Product information file (PIF)
&
safety report

for product:

TB ProBond Fiber

Name and Address of the Responsible Person:

nailARTS
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Cloefstr. 7
66693 Mettlach

place and date of file creation:
Münster, 01.08.2022

TOC

a) Product Description

Product Name:	**PRO BIO FIBERBOND**
type:	Nail cosmetic (category, formal) Level 1-3 Nail and cuticle products Nail varnish and remover products Nail varnish / Nail gel
Characterization of the purpose (function)	The present formulation is a mixture of polymers, solvents and pigments / colorants, which is used in nail design.
Recipe number / version:	1.0
material number	211217-001-5-2-1
Document information	The full version of the safety report and PIF is kept at the manufacturer's address and will be made available to official authorities within 72 hours.
Supplier:	Company: nailARTS Irina Markova Address: Cloefstr. 7, 66693 Mettlach, Germany Telefon: +49 (0) 6861 9087259 E-Mail: info@nailarts-irina-markova.shop Internet: www.nailarts-irina-markova.shop

b) safety report

Part A: Safety information relating to cosmetic products

1 Composition of the product

1.1 Quantitative List of Ingredients

INGREDIENTS / INCI	CAS	EINECS	FDA
URETHANE METHACRYLATE	n/	n/	A
ALIPHATIC URETHANE ACRYLATE	n/	n/	C
BENZYL METHACRYLATE	2495-37-6	219-674-4	D
TRIETHYLENE GLYCOL DIMETHACRYLATE	109-16-0	203-652-6	E
HYDROXYPROPYL METHACRYLATE	27813-02-1	248-666-3	E
HYDROXYCYCLOHEXYL PHENYL KETONE	947-19-3	213-426-9	F
ETHYL TRIMETHYLBENZOYL PHENYLPHOSPHINATE	84434-11-7	282-810-6	F
CALCIUM SODIUM PHOSPHOSILICATE	n/a	n/a	F
POLYACRYLONITRILE	n/	n/	F
BHT	128-37-0	204-881-4	F
P-HYDROXYANISOLE	150-76-5	205-769-8	G
CI 60725	81-48-1	201-353-5	G

1.2 Formulation of the raw materials

Position	Article-No:	Trade name	Function	amount in product [%]
1	(confidential)	(confidential)	Film former	5 - 10
2	(confidential)	(confidential)	Photoinitiator	0,1 - 1
3	(confidential)	(confidential)	Photoinitiator	0,1 - 1
4	(confidential)	(confidential)	Effect	< 0,1
5	(confidential)	(confidential)	Film former	50 - 75
6	(confidential)	(confidential)	Film former	< 0,1
7	(confidential)	(confidential)	Film former	10 - 25
8	(confidential)	(confidential)	Colourant	< 0,1

2 Physical and chemical properties, stability, and microbiology

2.1 Properties and stability of the finished product

2.1.1 Specification of the finished product

Parameters	Unit	Spezification
density(20°C)	g/ml	~ 1 - 2
pH-value (20°C)		-
Viscosity (20°C)	mPas	-
Refractive index (20°C)		-
colour:		slightly purple
odour:		characteristic
form:		liquid or solid (after curing)

2.1.2 Stability of the cosmetic product

Chemical - physical stability:

a) stability after first use

Chemical and physical stability:

The product shows no physical or sensory abnormalities when properly stored.

(if applicable, refer to documents annexed)

b) long-term stability

The product should be stored at temperatures between 5 and 30 ° C. Under these conditions, a minimum shelf life of 30 months is given.

(if applicable, refer to documents annexed)

2.2 Microbiological quality of the finished product

a) stability after first use

The product is stable due to the lack of water content. A germ strain test therefore does not have to be carried out.

