02	
	Lanette® 16	0.03	
	Cetiol® 868	0.08	
	Neossance Squalane	0.07	
	Lanette® O	0.02	
	TEGO® Natural Betaine	0.03	**0.334**
Oxalic acid [ppm]	Zitronensäure monohydrat E330	0.17	**0.17**
Phenol [ppm]	euxyl® PE 9010	0.1	**0.1**
Total pesticide content [ppm]	Aloe Vera Saft 1:1 rekonstruiert Bio [99,5% H2O / 0,5% 1000 Aloe 200x]	0.00025	**0.00025**

The impurities in the raw materials used do not exceed the maximum amount regulated in the EU

cosmetics regulation. This also applies to the entire formulation.

Generally, the raw materials used meet the requirements for food, cosmetic and pharmaceutical quality. If this is not the case, the possible contaminants were considered separately for their safety for the end consumer in cosmetic products in the assessment.

If no quantitative information on maximum amounts of contaminants has been provided by the raw material manufacturers, there are at least corresponding statements that guarantee compliance with the applicable maximum amounts of the qualities mentioned in the previous section.

A.4.2. Primary packaging materials

Finished product No.	Finished product name	Filling Quantity	Name packaging	Description packaging	Supplier	Shelf life
FW-001	Beispielcreme 01	100ml	PE-Tube	PE-Tube weiss, mit Klappscharnier verschluss	MULTITUBES GROUP	PAO 12M
FW-002	Beispielcreme 01	50ml	Glasstiegel	Glasstiegel mit Abdeckscheibe und Schraubverschluss	LUMSON DEUTSCHLAND	PAO 3M

Compliance with the relevant Article 17 of EU Regulation 1223/2009, which requires the exclusion of migration of prohibited substances from the immediate packaging into the cosmetic product in accordance with Annex II, is guaranteed. The declarations of conformity according to EU-regulation 10/2011 can be found in the PIF.

A.5. Normal and reasonably foreseeable use

A.6. Exposure ot the cosmetic product

Parameter	Definition
Produt-type:	Gesichtscreme
Target group (age):	20 - 80 Jahre
Average weight of target group (kg):	60
Application Area:	Gesicht
Relative daily exposure, $E_{product-rel}$ (mg/kg bw/day)	24,14
Exposure route:	Dermal
Type of exposure:	Leave on
Retention factor R:	1
Appliaction Area A (cm^2):	565
Daily applied quantity (g/day) = G:	1,54
Frequence of application/day F:	2,14

The parameters listed in the table are taken, where available, from the Notes of Guidance (SCCS) in the current version. The calculated daily relative application rate ($E_{product-rel}$) is used as a basis for the exposure assessment of the individual components.

A.7. Exposure to the substances

The following formula is used to calculate systemic exposure to the substances:

$$SED_{Substance} = \text{dermal Absorption} * \text{Concentration (Substance)} * (E_{product-rel})$$

with

$SED_{Substance}$

= Systemic availability (exposure) of the substance in mg/kg bw/d

Conzentration (Substance)

=% Content of the substance in the formulation

Dermal absorption:

The dermal absorption was either taken from the literature or estimated.

The estimation is based on the classification of chemicals based on their physico-chemical properties with respect to their potential to be absorbed by the skin. The basis is the following table.

flux (Jmax µg/cm²/h)	*M [g/mol]*	*log Pow*	*max. Absorption*
0	> 1000	any	neglible
< 0,1	> 300	< - 1 or > 5	< 10%
0,1 - 1,0	~ 200 - 300	> 2,0 - 2,5	< 10%
1,0 - 10,0	~ 150 - 250	1,0 - 2,0	< 20%
10,0 - 100,0	~ 60 - 200	0,5 - 3,0	< 40%
> 100	< 150	0,5 - 1,5	< 80%
perfume oils, preservatives, extracts	any	any	100 % (worst case)

with log Pow = Partition coefficient octanol-water

(Kroes et al. Food Chemical Toxicol, 2007, modified by G. Nohynek, 2009)

SEDs of the individual substances are calculated at the end of Chapter 8.

A.8. Toxicological profiles and evaluation of substances

A.8.1. Toxicological profiles and evaluation of substances

INCI-Name: Aqua

	Result	Test Type	Test Description	Source
Dermal absorption, [%]	100	in silico	worst case	

INCI-Name: Squalane

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	> 1000	animal	OECD 422	TD0193
Bioavailability (NOAEL 90 days), [%]	50			
Acute oral toxicity (LD 50), [mg/kg bw/d]	> 40500	animal	50 mice	TD0192
Skin irritation	non-irritant	animal	Rabbit, shaved and unshaved skin, 24 h occlusive undiluted.	TD0192
Eye irritation	non-irritant	animal	Rabbit, 0.1 ml/eye, Draize	TD0192
Sensitization	non-sensitizing	clinical	204 subjects, HRIPT with 16.6% in formulation, 3 weeks	TD0192
Dermal absorption, [%]	10	in silico	SCCS	
Genotoxicity	non-mutagenic	in vitro	OECD 471	TD0193
Carcinogenicity	non-carcinogenic	animal	und. Application on mouse skin 3*daily in 14 weeks, tumor-protective effect proven.	TD0192
Toxicity to reproduction	non-toxic for reproduction	animal	OECD 422: NOEL > 1000 mg/kg bw/d	TD0193
Teratogenicity	non-teratogenic	animal	OECD 422: NOEL > 1000 mg/kg bw/d	TD0193
Phototoxicity	non-phototoxic	in silico	no adv. effects due to chem. structure to be expected	
Photosensitization	non-sensitizing	in silico	no adv. effects due to chem. structure to be expected	
Molecular weight [Dalton]	422.82			
CIR data	Squalane is considered safe by the CIR up to application concentrations of 97 %.			TD0121
Special consideration	Squalane is a triterpene hydrocarbon (only saturated bonds) and a component of human sebum; squalane is found as a component of human nutrition in fish liver oil and many vegetable oils.			

INCI-Name: Aloe Barbadensis Leaf Juice

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	> 100000	animal	resulting from NOEL (1549 mg/kg bw/d) for acemannan in 6 months study in rats	TD0062
Bioavailability (NOAEL 90 days), [%]	50			
Acute oral toxicity (LD 50), [mg/kg bw/d]	> 5000	animal	rats	TD0130
Skin irritation	non-irritant	clinical	48-hour occlusive application of Aloe Barbadensis Leaf Juice on 10 female backs	TD0062
Eye irritation	non-irritant	animal	Rabbit, diluted 1:200	TD0130
Sensitization	non-sensitizing	in silico	no adv. effects expected	
Dermal absorption, [%]	50	in silico	SCCS	
Genotoxicity	non-mutagenic	in silico	No adverse effects expected on the basis of the composition	
Carcinogenicity	non-carcinogenic	in silico	No adverse effects expected on the basis of the composition	
Toxicity to reproduction	non-toxic for reproduction	in silico	No adverse effects expected on the basis of the compositionNo adverse effects expected on the basis of the composition	
Teratogenicity	non-teratogenic	in silico	No adverse effects expected on the basis of the composition	
Phototoxicity	non-phototoxic	clinical	0.5 % formulation, 25 people	TD0062
Photosensitization	non-sensitizing	clinical	0.5 % formulation, 25 people	TD0062
CIR data	The CIR considers the use of Aloe Barbadensis Leaf Juice in cosmetics to be safe provided that the antraquinone content is below 50 ppm.			TD0062
Special consideration	It is the reconstituted aloe vera juice from the water storage tissue of the aloe plant, which was obtained by diluting a 200-fold juice concentrate, mainly consisting of D-glucose and D-mannose polysaccharides. It also contains simple sugars, vitamins, amino acids, glycoproteins and enzymes. Acemannan (polysaccharide) is contained to about 10%. For acemanan a NOEL (6 months feeding study in rats) of 1549 mg/kg bw/d was determined, theoretically the NOAEL based on acemanan for aloe vera juice would be 3 kg/kg bw/d.			

INCI-Name: Caprylic/Capric Triglyceride

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	> 1000	animal	Caprylic/Capric Glycerides are glycerides of saturated fatty acids that are part of the human diet.	TD0078
Bioavailability (NOAEL 90 days), [%]	50			
Acute oral toxicity (LD 50), [mg/kg bw/d]	> 5000	animal	rat	TD0079
Skin irritation	non-irritant	in silico	no adv. effects known from triglycerides of fatty acids	
Eye irritation	non-irritant	in silico	no adv. effects known from triglycerides of fatty acids	
Sensitization	non-sensitizing	animal		TD0079
Dermal absorption, [%]	10	in silico	derived from molar mass/distribution coefficient.	
Genotoxicity	non-mutagenic	in silico	no adv. effects known from triglycerides of fatty acids	
Carcinogenicity	non-carcinogenic	in silico	no adv. effects known from triglycerides of fatty acids	
Toxicity to reproduction	non-toxic for reproduction	in silico	no adv. effects known from triglycerides of fatty acids	
Teratogenicity	non-teratogenic	in silico	no adv. effects known from triglycerides of fatty acids	
Phototoxicity	non-phototoxic	in silico	no adv. effects known from triglycerides of fatty acids	
Photosensitization	non-sensitizing	in silico	no adv. effects known from triglycerides of fatty acids	
Molecular weight [Dalton]	> 500			
log POW	> 5		estimated	
SCCS data	Caprylic/Capric Triglycerides is considered safe by the CIR for leave-on and rinse-off products with an application concentration of up to 95.6 %.			TD0079
Special consideration	Caprylic/Capric Triglycerides are triglycerides of saturated fatty acids that are part of the human diet.			

INCI-Name: Ethylhexyl Stearate

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	> 800	animal	Hexyl laurate, OECD 408	TD0012
Bioavailability (NOAEL 90 days), [%]	50			
Acute oral toxicity (LD 50), [mg/kg bw/d]	> 2000	animal	Directive 84/449/EEC, B.1	TD0010
Skin irritation	non-irritant	animal	OECD 404	TD0010
Eye irritation	mildly irritating	animal	OECD 405	TD0010
Sensitization	non-sensitizing	animal	OECD 406	TD0010
Dermal absorption, [%]	10	in silico	Derived from Log POW/molar mass	
Genotoxicity	non-mutagenic	in vitro	OECD 471	TD0010
Carcinogenicity	non-carcinogenic	in silico	no adv. effects expected, since food	
Toxicity to reproduction	non-toxic for reproduction	animal	BASF-Test	TD0010
Teratogenicity	non-teratogenic	animal	BASF-Test	TD0010
Phototoxicity	non-phototoxic	in silico	no absorption in the relevant UV range	
Photosensitization	non-sensitizing	in silico	no absorption in the relevant UV range	
Molecular weight [Dalton]	396.7			
log POW	11		Experimental	TD0010
CIR data	Ethylhexyl stearate is considered safe by the CIR up to an application concentration of 25 % in cosmetics.			TD0011
Special consideration	Ethylhexyl stearates are esters of natural fatty acids/fatty alcohols found in the human diet, which are metabolised.			