(if applicable, refer to documents annexed)

b) long-term stability

see 2.2.a)

(if applicable, refer to documents annexed)

c) results of the Preservative Challenge Testing:

see separate document if applicable

Test	**Methods**	**Date**	**Institute**
Test For Efficacy Of Antimicrobial. Preservation	-	-	-
Result			
Not required, see 2.2.d)			

d) microbiological safety

A microbiological examination of the product microbiological profile was not performed.
The product complies with the requirements due to a lack of water content (a_w value <0.6).

microbiological specification

Parameters	**Unit**	**Acceptance criteria**	
Aerobic Count	CFU/ml	< 100	Products for infants and young children
	CFU/ml	< 100	Products for use around the eyes
	CFU/ml	< 1000	Other Products
Pseudomonas aeruginosa	in 0,1 ml	not detectable	all Products
Staphyloccocus aureus	in 0,1 ml	not detectable	
Escherichia Coli	in 0,1 ml	not detectable	
Candida Albicans	in 0,1 ml	not detectable	
Yeasts and molds	CFU/ml	< 100	Products for infants and young children
	CFU/ml	< 100	Products for use around the eyes
	CFU/ml	< 1000	Other Products

3 Information on the packaging material and impurities of the substances

3.1 Information about the packaging material

Information on the packaging material of the main package:

All packaging materials that are in direct contact with the cosmetic product are documented by the bulk manufacturer and distributer. The Manufacturer declares the conformity of compliance to 1935/2004/EC, 10/2011/EC, 2002/72/EC. The Packaging complies (amongst others) EN ISO 9001:2008. The material is free of SVHC substances (from REACH Regulation) and therefore suitable for this purpose.

(refer to documents annexed)

3.2 Information on impurities of the substances

a) Formation of nitrosamines

Nitrosamines are carcinogenic and may not appear in cosmetics. Nitrosamine formation is not expected through targeted selection of raw materials in this product.

b) Formaldehyde and formaldehyde releasers

Formaldehyde is classified as a carcinogen and must be declared in cosmetics from a concentration of 0.05%. (“contains formaldehyde”) Formaldehyde and formaldehyde releasers are not part of these formulations

c) Heavy metals

The cosmetic product does not exceed the following concentrations of heavy metals:

Element	Cosmetic products in general	Toothpaste
Lead (Pb)	2.0 mg / kg*	0.5 mg / kg
Cadmium (Cd)	0.1 mg / kg	0.1 mg / kg
Mercury (Hg)	0.1 mg / kg	0.1 mg / kg
Arsenic (As)	0.5 mg / kg**	0.5 mg / kg
Antimony (Sb)	0.5 mg / kg	0.5 mg / kg

* For the product groups make-up powder, rouge, eye shadow, kajal, incl. eyelid line and eyeliner as well as theatre, fan and carnival make-up: 5 mg / kg ** For theatre, fan and carnival make-up: 2.5 mg / kg; source: BVL

If required a bioavailability test for the safety of the revised formulation (to the responsible authorities) will be documented.

d) Other:

Prohibited substances are not included in amounts that adversely affect the safety of the product and if any technically unavoidable.

4 Normal and reasonably foreseeable use

Normal use: Can be clearly derived from the labelling elements on the package.

Label elements:
- Product: nail polish / gel
- Application: nails
- Durability: > 12 Months / irrelevant

Additional reasonably foreseeable use: the particular information is clear.

Specific information:
- Product Type: leave on, nail polish / gel
- Purpose: nails gel
- The application site: finger- and foot nails
- Application group: all
- Application condition: see safety instructions / warning notices
- Private / Commercial application: commercial

Note:
Properly used, no product is left on the skin, only on the fingernails.

5 Exposure to the cosmetic product

5.1 Exposure

The toxicological exposure in mg / kg body weight (human, base 60 kg) can either be calculated with formula (1) [LIT0201, LIT0202]:

SED = (A (mg/day) x C (%)/100 x DAp (%)/100) x F x R / 60 kg (1)

or calculated with formula (2) [LIT0201]:

SED = (DA_a (mg/cm²) x SSA (cm²) x F (day-1) x R) / 60 kg (2)

a) Use as nail polish (intended use)

I) Permeation through nails

Use 1 x per day (F) with 1 g product total per daily application (A)

exposed body surface (SSA) = 15 cm^2

Retention factor for the product = 1 (leave on)

II) Permeation through skin

Use 1 x per day (F) with 1 g product total per daily application (A)
max. 5% reach the skin

exposed body surface (SSA) = 1,5 cm^2

Retention factor for the product = 0,1 (due to the fast curing of the material and subsequent cleaning of the skin, a corresponding retention factor is applied.)

III) Exposition by inhalation

By working on the nail gels, abrasion dust can arise. The home application is not considered, as manual files produced no relevant amount of dust. If no ventilation system exists, the exposure is: 2.5 / week with 1 g of product, which produces max. 10% of dust due to handling and max. 10% absorption of the product by breathing air.

The SED of the product is calculated from exposure I + II.
For the permeation of the nails the value of 1% is selected as the default, wherein the permeation through the skin is 100%. If necessary a default of 50% can be used according to TTC concept.

b) Use as reasonably foreseeable application

none known

c) Use as misuse

none known

5.2 Exposure to substances and toxicological profiles of raw materials

Remarks:

LD_{50} (oral, dermal) = if no data is available and the substance is not classified as harmful or toxic according to 67/648 EEC, the lowest threshold 2000 mg/kg is used as an estimate in parentheses. Toxic substances are considered at least with an LD_{50} of 25 mg /kg (oral). Less toxic are considered at least with 200 mg/kg LD_{50} (oral).

NOAEL = if no data or no data from other species [LIT0203] are available, a derivation from LOAEL [LIT0204], NOEL, ADI values can be applied. LOAEL and NOAEL values from 28-day studies are divided by the factor 3.

Furthermore, a calculation can be done by means of a tolerable upper intake level or recommended daily amounts and known supply amounts. In particular for additives or ingredients or ingredients in the food industry an estimation of a per capita consumption can be used to determine a suitable safety threshold. It is empirical known in the food industry due to long experience that common supply quantities are foreseen to be safe. However a safety factor can be varied between 0-10 (human variability intra species variation) rather than use of the default factor 100. (Includes interspecies variation)

The proposed lower safety factor is noted next to the NOAEL and will be later incorporated in the calculation of the MoS due to the fact that the calculation of the MoS is usually performed on animal data and not on human data.

The derivation of the NOAEL from the acute toxicity LD_{50} (Minimium: dermal, oral) is only a rough estimate. Although a derivation of the NOAEL from LD_{50} values is not possible, an estimate of the NOAEL (for example 0.1% -5% of the LD_{50}) would predominantly lead to correct predictions in terms of magnitude as a correlation of LD_{50} values and NOAEL values shows. [LIT0205] Derivation of the NOAEL by means of structurally analogous compounds, and the use of the TTC concept [LIT0206] has always to be preferred in comparison. A safety factor is not specified with regard to the TTC concept because it is already included in the concept.

Percutaneous permeation = if no data is available for Chapter 6, the value of the octanol-water partition coefficient and molecular weight MW has been estimated or calculated.

As a basis for estimation according to the EU standard default [LIT0207] see below:

MW > 500 and POW > 4 < - 1 = 10 %

MW < 500 and/or POW > -1 < 4 = 100 % (eventually 50% see TTC concept)

Other assessments may need an appropriate remark. Thus, substances with a molecular weight above 1000 the percutaneous permeation is estimated to 1%. Substances having a molecular weight of 150-300 and a higher lipophilicity (log POW 4-8) an estimation can be done using the following formula: % dermal penetration = 90.6 - 0.3 MW

Substances with a log POW > 4 or 5 and a molecular weight > 300 can be estimated with 20% percutaneous permeation. The reason for this is the fact that high lipophilic substances usually do not diffuse into deeper skin-layers, but remain in the lipophilic upper area. Substances such as Salts with log POW> -5 and> 300 MW can be estimated with 20%, as QSAR computational models are not applicable. Completely insoluble inorganic materials such as oxides can also be estimated with 1% (or less) Skin permeation independent of molecular weight and log p / ow. As these substances are also not lipophilic, the permeation paths are blocked by the cornea with lipophilic and hydrophilic passages. Exceptions are nanoparticles or emulsions.

When considering the TTC concept of skin absorption, it is also estimated according to H. Greim as follows:

Default Factors for Skin Absorption of Cosmetics

Compounds	Times oral TTC
MW > 500, log P_{OW} < -1 to >4; solvents or substances insoluble in water	10
MW < 500, log P_{OW} < -1 to >4	5
MW > 500, log P_{OW} -1 to 4	5
MW < 500, log P_{OW} -1 to 4	2
Orally exposed substances like lipsticks, toothpaste, mouthwash or used under occlusive conditions (deodorants)	1

In the presence of liposomer transport materials and in case of inadequate or lack of available data as well as extremely dubious substances or substances of concern a percutaneous permeation of up to 100% for all substances can be implemented independent of the log POW and MW (worst case). If dermal NOAEL data is available, the value is set to 100%.