INCI-Name: Glycerin

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	> 2200	clinical	50-day study, administration via food to 10 men and 4 women	TD0013
Bioavailability (NOAEL 90 days), [%]	50			
Acute oral toxicity (LD 50), [mg/kg bw/d]	> 2530	animal	rats	TD0013
Skin irritation	non-irritant	clinical	Human, 25% solution, 24 h	TD0013
Eye irritation	mildly irritating	clinical	human 100%, burning and tears of the eyes, no permanent damage	TD0013
Sensitization	non-sensitizing	clinical	HRIPT	TD0013
Dermal absorption, [%]	50	in silico	SCCS	
Genotoxicity	non-mutagenic	animal	OECD 471	TD0013
Carcinogenicity	non-carcinogenic	animal	no adv. effects expected	
Toxicity to reproduction	non-toxic for reproduction	animal	BASF-Test	TD0013
Teratogenicity	non-teratogenic	animal	BASF-Test	TD0013
Phototoxicity	non-phototoxic	animal	no adv. effects expected	
Photosensitization	non-sensitizing	animal	no adv. effects expected	
Molecular weight [Dalton]	92.1			
log POW	-1.76			TD0013
SCCS data	Glycerol is considered safe by the CIR up to an application concentration of 79 % in cosmetics.			TD0013
Special consideration	Glycerine is a component of natural fats found in human food, which are metabolised to fatty acids and glycerine. There is no ADI for the food additive E 422 (glycerol).			

INCI-Name: Betaine

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	> 2500	animal	OECD 453, 52-month feeding study in rats with 5% betaine in food (rats consume approx. 5 g of food per 100 g bw, thus 5% in the diet corresponds to 2500 mg/kg bw/d)	TD0336
Bioavailability (NOAEL 90 days), [%]	50			
Acute oral toxicity (LD 50), [mg/kg bw/d]	11179	animal	OECD 401	TD0336
Skin irritation	non-irritant	clinical	5 % betaine in different formulations, 26 subjects, 24 h occlusive patch	TD0336
Eye irritation	non-irritant	animal	OECD 405, 10% solution	TD0336
Sensitization	non-sensitizing	animal	OECD 406, 50% induction, 20% challenge, no sens.	TD0336
Dermal absorption, [%]	1	in vitro	OECD 428, < 0.1 % penetrated through the skin	TD0336
Genotoxicity	non-mutagenic	in vitro	OECD 474 + 476	TD0336
Carcinogenicity	non-carcinogenic	animal	OECD 453, 52-month feeding study in rats with 5% betaine in feed, no adv. effects	TD0336
Toxicity to reproduction	non-toxic for reproduction	in silico	QSAR regarding binding potential to estrogen receptor B-negative	TD0336
Teratogenicity	non-teratogenic	in silico	no adv. effects due to chem. structure to be expected	
Phototoxicity	non-phototoxic	in silico	no adv. effects to be expected due to lack of absorption in the relevant UV range	
Photosensitization	non-sensitizing	in silico	no adv. effects to be expected due to lack of absorption in the relevant UV range	
Molecular weight [Dalton]	117.15			
log POW	- 3.1		OECD 107	TD0336
CIR data	Betaine is in kosmet. Products up to 8.7%, the use is evaluated as safe by the CIR.			TD0335
Special consideration	Betaine is the N,N,N trimethylammonium zwitterion of glycine.			

INCI-Name: Cetearyl Alcohol

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	750	animal	1-hexadecanol, 13 weeks, rats	TD0019
Bioavailability (NOAEL 90 days), [%]	50			
Acute oral toxicity (LD 50), [mg/kg bw/d]	> 5000	animal	rat	TD0017
Skin irritation	non-irritant	animal	OECD 404	TD0017
Eye irritation	mildly irritating	animal	OECD 405	TD0017
Sensitization	non-sensitizing	animal	OECD 406, C16-C18 Alcohols	TD0019
Dermal absorption, [%]	50	in silico		
Genotoxicity	non-mutagenic	in vitro	SCCS	TD0017
Carcinogenicity	non-carcinogenic	in silico	no adv. effects due to chem. structure to be expected	
Toxicity to reproduction	non-toxic for reproduction	animal	rats, no adverse effect on reproductive organs at 1822 mg/kg bw/d	TD0019
Teratogenicity	non-teratogenic	animal	Rats, no teratogenic effect	TD0019
Phototoxicity	non-phototoxic	in silico	no adv. effects due to chem. structure to be expected	
Photosensitization	non-sensitizing	in silico	no adv. effects due to chem. structure to be expected	
Molecular weight [Dalton]	270.49			
log POW	7.05		Experimental	TD0017
CIR data	Long-chain aliphatic fatty alcohols are considered safe by the CIR up to an application concentration of up to 50 % in cosmetics.			TD0018
Special consideration	Cetearyl Alcohol is a mixture of cetyl (approx. 30%) and stearyl (approx. 70%) alcohol. Cetearyl Alcohol is metabolized in the human body after enzymatic oxidation via fatty acid degradation.			

INCI-Name: Heptyl Undecylenate

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	100	animal	OECD 408 with undec-10-enoic acid (ECHA: OECD 408 with heptanol NOAEL = 1000 mg/kg bw/d)	TD0483
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	non-irritant	clinical	HRIPT on 51 subjects	TD0394
Eye irritation	non-irritant	animal	no adv effects of alkyl esters in this molecular weight range known	TD0011
Sensitization	non-sensitizing	clinical	OECD 422C (DPRA) + HRIPT on 51 subjects	TD0394
Dermal absorption, [%]	50	in silico	SCCS	
Genotoxicity	non-mutagenic	in vitro	OECD 471 with heptanol and undec-10-enoic acid	TD0482
Carcinogenicity	non-carcinogenic	in silico	no adv. effects due to chem. structure to be expected	
Toxicity to reproduction	non-toxic for reproduction	animal	OECD 421 with undec-10-enoic acid, NOAEL > 450 mg/kg bw/d, OECD 422 with heptanol, NOAEL > 1000 mg/kg bw/d	TD0482
Teratogenicity	non-teratogenic	animal	OECD 421 with undec-10-enoic acid, NOAEL > 450 mg/kg bw/d, OECD 422 with heptanol, NOAEL > 1000 mg/kg bw/d	TD0483
Phototoxicity	non-phototoxic	in silico	no absorption in the relevant UV range	
Photosensitization	non-sensitizing	in silico	no absorption in the relevant UV range	
Molecular weight [Dalton]	282.46			
log POW	7.5		calculated	TD0011
CIR data	Heptyl Undecylenate is used up to 26% in cosmetic products and its use is considered safe by the CIR.			TD0011
Special consideration	Heptyl undecylenates are esters of heptanol (C7) with undec-10-enoic acid (C11), which are formed under physiological conditions. Therefore, the lowest values of the respective individual substances were used to assess systemic toxicity.			

INCI-Name: Cetearyl Glucoside

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	> 1000	animal	C10 - 16 alkyl glucoside, 90d, rats	TD0221
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	mildly irritating	clinical	2.0 % lauryl or coco-glucosides in 20 volunteers, 24 h occlusive	TD0064
Eye irritation	irritant	animal	OECD 405 with C 12 - 16 alkyl glucosides	TD0064
Sensitization	non-sensitizing	animal	C16-C18 Glucosid, LLNA 2.5 - 10%	TD0064
Dermal absorption, [%]	50	in silico	SCCS	
Genotoxicity	non-mutagenic	in vitro	C10 - 16 alkyl glucosides: Ames test and OECD 473 (chromosome aberration test on CHO cells)	TD0221
Carcinogenicity	non-carcinogenic	in silico	no adv. effects to be expected, as components are food-components	
Toxicity to reproduction	non-toxic for reproduction	animal	C12- 14 Alkyl Glucoside, OECD 421, NOAEL> 1000 mg/kg bw/d	TD0221
Teratogenicity	non-teratogenic	animal	C12- 14 Alkyl Glucoside, OECD 421, NOAEL> 1000 mg/kg bw/d	TD0221
Phototoxicity	non-phototoxic	in silico	no adv. effects to be expected due to molecular structure.	
Photosensitization	non-sensitizing	in silico	no adv. effects to be expected due to molecular structure.	
CIR data	Cetearyl glucoside is used in rinse-off products up to 3 % and in leave-on products up to 2 %. These concentrations are assessed as safe by the CIR.			TD0064
Special consideration	It is the condensation product of cetyl/stearyl alcohol with glucose. In the body these are split to the corresponding fatty alcohol and glucose and metabolically utilized.CG has a skin and mucous membrane irritating potential, but the application concentration of the formulation evaluated here is below the threshold of the irritating effect, this was proven in a clinical application test.			

INCI-Name: Cetyl Alcohol

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	> 4257	animal	90 days feeding study in rats	TD0248
Bioavailability (NOAEL 90 days), [%]	50			
Acute oral toxicity (LD 50), [mg/kg bw/d]	> 2000	animal		TD0248
Skin irritation	non-irritant	clinical	HRIPT with 6.36 % in cream, 229 test persons	TD0246
Eye irritation	mildly irritating	animal	OECD 405, reversible adv. effects with pure substance	TD0248
Sensitization	non-sensitizing	clinical	HRIPT with 6.36 % in cream, 229 test persons	TD0246
Dermal absorption, [%]	50	in silico	SCCS	
Genotoxicity	non-mutagenic	in vitro	OECD 471	TD0248
Carcinogenicity	non-carcinogenic	in silico	no adv. effects based on the chem. structure to be expected	
Toxicity to reproduction	non-toxic for reproduction	animal	OECD 422, NOAEL > 2000 mg/kg bw/d	TD0248
Teratogenicity	non-teratogenic	animal	OECD 422, NOAEL > 2000 mg/kg bw/d	TD0248
Phototoxicity	non-phototoxic	clinical	Photo-HRIPT with 4 % in lipstick, 52 subjects	TD0246
Photosensitization	non-sensitizing	clinical	Photo-HRIPT with 4 % in lipstick, 52 subjects	TD0246
Molecular weight [Dalton]	242.44			
CIR data	Cetyl alcohol is used up to 15% in cosmetic products, this concentration is considered safe by the CIR.			TD0245
Special consideration	It is saturated, linear C16 alcohol. Mucosa-irritating effects are not to be expected at low application concentrations.			