The acquisition of medium range log POW values respectively their calculation can be carried out [LIT0208] based on pure QSAR calculations or semi-empirical calculations QSAR. For the latter tlag and / or the permeation coefficient Kp is used.

For products which are applied to fingers or toe nails it must be recognized that the diffusion of substances is here in order of magnitude 100x lower (10-7 cm / s - 10-9 cm / s) compared with (10-1 cm / s - 10-5 cm / s). For this reason, a standard permeation of 1% will be applied. The dependence of permeability is linearly dependent on the molecular size. (hydrophilic gel membrane) Ionic compounds are about 10 times less permeable than non-ionic substances. Permeation is independent of the lipophilicity of the substance, and therefore independent of the log POW. [LIT0209]

Essentially, a worst case assessment, or a default judgment have a higher priority than calculations. Other approaches require a remark or statement ("calculated" Abr: calc) with regard to evaluation of individual substances.

Is the dermal absorption DA known, it is used in chapter 8 to calculate the SED. (Systemic Exposure Dosage)

For herbal extracts and natural oils with a complex and/or uncertain composition a toxicological data set can be assembled by means of the known end points of the most critical properties of different substances or by means of a major ingredient and calculating 100% percentage. If the proportion of substances is known from literature or specifications, they can be listed individually with a known concentration. The remaining substances could be disregarded when a risk can be excluded. Particularly critical ingredients of known concentration should always be considered individually. Sometimes published basic formulation from e. g. essential oils can be used as a data base [LIT0210]

Note: Substances which have been evaluated on the basis of daily intakes are also listed in the MOS table. Here, no safety factor is normally applied. To make the evaluation with the criterion for the margin of safety higher than 100 uniform and clear, for this substances the MoS is multiplied by 100 for safety factor = 0 or 10 for safety factor 10.

a) toxicological profiles of raw materials:

commodity #1		
commodity name:	(confidential)	
product code:	(confidential)	
product code (manufacturer):	(confidential)	
concentration:	(confidential)	
Manufacturer:	(confidential)	
specification:	(confidential)	
Formulation component (substance)	Benzylmethacrylate	
structure		
CAS-No.	2495-37-6	
EINECS-No.	219-674-4	
Reach-No.		
INCI	BENZYL METHACRYLATE	
MW (g/mol)	(g/mol)	(g/mol)
Acute oral toxicity LD50 rat	3980 mg/kg [LIT0001]	mg/kg []
Acute dermal toxicity LD50, rabbit	>2000 mg/kg [LIT0001]	mg/kg []
Subchronic toxicity (90d, OECD 408), NOAEL	500 mg/kg [LIT0001]	mg/ kg []
Dermal Absorption DA	mg/cm^2 [ ]	mg/cm^2 [ ]
Percutane Permeation [%]	1,00 [%] [skin permeation 50%, acc. to TTC concept]	1,00 [%] [skin permeation 50%, acc. to TTC concept]
Percutane Permeation [%] calc.	n/a [QSAR]	n/a [QSAR]
Permeation Coefficient KP	[cm/h]	[cm/h] []
Lag Time (tlag)	[h] []	[h] []
Dermal Irritation (rabbit, OECD 404)	positive [LIT0001]	
Mucosal irritation (rabbit, OECD 405)	negative [LIT0001]	
Sensitization (guinea pig, OECD 406)	positive [LIT0001]	
Mutagenicity (Ames Test, OECD 471)	negative [LIT0001]	
Carcinogenicity (OECD 451,452,453)	no data available	
Reproductive toxicity (OECD 415,416,421,422)	NOAEL = 500 mg/kg [LIT0001]	
Developmental toxicity (OECD 414)	NOAEL = 500 mg/kg [LIT0001]	
Log POW	3,1, [LIT0001]	[]
Assessment:	There is no limitation regarding the Cosmetics Regulation. The substance is considered to be safe in the preceding application concentration	

commodity #2		
commodity name:	(confidential)	
product code:	(confidential)	
product code (manufacturer):	(confidential)	
concentration:	(confidential)	
Manufacturer:	(confidential)	
specification:	(confidential)	
Formulation component (substance)	Ethylphenyl(2,4,6-trim ethylbenzoyl)phosphinate	
structure		
CAS-No.	84434-11-7	
EINECS-No.	282-810-6	
Reach-No.		
INCI	ETHYL TRIMETHYLBENZOYL PHENYLPHOSPHINATE	
MW (g/mol)	316 (g/mol)	(g/mol)
Acute oral toxicity LD50 rat	> 2000 mg/kg [SDB]	mg/kg []
Acute dermal toxicity LD50, rabbit	mg/kg []	
Subchronic toxicity (90d, OECD 408), NOAEL	100 mg/kg [LIT0001] Diphenyl-(2,4,6-trimethylbenzoyl)-phosphinoxid	mg/ kg []
Dermal Absorption DA	mg/cm^2 [ ]	mg/cm^2 [ ]
Percutane Permeation [%]	1 [default] [50% skin permeation according to TTC concept]	1 [%] [skin permeation 50%, acc. to TTC concept]
Percutane Permeation [%] calc.	N/A [semi QSAR (KP, tlag)/QSAR]	n/a [QSAR]
Permeation Coefficient KP	[cm/h]	[cm/h] []
Lag Time (tlag)	[h] []	[h] []
Dermal Irritation (rabbit, OECD 404)	negative [SDB]	
Mucosal irritation (rabbit, OECD 405)	negative [SDB]	
Sensitization (guinea pig, OECD 406)	no data available	
Mutagenicity (Ames Test, OECD 471)	no data available	
Carcinogenicity (OECD 451,452,453)	no data available	
Reproductive toxicity (OECD 415,416,421,422)	no data available	
Developmental toxicity (OECD 414)	no data available	
Log POW	4,89 [calc]	[]
Assessment:	There is no limitation regarding the Cosmetics Regulation. The substance is considered to be safe in the preceding application concentration.	

commodity #3		
commodity name:	(confidential)	
product code:	n/a	
product code (manufacturer):	(confidential)	
concentration:	(confidential)	
Manufacturer:	(confidential)	
specification:	(confidential)	
Formulation component (substance)	1-Hydroxycyclohexyl phenyl keton	
structure		
CAS-No.	947-19-3	
EINECS-No.	213-426-9	
Reach-No.		
INCI	HYDROXYCYCLOHEXYL PHENYL KETON	
MW (g/mol)	204,00 (g/mol)	(g/mol)
Acute oral toxicity LD50 rat	2500,00 mg/kg [LIT0001]	mg/kg []
Acute dermal toxicity LD50, rabbit	mg/kg []	mg/kg []
Subchronic toxicity (90d, OECD 408), NOAEL	300,00 mg/ kg [SDB Esschem Co.]	mg/ kg []
Dermal Absorption DA	mg/cm^2 [ ]	mg/cm^2 [ ]
Percutane Permeation [%]	1,00 [%] [skin permeation 50%, acc. to TTC concept]	1,00 [%] [skin permeation 50%, acc. to TTC concept]
Percutane Permeation [%] calc.	n/a [QSAR]	n/a [QSAR]
Permeation Coefficient KP	[cm/h]	[cm/h] []
Lag Time (tlag)	[h] []	[h] []
Dermal Irritation (rabbit, OECD 404)	negative [SDB Ciba USA]	
Mucosal irritation (rabbit, OECD 405)	negative [SDB Ciba USA]	
Sensitization (guinea pig, OECD 406)	negative [SDB Ciba USA]	
Mutagenicity (Ames Test, OECD 471)	negative [SDB Ciba USA]	
Carcinogenicity (OECD 451,452,453)	no data available	
Reproductive toxicity (OECD 415,416,421,422)	no data available	
Developmental toxicity (OECD 414)	no data available	
Log POW	2,35 [SDB Sigma Aldrich]	[]
Assessment:	There is no limitation regarding the Cosmetics Regulation. The substance is considered to be safe in the preceding application concentration.	