INCI-Name: Pentaerythrityl Distearate

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	483	animal	NOAEL 30 d, factor 3	TD0395
Bioavailability (NOAEL 90 days), [%]	50			
NOAEL (30 days), [mg/kg bw/d]	1450	animal	OECD 407 with pentaerythritol ester, tetrasubstituted	TD0395
Skin irritation	non-irritant	animal	OECD 404	TD0395
Eye irritation	non-irritant	animal	OECD 405	TD0395
Sensitization	non-sensitizing	animal	OECD 429 with Fatty acids, C5-10, esters with pentaerythritol	TD0395
Dermal absorption, [%]	10	in silico	virtually no absorption possible due to ratio molar mass/distribution coefficient	
Genotoxicity	non-mutagenic	in vitro	Ames-Test	TD0395
Carcinogenicity	non-carcinogenic	in silico	no adv. effects expected due to structure	
Toxicity to reproduction	non-toxic for reproduction	in silico	no adv. effects expected due to structure	
Teratogenicity	non-teratogenic	animal	OECD 414 with Trimethylolpropane caprylate caprate	TD0395
Phototoxicity	non-phototoxic	in silico	No absorption in relevant UV range	
Photosensitization	non-sensitizing	in silico	No absorption in relevant UV range	
Molecular weight [Dalton]	669.1			
log POW	30.8		Experimental	TD0395
Special consideration	2,2-bis(Hydroxymethyl)propane-1,3-diyl distearate			

INCI-Name: Phenoxyethanol

Special consideration	Phenoxyethanol is a preservative authorised per se in Annex V of the Cosmetics Regulation with a maximum use concentration of 1.0%. This concentration is complied with for the product evaluated here.	

INCI-Name: Tocopherol

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	167	animal	calculated from LOAEL (factor 3)	TD0005
Bioavailability (NOAEL 90 days), [%]	50			
LOAEL, [mg/kg bw/d]	500	animal	alpha-tocopherol: US Food and Nutrition Board: Adoption of a LOAEL based on various animal test results	TD0005
Skin irritation	non-irritant	clinical	Patch test on 4454 persons from NACDG, 48 h, 0.7% positive reaction	TD0004
Eye irritation	non-irritant	in silico	no adv. effects expected	
Sensitization	non-sensitizing	in silico	no adv. effects expected	
Dermal absorption, [%]	51.2	in vitro	highest value for different test models.	TD0004
Genotoxicity	non-mutagenic	in vitro	various studies on mammalian cell lines	TD0004
Carcinogenicity	non-carcinogenic	in silico	no adv. effects expected	
Toxicity to reproduction	non-toxic for reproduction	in silico	no adv. effects expected	
Teratogenicity	non-teratogenic	in silico	no adv. effects expected	
Phototoxicity	non-phototoxic	clinical	0.2 ml, occlusive photo-patch test, 24h, 11 persons	TD0004
Photosensitization	non-sensitizing	in silico	no adv. effects expected	
Molecular weight [Dalton]	430.71			
CIR data	Tocopherol is considered safe by the CIR for leave on and rinse off products with an application concentration of up to 5.4 %.			TD0004
Special consideration	Vitamin E is an essential part of the human diet, and EFSA states a tolerable daily intake through food (UL) of 300 mg for adults.			TD0006

INCI-Name: Sodium Stearoyl Glutamate

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	1200	animal	N-cocoacyl glutamic acid, sodium salts: Male albino rats, 112 days feeding	TD0040
Bioavailability (NOAEL 90 days), [%]	50			
Acute oral toxicity (LD 50), [mg/kg bw/d]	> 2000	animal	OECD 401	TD0038
Acute dermal toxicity (LD50), [mg/kg bw/d]	> 5000	animal	OECD 402	TD0038
Skin irritation	non-irritant	animal	OECD 404	TD0038
Eye irritation	non-irritant	animal	OECD 405	TD0038
Sensitization	non-sensitizing	in silico	no adv. effects based on chem. structure to be expected	
Dermal absorption, [%]	10	in silico	derived from molar mass/distribution coefficient	
Genotoxicity	non-mutagenic	in vitro	Ames-Test	TD0039
Carcinogenicity	non-carcinogenic	in silico	no adv. effects based on chem. structure to be expected	
Toxicity to reproduction	non-toxic for reproduction	in silico	no adv. effects based on chem. structure to be expected	
Teratogenicity	non-teratogenic	in silico	no adv. effects based on chem. structure to be expected	
Phototoxicity	non-phototoxic	clinical	Photo-Patch with 5 % Sodium Lauroyl Glutamate in cosmetic formulation	TD0039
Photosensitization	non-sensitizing	in silico	no adv. effects based on chem. structure to be expected	
Molecular weight [Dalton]	435.58			
log POW	-1.85		Experimental	TD0038
CIR data	Sodium Steaoryl Glutamate is considered safe by the CIR up to 2 %.			TD0039
Special consideration	Sodium stearoyl glutamate is split into stearic acid and glutamic acid after dermal absorption by amidases. Both substances are part of the human diet.			

INCI-Name: Xanthan Gum

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	> 1000	animal	107-week study on beagles, feeding study	TD0046
Bioavailability (NOAEL 90 days), [%]	5			
Acute oral toxicity (LD 50), [mg/kg bw/d]	> 20000	animal	Feeding study in dogs	TD0046
Skin irritation	non-irritant	animal	Albino rabbit, shaved back, moistened xanthan gum	TD0046
Eye irritation	mildly irritating	animal	Albino rabbits, 55 mg xanthan gum per eye.	TD0046
Sensitization	non-sensitizing	animal	intracutaneous injection in guinea pigs with 0.1% solution, 3 times per week	TD0046
Dermal absorption, [%]	1	in silico	due to high molecular weight (>10.000) absorption is not possible.	
Genotoxicity	non-mutagenic	in silico	no adv. effects to be expected, since food	
Carcinogenicity	non-carcinogenic	in silico	no adv. effects to be expected, since food	
Toxicity to reproduction	non-toxic for reproduction	animal	3-generation study in rats, NOAEL > 500 mg/kg bw/d	TD0046
Teratogenicity	non-teratogenic	animal	3-generation study in rats, NOAEL > 500 mg/kg bw/d	TD0046
Phototoxicity	non-phototoxic	in silico	no adv. effects to be expected, since no absorption in the relevant UV range	
Photosensitization	non-sensitizing	in silico	no adv. effects to be expected, since no absorption in the relevant UV range	
Molecular weight [Dalton]	> 10000			
CIR data	Xanthan gum is rated as safe by the CIR in leave-on products up to 6% and in rinse off products up to 6%.			TD0047
Special consideration	Xanthan Gum is a polysaccharide which cannot be split and utilized by humans due to the beta-glycosidic bonds of the sugars among themselves. Xanthan gum is an approved food additive (E415) for which no ADI value is set.			TD0048

INCI-Name: Citric Acid

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	> 241	animal	Lowest value from reproductive toxicity	TD0030
Bioavailability (NOAEL 90 days), [%]	50			
Acute oral toxicity (LD 50), [mg/kg bw/d]	> 5400	animal	OECD 401	TD0030
Acute dermal toxicity (LD50), [mg/kg bw/d]	> 2000	animal	OECD 402	TD0030
Skin irritation	non-irritant	clinical	HRIPT with 4 % citric acid in skin cream	TD0029
Eye irritation	mildly irritating	animal	Rabbit, 10 % solution	TD0029
Sensitization	non-sensitizing	clinical	HRIPT with 4 % citric acid in skin cream	TD0029
Dermal absorption, [%]	50	in silico	SCCS	
Genotoxicity	non-mutagenic	in vitro	Ames test: antimutagenic effects observed.	TD0029
Carcinogenicity	non-carcinogenic	in silico	no adv. effects expected, as food additive	
Toxicity to reproduction	non-toxic for reproduction	animal	Mice, multi-generation study, lowest NOAEL=241 mg/kg bw/d	TD0030
Teratogenicity	non-teratogenic	animal	Mäuse, Multigenerationenstudie, niedrigster NOAEL=241 mg/kg bw/d	TD0030
Phototoxicity	non-phototoxic	in silico	no adv. effects to be expected due to lack of absorption in the relevant UV range	
Photosensitization	non-sensitizing	in silico	no adv. effects to be expected due to lack of absorption in the relevant UV range	
Molecular weight [Dalton]	210.14			
CIR data	Citric acid is considered safe by the CIR in leave-on products up to 4% and in rinse off products up to 10%.			TD0029
Special consideration	Citric acid is part of the human diet and is fully utilised in the body. Citric acid is an approved food additive (E330), an ADI value is not set.			

INCI-Name: Parfum

Special consideration	Perfume - Assessment is made in the perfume oil safety report.	

INCI-Name: Salix Alba Bark Extract

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	26.2	clinical	4 weeks oral administration of 1572 mg/d SABE (equivalent to 240 mg salicin) to 70 patients for relief of back pain, 1 allergic reaction noted. 1572 mg/d corresponds to 26.2 mg/kg bw/d.	TD0550
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	non-irritant	clinical	dermatological test with the formulation evaluated here	
Eye irritation	non-irritant	in silico	no adv. effects at very low concentration to be expected	
Sensitization	non-sensitizing	in silico	Based on data on salicylic acid no adv. effects expected.	TD0243
Dermal absorption, [%]	100	in silico	worst case	
Genotoxicity	non-mutagenic	in vitro	Ames test, chromosome aberration tests with salicylic acid on CHO cells	TD0243
Carcinogenicity	non-carcinogenic	animal	Salicylic acid in drinking water in mice (5%) and rats (2%)	TD0243
Toxicity to reproduction	non-toxic for reproduction	animal	3-generation study (OECD 416) with methyl salicylate in rats, NOAEL = 250 mg/kg bw/d	TD0244
Teratogenicity	non-teratogenic	animal	3-generation study (OECD 416) with methyl salicylate in rats, NOAEL = 75 mg/kg bw/d	TD0244
Phototoxicity	non-phototoxic	in silico	Based on data on salicylic acid no adv. effects expected.	TD0243
Photosensitization	non-sensitizing	in silico	Based on data on salicylic acid no adv. effects expected.	TD0243
Special consideration	Salix Alba Bark Extract (SABE) is the aqueous extract from the bark of the silver willow tree. The bark of the willow tree contains the pain-relieving and antipyretic salicin. In the 12th century, Hildegard von Bingen recommended willow bark tea against fever, gout and rheumatoid arthritis. In the 17th century, the bark was used to make medicine against gout and rheumatism. The extract contains 53-65% salicylic acid derivatives, including salicin, a glucoside in which salicyl alcohol (saligenin) ß is present as a glucoside-bound glucose. Due to teratogenic effects of the related substance acetylsalicylic acid in rats, the formulation evaluated here should not be used in pregnant women. Furthermore the classification of salicylic acid in the Cosmetic Decree also applies for the extract evaluated here (children!).			