commodity #4		
commodity name:	(confidential)	
product code:	n/a	
product code (manufacturer):	(confidential)	
concentration:	(confidential)	
Manufacturer:	(confidential)	
specification:	(confidential)	
Formulation component (substance)	Calcium Natrium Phosphosilikat	
structure		
CAS-No.	65997-17-3	
EINECS-No.	266-046-0	
Reach-No.		
INCI	CALCIUM SODIUM PHOSPHOSILICATE / GLASS	
MW (g/mol)	(g/mol)	(g/mol)
Acute oral toxicity LD50 rat	> 5000 mg/kg [LIT1281]	mg/kg []
Acute dermal toxicity LD50, rabbit	> 2000 mg/kg [LIT1281]	mg/kg []
Subchronic toxicity (90d, OECD 408), NOAEL	497 mg/kg [LIT0307] (read-across Silica)	mg/ kg []
Dermal Absorption DA	10,0 [%] [EU default] (low abs.)	mg/cm^2 [ ]
Percutane Permeation [%]	1 [%] [LIT1122]	1,00 [%] [skin permeation 50%, acc. to TTC concept]
Percutane Permeation [%] calc.	[QSAR]	n/a [QSAR]
Permeation Coefficient KP	[cm/h] []	[cm/h] []
Lag Time (tlag)	[h] []	[h] []
Dermal Irritation (rabbit, OECD 404)	negative [LIT0001]	
Mucosal irritation (rabbit, OECD 405)	negative [LIT0001]	
Sensitization (guinea pig, OECD 406)	negative [LIT0001]	
Mutagenicity (Ames Test, OECD 471)	negative [LIT0001]	
Carcinogenicity (OECD 451,452,453)	possibly carcinogenic, if in powder form with a particle size of < 10 µm, if inhaled [LIT0001]	
Reproductive toxicity (OECD 415,416,421,422)	no data available	
Developmental toxicity (OECD 414)	no data available	
Log POW	[]	
Assessment:	There is no limitation regarding the Cosmetics Regulation. The substance is considered to be safe in the preceding application concentration.	

commodity #5a		
commodity name:	(confidential)	
product code:	n/a	
product code (manufacturer):	(confidential)	
concentration:	(confidential)	
Manufacturer:	(confidential)	
specification:	(confidential)	
Formulation component (substance)	Urethane Methacrylate	4-Methoxyphenol
structure		
CAS-No.	n/a	150-76-5
EINECS-No.	n/a	205-769-8
Reach-No.		
INCI	URETHANE METHACRYLATE	P-HYDROXYANISOLE
MW (g/mol)	(g/mol)	(g/mol)
Acute oral toxicity LD50 rat	2260 mg/kg [LIT001] (worst case Methacrylsäure)	1600 mg/kg [LIT0431]
Acute dermal toxicity LD50, rabbit	750 mg/kg [LIT001] (worst case Methacrylsäure)	>2000 mg/kg [LIT0001]
Subchronic toxicity (90d, OECD 408), NOAEL	30,00 mg/kg [worst case Methacrylate] oder 40 mg/kg für Acrylsäure [LIT0002]	50 mg/ kg [LIT0001] NOAEL/3 28 d
Dermal Absorption DA	mg/cm^2 [ ]	mg/cm2 [ ]
Percutane Permeation [%]	1 [%] [skin permeation 50%, acc. to TTC concept]	1 [default] [50% skin permeation according to TTC concept]
Percutane Permeation [%] calc.	n/a [QSAR]	N/A [semi QSAR (KP, tlag)/QSAR]
Permeation Coefficient KP	[cm/h] []	[cm/h] []
Lag Time (tlag)	[h] []	[h] []
Dermal Irritation (rabbit, OECD 404)	negative [LIT1163] 9011-14-7	slightly irritating, not relevant for classtification [LIT0001]
Mucosal irritation (rabbit, OECD 405)	possible [LIT1163] 9011-14-7	irritating, relevant for classtification [LIT0001]
Sensitization (guinea pig, OECD 406)	negative [LIT1163] 9011-14-7	positive [LIT0001]
Mutagenicity (Ames Test, OECD 471)	negative [LIT1163] 9011-14-7	negative [LIT0001]
Carcinogenicity (OECD 451,452,453)	no data available	no data available
Reproductive toxicity (OECD 415,416,421,422)	no data available	NOAEL > 300 mg/kg [LIT0001]
Developmental toxicity (OECD 414)	no data available	no data available
Log POW	[]	1,58 [ChemID]
Assessment:	There is no limitation regarding the Cosmetics Regulation. The substance is considered to be safe in the preceding application concentration	The material is approved: Annex III to Regulation (EC) No 1223/2009 # 95: Maximum: 0.02% (after mixing for use) Warnings: - For professional use - Avoid contact with skin - Application instructions please read carefully. The substance is to be regarded as safe when standing before use concentration and proportion of raw materials.

commodity #5b		
commodity name:	(confidential)	
product code:	n/a	
product code (manufacturer):	(confidential)	
concentration:	(confidential)	
Manufacturer:	(confidential)	
specification:	(confidential)	
Formulation component (substance)	3,5-Bis(1,1-dim ethylethyl)-4-hydroxytoluene	
structure		
CAS-No.	128-37-0	
EINECS-No.	204-881-4	
Reach-No.		
INCI	BHT	
MW (g/mol)	(g/mol)	(g/mol)
Acute oral toxicity LD50 rat	2930 mg/kg [LIT0417]	mg/kg []
Acute dermal toxicity LD50, rabbit	mg/kg [LIT0417]	
Subchronic toxicity (90d, OECD 408), NOAEL	5 mg/kg [aus ADI-JECFA (1995)]	mg/ kg []
Dermal Absorption DA	mg/cm2 [ ]	mg/cm^2 [ ]
Percutane Permeation [%]	1 [%] [skin permeation 50%, acc. to TTC concept]	1 [%] [skin permeation 50%, acc. to TTC concept]
Percutane Permeation [%] calc.	n/a [QSAR]	n/a [QSAR]
Permeation Coefficient KP	[cm/h] []	[cm/h] []
Lag Time (tlag)	[h] []	[h] []
Dermal Irritation (rabbit, OECD 404)	positive [LIT0417]	
Mucosal irritation (rabbit, OECD 405)	positive [LIT0417]	
Sensitization (guinea pig, OECD 406)	negative [LIT0417]	
Mutagenicity (Ames Test, OECD 471)	negative [LIT0417]	
Carcinogenicity (OECD 451,452,453)	negative [LIT0417]	
Reproductive toxicity (OECD 415,416,421,422)	NOAEL = 25 mg/kg [LIT0417]	
Developmental toxicity (OECD 414)	NOAEL = 800 mg/kg [LIT0417]	
Log POW	5,10 [LIT0001]	
Assessment:	There is no limitation regarding the Cosmetics Regulation. The substance is considered to be safe in the preceding application concentration	

commodity #6		
commodity name:	(confidential)	
product code:	n/a	
product code (manufacturer):	(confidential)	
concentration:	(confidential)	
Manufacturer:	(confidential)	
specification:	(confidential)	
Formulation component (substance)	Acrylnitrilpolym erisate	
structure		
CAS-No.	26658-88-8	
EINECS-No.	n/a	
Reach-No.		
INCI	CARBON FIBER	
MW (g/mol)	(g/mol)	(g/mol)
Acute oral toxicity LD50 rat	> 2000 mg/kg [geschätzt]	mg/kg []
Acute dermal toxicity LD50, rabbit	mg/kg []	
Subchronic toxicity (90d, OECD 408), NOAEL	40 mg/kg [Acrylsäure, worst case] [LIT0001]	mg/ kg []
Dermal Absorption DA	mg/cm^2 [ ]	mg/cm^2 [ ]
Percutane Permeation [%]	1 [default] [50% skin permeation according to TTC concept]	1 [%] [skin permeation 50%, acc. to TTC concept]
Percutane Permeation [%] calc.	N/A [semi QSAR (KP, tlag)/QSAR]	n/a [QSAR]
Permeation Coefficient KP	[cm/h]	[cm/h] []
Lag Time (tlag)	[h] []	[h] []
Dermal Irritation (rabbit, OECD 404)	positive [LIT0001] Acrylic acid	
Mucosal irritation (rabbit, OECD 405)	positive [LIT0001] Acrylic acid	
Sensitization (guinea pig, OECD 406)	positive [LIT0001] Acrylic acid	
Mutagenicity (Ames Test, OECD 471)	negative [LIT0001] Acrylic acid	
Carcinogenicity (OECD 451,452,453)	negative [LIT0001] Acrylic acid	
Reproductive toxicity (OECD 415,416,421,422)	negative [LIT0001] Acrylic acid	
Developmental toxicity (OECD 414)	negative [LIT0001] Acrylic acid	
Log POW	[]	[]
Assessment:	There is no limitation regarding the Cosmetics Regulation. The substance is considered to be safe in the preceding application concentration	