INCI-Name: Ethylhexylglycerin

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	50	animal	Rat, oral, 90d feeding	TD0036
Bioavailability (NOAEL 90 days), [%]	50			
Acute oral toxicity (LD 50), [mg/kg bw/d]	> 2000	animal	OECD 401	TD0036
Acute dermal toxicity (LD50), [mg/kg bw/d]	> 2000	animal	OECD 402	TD0036
Skin irritation	mildly irritating	animal	OECD 404	TD0036
Eye irritation	mildly irritating	animal	5 % sol. OECD 405	TD0036
Sensitization	non-sensitizing	animal	OECD 406	TD0036
Dermal absorption, [%]	55	in vitro	Human skin, 2% in cream	TD0037
Genotoxicity	non-mutagenic	in vitro	OECD 474	TD0036
Carcinogenicity	non-carcinogenic	in silico	no adv. effects based on chem. structure to be expected	
Toxicity to reproduction	non-toxic for reproduction	in silico	no adv. effects based on chem. structure to be expected	
Teratogenicity	non-teratogenic	animal	OECD 414	TD0036
Phototoxicity	non-phototoxic	in silico	no absorption in the relevant UV range	
Photosensitization	non-sensitizing	in silico	no absorption in the relevant UV range	
Molecular weight [Dalton]	204.31			
log POW	2.53		Experimental	TD0036
CIR data	Ethylhexylglycerol is considered safe by the CIR in leave-on products up to 2 % and in rinse-off products up to 8 %.			TD0037

INCI-Name: Helianthus Annuus Seed Oil

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	5200	animal	13-week feeding study with triglycerides (88% oleic acid), male and female rats	TD0042
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	non-irritant	clinical	HRIPT, with 20 % in facial serum on 108 subjects	TD0041
Eye irritation	non-irritant	in silico	no adv. effects based on composition to be expected	
Sensitization	non-sensitizing	clinical	HRIPT, with 20 % in facial serum on 108 subjects	TD0041
Dermal absorption, [%]	50	in silico	worst case, SCCS default value	
Genotoxicity	non-mutagenic	in silico	no adv. effects to be expected on the basis of composition	
Carcinogenicity	non-carcinogenic	in silico	no adv. effects to be expected, since food	
Toxicity to reproduction	non-toxic for reproduction	in silico	no adv. effects to be expected, since food	
Teratogenicity	non-teratogenic	in silico	no adv. effects to be expected, since food	
Phototoxicity	non-phototoxic	in silico	no adv. effects based on composition to be expected	
Photosensitization	non-sensitizing	in silico	no adv. effects based on composition to be expected	
CIR data	Sunflower oil is rated up to 96% safe by the CIR in Leave on and Rinse of products.			TD0041
Special consideration	Sunflower oil contains triglycerides of saturated/unsaturated fatty acids, which are part of the human diet. The two main components are oleic acid (approx. 30 %) and linoleic acid (approx. 60 %).			TD0041

INCI-Name: Hamamelis Virginiana Leaf Extract

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	> 100	animal	HVLE, rats, oral, 90 d	TD0158
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	non-irritant	clinical	Hametum wound and healing ointment (with 6.25 % HVLE) in 309 children with skin inflammation, only in 2 children adverse effects by treatment detected	TD0158
Eye irritation	non-irritant	in vitro	EpiOcular assay with whole plant extract (5 % in cyclopentasiloxanes)	TD0157
Sensitization	non-sensitizing	clinical	HRIPT with cream containing 0.45% HVLE in 108 persons.	TD0157
Dermal absorption, [%]	50	in silico	worst case	
Genotoxicity	non-mutagenic	in vitro	Ames test with 6% HVLE	TD0157
Carcinogenicity	non-carcinogenic	animal	Test with leaf extract (6%), subcutaneously in rats over 78 weeks, no adv. effects, Tarragol: cancerous. Potential, based on animal experiments an hT25 (human threshold, at this dose 25% of humans are expected to develop tumours) of 5.21 mg/kg bw/d was determined.	TD0158
Toxicity to reproduction	non-toxic for reproduction	in silico	no adv. effects expected at low concentration	
Teratogenicity	non-teratogenic	in silico	no adv. effects expected at low concentration	
Phototoxicity	non-phototoxic	in vitro	Phototox. assay with HVLE on 3T3 cells	TD0157
Photosensitization	non-sensitizing	in silico	no adv. effects expected at low concentration	
CIR data	Witch hazel extracts have been used in cosmetic products for a long time. Its use is classified as safe by the CIR.			TD0157
Special consideration	Hamamelis Virginiana Leaf Extract (HVLE) is the aqueous ethanolic extract of the leaves of the Virginian witch hazel. Main components are hydrocarbons, alkanes, alkenes (approx. 50%), alcohols (approx. 3%), aldehydes (approx. 5%), ketones (approx. 1.2%), esters (approx. 0.6%), monoterpenes (approx. 8%), sesquiterpenes (approx. 10%), diterpenes (approx. 0.8%), phenylpropanoids (approx. 3%) and trans- phytol (approx. 5%). For phytol a NOAEL of 160 mg/kg bw/d was determined, for the other substance groups the NOAEL values are higher. A NOAEL > 100 mg/kg bw/d was determined for a leaf extract, which was used as the basis for the MOS calculation. Special consideration was given to tarragol and safrole, both substances can be present in the extract up to 5 ppm. This results in maximum exposures from the cosmetic product of 0.003 µg/kg bw/d. Derived from the hT25 value of 5.21 mg/kg bw/d for estragole, there is a theoretical probability of 1:1,000,000 of developing cancer at a dose of 0.21 µg/kg; at a dose of 0.003 µg/kg this theoretical probability decreases to 1:70,000,000.			TD0158

INCI-Name: Limonene

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	500	animal	OECD 408	TD0710
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	irritant	animal	OECD 404, R38, no adv. effects expected in dilution	TD0710
Eye irritation	non-irritant	animal	OECD 405	TD0710
Sensitization	weakly sensitizing	animal	LLNA (OECD 429), EC3 = 22%	TD0710
Dermal absorption, [%]	50	in silico	SCCS	
Genotoxicity	non-mutagenic	animal	OECD 471 + 476 + Comet-Assay	TD0710
Carcinogenicity	non-carcinogenic	animal	Limonene is a component of many foods, carcinogenic effect in animal experiments in male rats not relevant for classification.	TD0710
Toxicity to reproduction	non-toxic for reproduction	animal	OECD 408, NOAEL concerning reproductive organs = 500 mg/kg bw/d	TD0710
Teratogenicity	non-teratogenic	animal	Rabbit fetuses, NOAEL = 1000 mg/kg bw/d	TD0710
Phototoxicity	non-phototoxic	in silico	no greater effects than are to be expected from non-photo-induced irritation	
Photosensitization	non-sensitizing	in silico	no greater effects are to be expected than with non-photo-induced sensitization.	
Special consideration	Limonene, (R)-p-mentha-1,8-diene is an allergenic fragrance which is declared on the packaging in accordance with the Cosmetics Regulation if the respective product class-specific concentration is exceeded.			

INCI-Name: Benzyl Salicylate

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	360	animal	OECD 408 with Cyclohexylsalicilate	TD0324
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	non-irritant	animal	Annex V test methods EEC Directive 79/831	TD0324
Eye irritation	non-irritant	in vitro	OECD 437 (BCOP)	TD0324
Sensitization	sensitizing	animal	LLNA, EC3-Wert = 2,9%	TD0324
Dermal absorption, [%]	50	in silico	SCCS	
Genotoxicity	non-mutagenic	in vitro	Ames-Test	TD0324
Carcinogenicity	non-carcinogenic	in silico	no adv. effects to be expected, since GRAS status	
Toxicity to reproduction	non-toxic for reproduction	animal	OECD 415 with Cyclohexylsalicylat, NOAEL = 180 mg/kg bw/d	TD0324
Teratogenicity	non-teratogenic	animal	OECD 414 with Cyclohexylsalicylat, NOAEL = 360 mg/kg bw/d	TD0324
Phototoxicity	non-phototoxic	animal	Guinea pigs, 30 % in ethanol	TD0325
Photosensitization	non-sensitizing	animal	Photo guinea pig maximization test with 10 % in ethanol (occlusive)	TD0325
CIR data	Benzyl Salicylate as a light stabilizer is used up to 0.15% in leave on and up to 0.5% in rinse off products, the use is evaluated as safe by the CIR. For use in the fragrance industry, IFRA has recommended an application concentration of benzyl salicylate depending on the product type:. The restrictions include 12.8% for oral care products and a limit of 0.5% for lip products.			TD0325
Special consideration	Benzyl Salicylate is an allergenic fragrance which is declared on the packaging in accordance with the Cosmetics Regulation if the respective product class-specific concentration is exceeded.			

INCI-Name: Potassium Sorbate

Special consideration	Potassium sorbate is the potassium salt of sorbic acid. Sorbic acid and its potassium, calcium and sodium salts are per se authorised preservatives in Annex V of the Cosmetic Regulation with a maximum use concentration (based on acid) of 0.6 % . The maximum permissible concentration is complied with for the product evaluated here.	

INCI-Name: Sodium Benzoate

Special consideration	Sodium benzoate is the sodium salt of benzoic acid. Benzoic acid and its sodium salts are per se authorised preservatives in Annex V of the Cosmetic Regulation with a maximum use concentration (based on acid) of 0.5% (leave on), 1.7% (mouth), 2.5% (rinse off). The maximum permissible concentration of the relevant product group is complied with for the product evaluated here.	

INCI-Name: Citronellol

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	290	animal	13-week feeding study in rats with citronellyl acetate that is metabolised into Citronellol	TD0718
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	irritant	animal	OECD 404, pure form. No adv. effects expected in dilution	TD0718
Eye irritation	mildly irritating	animal	OECD 405, mildly irritating. No adv. effects expected in dilution.	TD0718
Sensitization	weakly sensitizing	animal	LLNA, EC3 = 43,5%	TD0718
Dermal absorption, [%]	6.6	in vitro	OECD 428, 5 % citronellol in DEP/ethanol (3:1)	TD0718
Genotoxicity	non-mutagenic	animal	Ames test + micronucleus test	TD0718
Carcinogenicity	non-carcinogenic	animal	2 year NTP feeding study in rats with citronellyl acetate, NOAEL = 2000 mg/kg bw/d	TD0718
Toxicity to reproduction	non-toxic for reproduction	animal	dermal application of geraniol (metabolite of citronellol) in rats (300 mg/kg bw/d), no adv. effects	TD0711
Teratogenicity	non-teratogenic	animal	oral administration of geraniol (metabolite of citronellol) to rats between day 6 - 19 of gestation, NOAEL = 300 mg/kg bw/d	TD0711
Phototoxicity	non-phototoxic	in silico	no greater effects than are to be expected from non-photo-induced irritation	
Photosensitization	non-sensitizing	in silico	no greater effects are to be expected than with non-photo-induced sensitization	
Special consideration	Citronellol (3,7-dimethyloct-6-en-1-ol) is an allergenic fragrance which is declared on the packaging in accordance with the Cosmetics Regulation if the respective product class-specific concentration is exceeded.			

INCI-Name: Alpha-Isomethyl Ionone

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	3.55	animal	90 d Feeding to rats	TD0746
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	non-irritant	clinical	23 volunteers, 24 h occlusive patch test, 10% in ethanol	TD0746
Eye irritation	non-irritant	animal	rabbit eye; 0.1ml/eye	TD0746
Sensitization	weakly sensitizing	animal	OECD 429, EC3=21.8%	TD0746
Dermal absorption, [%]	50	in silico	SCCS	
Genotoxicity	non-mutagenic	animal	Ames- Test + Mammalian cell gene mutation assay + mammalian bone marrow chromosome aberration test	TD0746
Carcinogenicity	non-carcinogenic	animal	no adv. effects to be expected on the basis of the mutagenicity studies	
Toxicity to reproduction	non-toxic for reproduction	animal	OECD 421, NOAEL = 500 mg/kg bw/d	TD0746
Teratogenicity	non-teratogenic	animal	2-generation study in rats, NOAEL = 30 mg/kg bw/d	TD0746
Phototoxicity	non-phototoxic	animal	no absorption in the relevant UV range	
Photosensitization	non-sensitizing	animal	no absorption in the relevant UV range	
Molecular weight [Dalton]	206.327			
log POW	4.84		calculated	
Special consideration	Alpha-Isomethyl Ionone [3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one] is an allergenic fragrance listed on the packaging INCI according to the Cosmetics Regulation.			

INCI-Name: Benzyl Benzoate

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	800	animal	Feeding study in rats for 7 months	TD0737
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	non-irritant	animal	OECD 404	TD0737
Eye irritation	non-irritant	animal	OECD 405	TD0737
Sensitization	non-sensitizing	animal	OECD 429	TD0737
Dermal absorption, [%]	70	animal	Monkey, C14 labeled substance	TD0737
Genotoxicity	non-mutagenic	animal	Ames-Test + in vitro mammalian chromosome aberration test + in vivo mammalian cell study: DNA damage and/or repair	TD0737
Carcinogenicity	non-carcinogenic	in silico	no adv. effects are expected based on the results of the mutagenicity studies.	
Toxicity to reproduction	non-toxic for reproduction	in silico	no adv. effects to be expected based on the long-term feeding study	
Teratogenicity	non-teratogenic	animal	oral administration of up to 1% in food during day 0 - 20 of gestation, no adv. effects	TD0737
Phototoxicity	non-phototoxic	in silico	no adv. effects based on chem. structure to be expected	
Photosensitization	non-sensitizing	in silico	no adv. effects based on chem. structure to be expected	
Special consideration	Benzyl benzoate is an allergenic fragrance which is declared on the packaging in accordance with the Cosmetics Regulation if the respective product class-specific concentration is exceeded.			

INCI-Name: Geraniol

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	550	animal	112 days feeding to rats	TD0717
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	irritant	animal	OECD 404, pure form, in diluted application (< 1%) no adv. effects expected.	TD0717
Eye irritation	irritant	animal	OECD 405, pure form, in diluted application (< 1%) no adv. effects expected.	TD0717
Sensitization	sensitizing	animal	OECD 429, EC3=11,4 %	TD0717
Dermal absorption, [%]	50	in silico	SCCS	
Genotoxicity	non-mutagenic	animal	Ames test, chromosome aberration test + HPRT on mammalian cells, micronucleus test	TD0717
Carcinogenicity	non-carcinogenic	animal	NTP study (2-year feeding on rats) with citral metabolised to geraniol	TD0717
Toxicity to reproduction	non-toxic for reproduction	animal	dermal application in rats (300 mg/kg bw/d), no adv. effects	TD0717
Teratogenicity	non-teratogenic	animal	oral administration to rats between day 6 - 19 of gestation, NOAEL = 300 mg/kg bw/d	
Phototoxicity	non-phototoxic	in silico	no greater effects than are to be expected from non-photo-induced irritation	
Photosensitization	non-sensitizing	in silico	no greater effects are to be expected than with non-photo-induced sensitization	
Special consideration	Geraniol (2,6-octadien-1-ol, 3,7-dimethyl-, (2E)-) is an allergenic fragrance which is declared on the packaging in accordance with the Cosmetics Regulation if the respective product class-specific concentration is exceeded.			

INCI-Name: Butylphenyl Methylpropional

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	4.5	animal	Teratogen NOAEL	TD0753
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	irritant	animal	irritant in pure form, no irreversible effects observed in diluted application	TD0753
Eye irritation	irritant	animal	irritant in pure form, no irreversible effects observed in diluted application	TD0753
Dermal absorption, [%]	13.5	animal	OECD 428, highest value for various cosmetic product groups	TD0753
Genotoxicity	non-mutagenic	animal	OECD 471 + 476 + 487	TD0753
Carcinogenicity	non-carcinogenic	animal	No adverse effects expected based on the mutagenicity studies	TD0753
Toxicity to reproduction	non-toxic for reproduction	animal	1-generation study, rats, NOAEL = 10 mg/kg bw/d	TD0753
Teratogenicity	weakly teratogenic	animal	2-generation study, rats, NOAEL = 4.5 mg/kg bw/d	TD0753
Phototoxicity	non-phototoxic	animal	no structural signs of adv. effects	
Photosensitization	non-sensitizing	animal	no structural signs of adv. effects	
SCCS data	On individual product basis, Butylphenyl methylpropional (p-BMHCA) (CAS 80-54-6) with alpha-tocopherol at 200 ppm, can be considered safe when used as fragrance ingredient in different cosmetic leave-on and rinse-off type products. However, considering the first-tier deterministic aggregate exposure, arising from the use of different product types together, Butylphenyl methylpropional at the proposed concentrations cannot be considered as safe.			TD0753
Special consideration	Butylphenyl Methylpropional (2-(4-tert-butylbenzyl)propionaldehyde; BMHCA) is an allergenic fragrance according to the Cosmetics Regulation and is declared on the packaging INCI in accordance with the applicable regulations.			

INCI-Name: Linalool

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	39	animal	Factor 3 from OECD 407	TD0711
Bioavailability (NOAEL 90 days), [%]	50			
NOAEL (30 days), [mg/kg bw/d]	117	animal	OECD 407 with coriander oil (contains 72.9 % linalool)	TD0711
Skin irritation	mildly irritating	animal	OECD 404, pure form. No adv. effects to be expected in diluted form	TD0711
Eye irritation	mildly irritating	animal	OECD 405, pure form. No adv. effects to be expected in diluted form	TD0711
Sensitization	non-sensitizing	clinical	HRIPT with 12.7 % linalool, 135 subjects	TD0711
Dermal absorption, [%]	12.7	in vitro	OECD 428 (24h, occlusiv)	TD0711
Genotoxicity	non-mutagenic	animal	OECD 471 + 473 + 474 + 476	TD0711
Carcinogenicity	non-carcinogenic	in silico	Linalool is a component of many foods, carcinogenic effect in animal experiments not relevant for classification.	TD0711
Toxicity to reproduction	non-toxic for reproduction	animal	OECD 421 with structural analogues dehydrolinalool, NOAEL = 200 mg/kg bw/d	TD0711
Teratogenicity	non-teratogenic	animal	oral administration to rats during day 7 - 17 of gestation, NOAEL(fetal)=1000 mg/bw/d, NOAEL(maternal)=1000 mg/bw/d	TD0711
Phototoxicity	non-phototoxic	in silico	no greater effects are to be expected than with non-photo-induced irritation.	
Photosensitization	non-sensitizing	in silico	no greater effects are to be expected than with non-photo-induced sensitisation.	
Special consideration	Linalool (3,7-dimethyl octa-1,6-diene-3-ol) is an allergenic fragrance which is declared on the packaging in accordance with the Cosmetics Regulation if the respective product class-specific concentration is exceeded.			

INCI-Name: Citral

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	100	animal	OECD 453 (2-year NTP study)	TD0720
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	irritant	animal	Rabbit skin, category 2, pure form, in diluted application (< 1%) no adv. effects expected.	TD0720
Eye irritation	irritant	animal	OECD 405, category 2, pure form, in diluted application (< 1%) no adv. effects expected.	TD0720
Sensitization	sensitizing	animal	OECD 406, LLNA: EC3=5,7%	TD0720
Dermal absorption, [%]	50	animal	C14-labelled citral, guinea pig	TD0720
Genotoxicity	non-mutagenic	animal	OECD 471 + 473 + 474 + 476 + 479	TD0720
Carcinogenicity	non-carcinogenic	animal	OECD 453 (2-year NTP study)	TD0720
Toxicity to reproduction	toxic for reproduction	animal	OECD 421, NOAEL = 200 mg/kg bw/d	TD0720
Teratogenicity	non-teratogenic	animal	OECD 414, NOAEC(maternal)=34 ppm, NOAEC(fetal)=68 ppm	TD0720
Phototoxicity	non-phototoxic	in silico	no greater effects than are to be expected from non-photo-induced irritation	
Photosensitization	non-sensitizing	in silico	no greater effects are to be expected than with non-photo-induced sensitization	
Special consideration	Citral (3,7-dimethyl-2,6-octadienal) is an allergenic fragrance which is declared on the packaging in accordance with the Cosmetics Regulation if the respective product class-specific concentration is exceeded.			

INCI-Name: Benzyl Cinnamate

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	600	animal	OECD 422	TD0752
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	non-irritant	in vitro	OECD 439	TD0752
Eye irritation	non-irritant	in vitro	OECD 405	TD0752
Sensitization	weakly sensitizing	animal	LLNA, EC3=18,4%	TD0752
Dermal absorption, [%]	50	in silico	SCCS	TD0752
Genotoxicity	non-mutagenic	in vitro	OECD 471	TD0752
Carcinogenicity	non-carcinogenic	in silico	no structural signs of carcinogenicity	
Toxicity to reproduction	non-toxic for reproduction	animal	OECD 422, NOAEL = 600 mg/kg bw/d	TD0752
Teratogenicity	non-teratogenic	animal	OECD 422, NOAEL = 600 mg/kg bw/d	TD0752
Phototoxicity	non-phototoxic	in silico	no structural signs of adv. effects	
Photosensitization	non-sensitizing	in silico	no structural signs of adv. effects	
Special consideration	Benzyl cinnamate (2-propenoic acid, 3-phenyl, phenylmethyl ester) is an allergenic fragrance according to the Cosmetics Regulation and is declared on the packaging INCI in accordance with the applicable regulations.			

INCI-Name: Benzyl Alcohol

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	400	animal	OECD 451 (2-year feeding study in rats)	TD0739
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	mildly irritating	animal	OECD 404, pure form. No adv. effects to be expected in diluted form	TD0739
Eye irritation	mildly irritating	animal	OECD 405, pure form. No adv. effects to be expected in diluted form	TD0739
Sensitization	non-sensitizing	animal	OECD 429, EC3> 50%	TD0739
Dermal absorption, [%]	80	animal	Monkey	TD0739
Genotoxicity	non-mutagenic	in vitro	OECD 471	TD0739
Carcinogenicity	non-carcinogenic	animal	OECD 451 (2-year feeding study in rats)	TD0739
Toxicity to reproduction	non-toxic for reproduction	animal	no adv. effects found in various studies (NOAEL > 200 mg/kg bw/d)	TD0739
Teratogenicity	non-teratogenic	animal	no adv. effects found in various studies (NOAEL > 200 mg/kg bw/d)	TD0739
Phototoxicity	non-phototoxic	animal	no adv. effects based on chem. structure to be expected.	
Photosensitization	non-sensitizing	animal	no adv. effects based on chem. structure to be expected.	
Special consideration	Benzyl alcohol is a preservative per se authorised in Annex V of the Cosmetic Decree with a maximum use concentration of 1.0%. This concentration is complied with in the product evaluated here. Furthermore benzyl alcohol is an allergenic fragrance which is declared on the packaging according to the Cosmetics Regulation if the respective product class-specific concentration is exceeded.			

INCI-Name: Farnesol

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	105	animal	OECD 422	TD0738
Bioavailability (NOAEL 90 days), [%]	80			
Skin irritation	irritant	animal	OECD 404, category 2, pure form, in low application concentration (< 1%) no adv. effects expected.	TD0738
Eye irritation	mildly irritating	animal	OECD 405, pure form, in low application concentration (< 1%) no adv. effects expected.	TD0738
Sensitization	sensitizing	animal	OECD 429, EC3=3,8%	TD0738
Dermal absorption, [%]	80	animal	Guinea pig, C14-labelled substance	TD0738
Genotoxicity	non-mutagenic	in vitro	OECD 471	TD0738
Carcinogenicity	weakly carcinogenic	in silico	No adv. effects based on chem. structure and mutagenicity tests.	
Toxicity to reproduction	non-toxic for reproduction	animal		TD0738
Teratogenicity	non-teratogenic	animal		TD0738
Phototoxicity	non-phototoxic	in silico	no greater effects are to be expected than with non-photo-induced irritation.	
Photosensitization	non-sensitizing	in silico	no greater effects are to be expected than with non-photo-induced sensitisation.	
Special consideration	Farnesol (2,6,10-dodecatrien-1-ol, 3,7,11-trimethyl-) is an allergenic fragrance which is declared on the packaging in accordance with the Cosmetics Regulation if the respective product class-specific concentration is exceeded.			

INCI-Name: Eugenol

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	600	animal	OECD 408	TD0740
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	mildly irritating	animal	OECD 404, only reversible effects, No adv. effects to be expected in diluted form	TD0740
Eye irritation	irritant	animal	OECD 405, Category 2, No adv. effects to be expected in diluted form	TD0740
Sensitization	sensitizing	animal	OECD 429, EC3=5,4%	TD0740
Dermal absorption, [%]	50	in silico	SCCS	
Genotoxicity	non-mutagenic	animal	OECD 471 +474 + 482	TD0740
Carcinogenicity	non-carcinogenic	animal	OECD 451	TD0740
Toxicity to reproduction	non-toxic for reproduction	animal	OECD 416, NOAEL = 700 mg/kg bw/d	TD0740
Teratogenicity	non-teratogenic	animal	OECD 414, NOAEL = 500 mg/kg bw/d	TD0740
Phototoxicity	non-phototoxic	in silico	no greater effects are to be expected than with non-photo-induced irritation.	
Photosensitization	non-sensitizing	in silico	no greater effects are to be expected than with non-photo-induced sensitisation.	
Special consideration	Eugenol (phenol, 2-methoxy-4-(2-propenyl)-) is an allergenic fragrance which is declared on the packaging in accordance with the Cosmetics Regulation if the respective product class-specific concentration is exceeded.			

INCI-Name: Isoeugenol

	Result	Test Type	Test Description	Source
NOAEL (90 days), [mg/kg bw/d]	600	animal	OECD 408	TD0740
Bioavailability (NOAEL 90 days), [%]	50			
Skin irritation	mildly irritating	animal	OECD 404, only reversible effects, No adv. effects to be expected in diluted form	TD0740
Eye irritation	irritant	animal	OECD 405, Category 2, No adv. effects to be expected in diluted form	TD0740
Sensitization	sensitizing	animal	OECD 429, EC3=5,4%	TD0740
Dermal absorption, [%]	50	in silico	SCCS	
Genotoxicity	non-mutagenic	animal	OECD 471 +474 + 482	TD0740
Carcinogenicity	non-carcinogenic	animal	OECD 451	TD0740
Toxicity to reproduction	non-toxic for reproduction	animal	OECD 416, NOAEL = 700 mg/kg bw/d	TD0740
Teratogenicity	non-teratogenic	animal	OECD 414, NOAEL = 500 mg/kg bw/d	TD0740
Phototoxicity	non-phototoxic	in silico	no greater effects are to be expected than with non-photo-induced irritation.	
Photosensitization	non-sensitizing	in silico	no greater effects are to be expected than with non-photo-induced sensitisation.	
Special consideration	Isoeugenol (phenol, 2-methoxy-4-(1-propenyl)-) is an allergenic fragrance which is declared on the packaging in accordance with the Cosmetics Regulation if the respective product class-specific concentration is exceeded. The data used in the toxicological evaluation all refer to eugenol.			

A.8.2. Calculation and evaluation of the margin of safety (MOS) of substances

MOS is calculated as follows:

MoS = NOAEL*systemic*/ $SED_{Substance}$

with

$NOAEL_{systemic}$ = NOAEL * *Bioavailability (NOAEL 90 Days)*

No observed adverse effect level in mg/kg bw/d after 90 oral gavage of the individual substances in test animals, if other studies have been used to determine the NOAEL value, this is documented in the toxicological profile of the individual components (8a).

INCI	% INCI	NOAEL [mg/kg bw/d]	Dermal absorption [%]	SED [mg/kg bw/d]	MOS
Aqua	60.574		100		*
Squalane	7	> 1000	10	0.16898	**2,959**
Aloe Barbadensis Leaf Juice	5	> 100000	50	0.6035	**82,850**

INCI	% INCI	NOAEL [mg/kg bw/d]	Dermal absorption [%]	SED [mg/kg bw/d]	MOS
Caprylic/Capric Triglyceride	4	> 1000	10	0.09656	**5,178**
Ethylhexyl Stearate	4	> 800	10	0.09656	**4,143**
Glycerin	3.764	> 2200	50	0.454327	**2,421**
Betaine	3	> 2500	1	0.007242	**172,604**
Cetearyl Alcohol	3	750	50	0.3621	**1,036**
Heptyl Undecylenate	3	100	50	0.3621	**138**
Cetearyl Glucoside	2	> 1000	50	0.2414	**2,071**
Cetyl Alcohol	1.5	> 4257	50	0.18105	**11,756**
Pentaerythrityl Distearate	1	483	10	0.02414	**10,004**
Phenoxyethanol	0.9				*
Tocopherol	0.21	167	51.2	0.025966	**3,216**
Sodium Stearoyl Glutamate	0.2	1200	10	0.004828	**124,275**
Xanthan Gum	0.2	> 1000	1	0.000483	**103,563**
Citric Acid	0.17	> 241	50	0.020519	**5,873**
Parfum	0.15				*
Salix Alba Bark Extract	0.1	26.2	100	0.02414	**543**
Ethylhexylglycerin	0.09991	50	55	0.013265	**1,885**
Helianthus Annuus Seed Oil	0.09	5200	50	0.010863	**239,345**
Hamamelis Virginiana Leaf Extract	0.0375	> 100	50	0.004526	**11,047**
Limonene	0.0044	500	50	0.000532	**470,311**
Benzyl Salicylate	0.0036	360	50	0.000434	**414,423**
Potassium Sorbate	0.002				*
Sodium Benzoate	0.002				*
Citronellol	0.00081	290	6.6	0.000013	**11,256,588**
Alpha-Isomethyl Ionone	0.00075	3.55	50	0.00009	**19,687**
Benzyl Benzoate	0.00059	800	70	0.0001	**4,005,320**
Geraniol	0.00041	550	50	0.000049	**5,604,861**
Butylphenyl Methylpropional	0.00038	4.5	13.5	0.000012	**184,111**
Linalool	0.00033	39	12.7	0.00001	**1,901,505**
Citral	0.00017	100	50	0.00002	**2,510,607**
Benzyl Cinnamate	0.00002	600	50	0.000003	**110,466,722**
Benzyl Alcohol	0.00002	400	80	0.000003	**69,041,701**
Farnesol	< 0.00001	105	80	0.000001	**144,987,572**
Eugenol	< 0.00001	600	50	< 0.000001	**1,657,000,829**
Isoeugenol	< 0.00001	600	50	< 0.000001	**1,657,000,829**

*: see separate consideration in chapter 8a

All raw materials used meet the requirements for cosmetic, pharmaceutical or food quality. For none of the raw materials used could any indications be found that would suggest a health risk in case of large-scale topical application. For all raw materials with a known NOAEL an MoS of more than 100 was determined.

A.9. Adverse effects and serious adverse reactions

The application of the raw materials used in cosmetic products has been described and tested for a long time. When used as intended, the raw materials show good skin and mucous membrane compatibility in the concentrations used. Due to the toxicological profile of the raw materials as well as the combination of the raw materials in the proportional compositions in the product, no adverse effects are to be expected when used as intended. Interactions of the ingredients are not to be expected due to the chemical nature.

The formulation is a face cream. Due to the composition, no irritating or sensitising potential is expected when used as intended.

At the time of the preparation of the safety report, there were no reports of adverse reactions according to Annex I, Part A 9.

When health-related complaints are received, the cases are subjected to the cosmetovigilance procedure under the responsibility of the responsible person, the results of which are then taken into account in the safety assessment.

A.10. Information about the cosmetic product (Additional tests)

A.11. Literature sources

A.11.1. General sources

1. Verordnung (EG) Nr. 1223/2009 des europäischen Parlaments und des Rates vom 30. November 2009 über kosmetische Mittel, in der aktuell gültigen Fassung

2. The SCCS´s notes of guidance for the testing of cosmetic substances and their safety evaluation, 9th Revision, The Scientific Committee on Consumer Safety, September 2015

3. Kroes et al. Food Chemical Toxicol, 2007, angepasst von G. Nohynek, 2009

A.11.2. Data sources for raw material valuations

Index	Literature source
TD0004	Safety Assessment of Tocopherols and Tocotrienols as Used in Cosmetic, Internat. Journal of Toxicology, Vol 37
TD0005	https://www.mattilsynet.no/kosmetikk/stoffer_i_kosmetikk/risk_profile_vitamin_e_280e.11322/binary/Risk%20Profile%20Vitamin%20E%20280e
TD0006	TOLERABLE UPPER INTAKE LEVELS FOR VITAMINS AND MINERALS, Scientific Committee on Food Scientific Panel on Dietetic Products, Nutrition and Allergies; Feb 2006
TD0010	SDB Cetiol 868. BASF, 11/2107
TD0011	Safety Assesment of Alkyl Esters as Used in Cosmetics, Internat. Journal of Toxicology, Vol 34
TD0012	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/13584
TD0013	Safety Assesment of Glycerin as Used in Cosmetics, CIR Final Report Jan. 14, 2015
TD0017	SDB Lanette O, BASF,11/2017
TD0018	Final Report on the Safety Assessment of Cetearyl Alcohol, J. of the american College of Tox, Vol.

Index	Literature source
	7, 1988
TD0019	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/16007
TD0029	CIR-Final Report On the Safety Assessment of Citric Acid, Inorganic Citrate Salts, and Alkyl Citrate Esters as Used in Cosmetics, 03/2012
TD0030	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15451/
TD0036	SDB Sensivia SC, Schülke, 08/2013
TD0037	CIR: Final Safety Assessment on the Safety Assessment ofAlkyl Glyceryl Ethers As Used in Cosmetics; 12/2012
TD0038	SDB Eumulgin SG, BTC, 06/2018
TD0039	Safety Assessment of Amino Acid Alkyl Amides as used in Comsetics, Int. J. of Tox, Vol. 36, 2017
TD0040	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/20719
TD0041	CIR: Safety Assessment of Plant-Derived Fatty Acid Oils, Int. J. Tox., Vol. 36, 2017
TD0042	Safety evaluation of oleic-rich triglyceride oil producedby a heterotrophic microalgal fermentation process; Food an Chemical Tox., Vol 65, 2014
TD0046	Summaries of Toxicological Studies, CP Kelco, 01/2014
TD0047	Safety Assessment of Microbial Polysaccharide Gums as used in Cosmetics, Int. J. of Tox., Vol35; 2016
TD0048	Re-evaluation of xanthan gum (E 415) as a food additive, EFSA-Opinion, 06/2017
TD0062	Final Report on the Safety Asessment of Aloe ...s, Int. J. of Tox., Vol. 26, 2007
TD0064	Safety Assessment of Decyl Glucoside and other Alkyl Glucosides as Used in Cosmetics, Int. J. of Tox., Vol. 32, 2013
TD0078	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15346
TD0079	CIR: Amended Safety Assessment of Triglycerides as Used in Cosmetics, 02/2018
TD0121	"Final Report on the Safety Assessment of Dimethicone and related compunds; IJT 22(Suppl. 2):11-35, 2003"
TD0130	Toxicity Summary for Aloe Vera Gel and Aloe Vera Powder, Terry Laboratories, 08/2012
TD0157	Safety Assessment of Hamamelis virginiana (Witch Hazel)-Derived Ingredients as Used in Cosmetics, 06/2018
TD0158	Safety Assessment for Extrapone Witch Hazel GW, Symrise, 02/2012
TD0192	CIR: Final Report on the Safety of Squalane and Squalene; JACT 1(2):36-56, 1982
TD0193	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14412
TD0221	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14407
TD0243	SCCS Opinion on Salicylic Acid, Submisison I, 06/2019
TD0244	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14544/
TD0245	Annual Review of Cosmetic Ingredient Safety Assessments 2005/2006; IJT 27(Suppl. 1):77-142, 2008
TD0246	Final Report o the Safety Assesment of Cetearyl Alcohol, Cetyl Alcohol, Isostearyl Alcohol, Myristyl Alcohol and Behenyl Alchohol; JACT 7(3):359-413, 1988
TD0248	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15942
TD0324	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/16100/
TD0325	CIR: Safety Assessment of Benzyl Salicylate As Used in Cosmetics; 06/2019
TD0335	Safety Assessment of Alkyl Betaines as used in Cosmetics; IJT 37(Suppl. 1):28-46, 2018
TD0336	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15954
TD0394	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/26247
TD0395	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/16125
TD0482	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/592
TD0483	Tox-Service: Undecylenic-Acid-GS-599-v-1.2-Certified-Feb-2016-EDF
TD0550	EMA; Assessment report on Salix [various species including S. purpurea L., S. daphnoides Vill., S. fragilis L.] , cortex; 01/2017

Index	Literature source
TD0710	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15256/
TD0711	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14501
TD0717	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14184
TD0718	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14242
TD0720	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/13515
TD0737	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/13634
TD0738	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/23466
TD0739	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14748/
TD0740	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/13694
TD0746	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/18602
TD0752	https://echa.europa.eu/de/registration-dossier/-/registered-dossier/16792
TD0753	SCCS - OPINION ON the safety of Butylphenyl methylpropional (p-BMHCA) in cosmetic products - Submission II - 05/2019

B. Safety assessment of the cosmetic product

B.1. Conclusions of the evaluation

The cosmetic product Sample-Cream, Bulk-Art.: 45000 [Fw-Art.: FW-001 (100ml), FW-002 (50ml)] is safe for health under normal, reasonably foreseeable conditions of use, taking into account the general toxicological profile of the ingredients, their chemical composition and the degree of exposure, taking into account the warnings and conditions of use. The present product is clearly identifiable as a cosmetic product. Misuse as food is not to be expected due to the packaging design, appearance and odour.

For raw materials for which no NOAEL has been deposited in the literature and thus no MoS calculation is possible, toxicological safety has been proven on the basis of other well-founded literature references. For none of the raw materials used, indications could be found which suggest a health risk in case of large-area topical application.

The microbiological stability is guaranteed, the PET was evaluated with criterion A.

The product stability was proven by stability tests. Under normal and expected application and storage conditions, no adverse health effects due to instability are to be expected.

Confirmations of the packaging material suppliers are available for the packaging material used (see PIF). The available packaging material data give no reason to suspect that migration of undesirable components from the packaging material into the product will occur or that the product will be altered or its safety impaired by the packaging material.

B.2. Warnings on the label and instructions for use

Special warnings are not required. No special instructions for use have been provided, as the product is clearly described and it can be assumed that the consumer uses the product correctly.

B.3. Justification

In principle, a safe cosmetic product has safety margins (margins of safety) for the individual raw materials of at least 100. The raw materials used in the present formulations have been evaluated as safe in terms of their toxicological profile either by experts of the Cosmetic Ingredient Review (CIR), the Food and Drug Administration (FDA) or the Scientific Committee on Cosmetic Safety (SCCS).

The cosmetic product Sample-Cream, Bulk-Art.: 45000 [Fw-Art.: FW-001 (100ml), FW-002 (50ml)] is to be assessed as safe based on the exposure assessment and calculation.

This report is based on the regulation EC 1223/2009 for cosmetic products, legal regulations, generally binding international assessments, recommendations of authorities and associations, as well as marketing experience. Within this framework, the raw materials and the finished product are considered with regard to their chemical structure, the toxicological profile of the ingredients and their stability. The final assessment results from the specific evaluation of available toxicological, dermatological data and the degree of exposure resulting from the product presentation and the conditions of use.

Place, date

Achern, 31.07.2021

Signature

Dr. Joachim Blank
Safety assessor

B.4. Qualification of the assessor and approval for Part B

B.4.1. Address

Person: Dr. Joachim Blank, geboren am 16.06.1962
Chemiker
Residence: Kurt Schumacher-Str. 180 B, 70565 Stuttgart
e-mail: Joachim.Blank@sicherheitsbewerter.de

B.4.2. Professional career

Since Juli 2021	Si-Kos GmbH, Achern / Stuttgart Sicherheitsbewerter, Regulatory Support, QS
Since Okt. 2020	Zellaerosol GmbH, Zell im Wiesental Leiter F&E / Regulatory Affairs
April 2018 - Nov. 2019	Mani GmbH, Düsseldorf / Stuttgart Vertrieb Kosmetikrohstoffe D, A, CH, Regulatory Support
Okt. 2017 - März 2018	Zellaerosol GmbH, Zell im Wiesental Leiter der Herstellung Kosmetik, Medizinprodukte, Pharma (nach AMWHV)
Since Juli 2017	Selbständiger Sicherheitsbewerter für kosmetische Mittel, in Stuttgart
Jan. 2016 - Juni 2017	INCI Experts GmbH, Hamburg / Stuttgart Sicherheitsbewerter für kosmetische Mittel
Februar 2016 - Aug. 2016	SLI Chemicals GmbH, Frankfurt, mit Homeoffice in Stuttgart Vertrieb Kosmetikrohstoffe D, A, CH
Januar 2015 - Juni 2015	Pera GmbH, Spinge-Eldagsen / Baar, CH und Stuttgart Vertriebsleiter Kosmetikrohstoffe
Juli 2013 - März 2015	Selbständiger Berater mit Standort Baar, Schweiz Projekte in Vertrieb, Marketing, Qualitätsmanagement, Regulatory Affairs
Sep. 2012 - Juli 2013	Blitz F10 AG (ehemals AC Serendip AG), Walchwil, Schweiz COO, Label zur Energieeffizient in der Kosmetikproduktion
2010 - 2012	Brenntag Schweizerhall AG, Basel, Schweiz Senior Sales Manager Specialty Chemicals Personal Care & Pharma

Since 2007	Qenax AG, Zug, Schweiz Mitbegründer, Geschäftsführer (bis 2010); Präsident des Verwaltungsrats
2004 - 2007	Cosmetochem International Ltd., Steinhausen, Schweiz Global Sales Director, Mitglied der Geschäftsleitung, Qualitätsdelegierter Vertrieb
2001 - 2004	Ciba Specialty Chemicals Inc., Basel, Schweiz Segment Plastic Additives, Business Line Base Stabilization Marketing Manager Europe
1997 - 2001	Ciba-Geigy Inc. / Ciba Specialty Chemicals Inc., Basel, Schweiz Additives Division, Regional Manager EMEA, Qualitätsdelegierter Verkauf der Konzernzentrale
1993 - 1996	Ciba-Geigy Marienberg GmbH, Lampertheim Business Unit PVC-Additive der Additives Division Technical Marketing Manager
1989 - 1993	IBM Germany, Halbleiter-Produktion Werk Böblingen / Hulb Schulungsreferent im Mitarbeiterqualifizierungsprogramm

B.4.3. Study

1987 - 1993	Institut für Anorganische Chemie, Universität Stuttgart Promotion / Praktikumsassistenz (unterbrochen durch 15 Mo. Grundwehrdienst)
1984 - 1987	EHICS (Europäische Hochschule für Industrielle Chemie in Strasbourg, ehemals ENSCS), Frankreich, Europäischer Studiengang Chemie
1981 - 1984	Universität Stuttgart, Vordiplom in Chemie (Dipl.)

B.4.4. Relevant additional qualifications/further training:

Mitglied in zahlreichen Berufs- und Fachverbänden (Kosmetik, Chemie)
- u.a. DGK, Sepawa, Swiss SCC
- Mitglied der DGK-Fachgruppe Hautreinigung

Ausbildungsgänge
2018 Zertifikat als IKW/DGK-zertifizierter Sicherheitsbewerter

SiKos
Sicherheitsbewerter.de

Gegr. 1957
DGK

DEUTSCHE GESELLSCHAFT FÜR WISSENSCHAFTLICHE
UND ANGEWANDTE KOSMETIK E.V.

ZERTIFIKAT

Dr. Joachim Blank

hat aufgrund seiner Ausbildung entsprechend Artikel 10 Abs. 2 der EG-Kosmetikverordnung 1223/2009,

dem erfolgreichen Abschluss folgender DGK-Fortbildungskurse für Sicherheitsbewerter

Exposition kosmetischer Produkte / Perkutane Penetration
Lokalverträglichkeit, Immunologie und Sensibilisierung
Metabolismus, Kinetik und Struktur-Wirkungsbeziehungen
Kanzerogenese und Mutagenese
Allgemeine und systemische Toxikologie – einschließlich Risikobewertung
Reproduktionstoxikologie
Mikrobiologische Produktsicherheit kosmetischer Mittel

und seiner mindestens dreimaligen Teilnahme an den DGK-Seminaren für Sicherheitsbewerter in den letzten drei Jahren

die Qualifikation

DGK-SICHERHEITSBEWERTER

erworben.

Hamburg / Kaiserslautern, den 31. März 2018

Dr. Hartmut Schmidt-Lewerkühne
Präsident der Deutschen Gesellschaft für Wissenschaftliche und Angewandte Kosmetik e.V.

Prof. Dr. G. Eisenbrand
Vorsitzender des Ausschusses für die Weiterbildung des Sicherheitsbewerters

Das Zertifikat ist 5 Jahre gültig.

Präsident: Dr. Hartmut Schmidt-Lewerkühne
Schatzmeister: Dr. Sven Munke

Schriftführer: Dr. Volker Wendel
Fortbildung: Andrea Weber

Fachgruppen:
Britta Klebon

SiKos
Sicherheitsbewerter.de

Gegr. 1957
DGK

DEUTSCHE GESELLSCHAFT FÜR WISSENSCHAFTLICHE
UND ANGEWANDTE KOSMETIK E.V.

TEILNAHMEBESTÄTIGUNG

Dr. Joachim Blank

hat mit Erfolg an der Fortbildungsreihe der Deutschen Gesellschaft für Wissenschaftliche und Angewandte Kosmetik (DGK e. V.)

GRUNDLAGEN DER SICHERHEITSBEWERTUNG KOSMETISCHER MITTEL
nach den Anforderungen des Artikels 10 und des Anhangs I
der Verordnung (EG) Nr. 1223/2009

teilgenommen. Die Einzelkurse behandelten die folgenden Themenkreise:

Exposition kosmetischer Produkte / Perkutane Penetration
Kursleitung Dipl.-Ing. B. Huber, Frankfurt

Lokalverträglichkeit, Immunologie und Sensibilisierung
Kursleitung Prof. Dr. U. Heinrich, Witten

Metabolismus, Kinetik und Struktur-Wirkungsbeziehungen
Kursleitung Prof. Dr. G. Eisenbrand, Kaiserslautern

Kanzerogenese und Mutagenese
Kursleitung Dr. R. Fautz, Darmstadt

Allgemeine und systemische Toxikologie
Kursleitung Dr. E. Schrader, Düsseldorf

Reproduktionstoxikologie
Kursleitung Dr. W. Schuh, Düsseldorf

Mikrobiologische Produktsicherheit kosmetischer Mittel
Kursleitung Dr. U. Eigener, Hamburg

Die erworbenen Kenntnisse wurden in jedem Kurs durch eine Prüfung nachgewiesen und zertifiziert.

Köln / Kaiserslautern, den 31. März 2018

Andrea Weber
DGK-Fortbildung
Sicherheitsbewertung

Prof. Dr. G. Eisenbrand
Vorsitzender des Ausschusses
für die Weiterbildung des Sicherheitsbewerters

SiKos
Sicherheitsbewerter.de

Gegr. 1957
DGK

DEUTSCHE GESELLSCHAFT FÜR WISSENSCHAFTLICHE
UND ANGEWANDTE KOSMETIK E.V.

CERTIFICATE

Dr. Joachim Blank

through his qualification according to Article 10, Paragraph 2 of the EC Cosmetics Regulation 1223/2009,

successful completion of the following DGK continuing education courses for safety assessors

Exposure to Cosmetic Products / Percutaneous Penetration
Topical Safety, Immunology and Sensitization
Metabolism, Kinetics and Structure-Activity Relationships
Carcinogenesis and Mutagenesis
General and Systemic Toxicology
Reproduction Toxicology
Microbiological Safety of Cosmetic Products

and his participation over the last three years in at least three DGK seminars for safety assessors

is certified as fulfilling the requirements of a

DGK SAFETY ASSESSOR

Hamburg / Kaiserslautern, 31st March 2018

Dr. Hartmut Schmidt-Lewerkühne
President of the German Society for
Scientific and Applied Cosmetics (DGK e. V.)

Prof. Dr. G. Eisenbrand
Chairman of the Committee on
Continuing Education for Safety Assessors

This certificate is valid for 5 years.

Präsident: Dr. Hartmut Schmidt-Lewerkühne
Schatzmeister: Dr. Sven Munke

Schriftführer: Dr. Volker Wendel
Fortbildung: Andrea Weber

Fachgruppen:
Britta Klebon

SiKos
Sicherheitsbewerter.de

Gegr. 1957
DGK

DEUTSCHE GESELLSCHAFT FÜR WISSENSCHAFTLICHE
UND ANGEWANDTE KOSMETIK E.V.

CERTIFICATE OF PARTICIPATION

Dr. Joachim Blank

successfully participated in the continuing education series of the German Society for Scientific and Applied Cosmetics (DGK e.V.)

BASIC PRINCIPLES OF THE SAFETY ASSESSMENT OF COSMETIC PRODUCTS
according to the requirements of Article 10 and Annex I of Regulation (EC) No 1223/2009

The individual courses covered the following topics:

Exposure to Cosmetic Products / Percutaneous Penetration
Course Leader Dipl.-Ing. B. Huber, Frankfurt

Topical Safety, Immunology and Sensitization
Course Leader Prof. Dr. U. Heinrich, Witten

Metabolism, Kinetics and Structure-Activity Relationships
Course Leader Prof. Dr. G. Eisenbrand, Kaiserslautern

Carcinogenesis and Mutagenesis
Course Leader Dr. R. Fautz, Darmstadt

General and Systemic Toxicology – Including Risk Assessment
Course Leader Dr. E. Schrader, Düsseldorf

Reproduction Toxicology
Course Leader Dr. W. Schuh, Düsseldorf

Microbiological Safety of Cosmetic Products
Course Leader Dr. U. Eigener, Hamburg

The knowledge acquired in each course was demonstrated through a final examination and certified.

Köln / Kaiserslautern, 31st March, 2018

Andrea Weber
DGK Coordinator
Safety Assessment

Prof. Dr. G. Eisenbrand
Chairman of the Committee on
Continuing Education for Safety Assessors

B.4.5. Diplomzeugnis

RÉPUBLIQUE FRANÇAISE

MINISTÈRE DE L'ÉDUCATION NATIONALE

DIPLÔME D'INGÉNIEUR

DE L'ÉCOLE EUROPÉENNE DES HAUTES ÉTUDES DES INDUSTRIES CHIMIQUES DE STRASBOURG

LE DIRECTEUR DES ÉTUDES ET LES PROFESSEURS DE L'ÉCOLE EUROPÉENNE DES HAUTES ÉTUDES DES INDUSTRIES CHIMIQUES DE STRASBOURG

certifient que Monsieur Joachim Blank
hereby certify that

né à Stuttgart (R.F.A.), *le* 16 juin 1962
place and date of birth

a satisfait aux conditions prescrites par la règlementation en vigueur et le règlement de scolarité pour l'obtention du Diplôme d'Ingénieur E.H.I.C.S.
has satisfied the conditions prescribed by the current regulations and has fulfilled the academic requirements for the

Fait à Strasbourg *le* 2 juillet 1987

Les Membres du Jury,

Le Directeur des Études

NOUS, DIRECTEUR DE L'ÉCOLE EUROPÉENNE DES HAUTES ÉTUDES DES INDUSTRIES CHIMIQUES DE STRASBOURG

Vu le décret n° 86.640 du 14 mars 1986

Vu l'article 11 du décret n° 47.204 du 16 janvier 1947

délivrons le présent diplôme à
in witness whereof, we confer this diploma upon

Monsieur Joachim Blank

Fait à Strasbourg *le* 2 NOV. 1987

Le Directeur de l' E. H. I. C. S.

M. DAIRE

Le Ministre de l'Éducation Nationale,
P/le Directeur des Enseignements Supérieurs
et par délégation

Le Titulaire,

C. MONTALCINO

N° 0670153 C 0496

B.4.6. Final declaration, signature

All information and assessments given in this safety assessment have been made according to the current state of knowledge.
Any subsequent changes to the formulations or the modification/addition of data relevant to the safety assessment will invalidate this assessment.

Place, date

Achern, 31.07.2021

Signature

Dr. Joachim Blank
Safety assessor