commodity #7a		
commodity name:	(confidential)	
product code:	(confidential)	
product code (manufacturer):	(confidential)	
concentration:	(confidential)	
Manufacturer:	(confidential)	
specification:	(confidential)	
Formulation component (substance)	Urethane Acrylate	4-Methoxyphenol
structure		
CAS-No.	n/a	150-76-5
EINECS-No.	n/a	205-769-8
Reach-No.		
INCI	ALIPHATIC URETHANE ACRYLATE	P-HYDROXYANISOLE
MW (g/mol)	(g/mol)	(g/mol)
Acute oral toxicity LD50 rat	> 2000 mg/kg [est.]	1600 mg/kg [LIT0431]
Acute dermal toxicity LD50, rabbit	mg/kg []	>2000 mg/kg [LIT0001]
Subchronic toxicity (90d, OECD 408), NOAEL	40 mg/kg [Acrylic acid, worst case] [LIT0001]	50 mg/ kg [LIT0001] NOAEL/3 28 d
Dermal Absorption DA	mg/cm2 [ ]	mg/cm2 [ ]
Percutane Permeation [%]	1 [default] [50% skin permeation according to TTC concept]	1 [default] [50% skin permeation according to TTC concept]
Percutane Permeation [%] calc.	N/A [semi QSAR (KP, tlag)/QSAR]	N/A [semi QSAR (KP, tlag)/QSAR]
Permeation Coefficient KP	[cm/h]	[cm/h] []
Lag Time (tlag)	[h] []	[h] []
Dermal Irritation (rabbit, OECD 404)	R28 [MSDS Manufacturer]	slightly irritating, not relevant for classtification [LIT0001]
Mucosal irritation (rabbit, OECD 405)	R26 [MSDS Manufacturer]	irritating, relevant for classtification [LIT0001]
Sensitization (guinea pig, OECD 406)	possibly positive [LIT0299]	positive [LIT0001]
Mutagenicity (Ames Test, OECD 471)	no data available	negative [LIT0001]
Carcinogenicity (OECD 451,452,453)	no data available	no data available
Reproductive toxicity (OECD 415,416,421,422)	no data available	NOAEL > 300 mg/kg [LIT0001]
Developmental toxicity (OECD 414)	no data available	no data available
Log POW		1,58 [ChemID]
Assessment:	There is no limitation regarding the Cosmetics Regulation. The substance is considered to be safe in the preceding application concentration.	The material is approved: Annex III to Regulation (EC) No 1223/2009 # 95: Maximum: 0.02% (after mixing for use) Warnings: - For professional use - Avoid contact with skin - Application instructions please read carefully. The substance is to be regarded as safe when standing before use concentration and proportion of raw materials.

commodity #7b		
commodity name:	(confidential)	
product code:	(confidential)	
product code (manufacturer):	(confidential)	
concentration:	(confidential)	
Manufacturer:	(confidential)	
specification:	(confidential)	
Formulation component (substance)	Tripropylene glykol diacrylate	
structure		
CAS-No.	42978-66-5	
EINECS-No.	256-032-2	
Reach-No.	01-2119484613-34	
INCI	TRIPROPYLENE GLYCOL DIACRYLATE	
MW (g/mol)	300,4 (g/mol)	(g/mol)
Acute oral toxicity LD50 rat	> 2000 mg/kg [LIT0001]	mg/kg []
Acute dermal toxicity LD50, rabbit	> 2000 mg/kg [LIT0001]	
Subchronic toxicity (90d, OECD 408), NOAEL	250 mg/kg [LIT0001]	mg/ kg []
Dermal Absorption DA	mg/cm2 [ ]	mg/cm^2 [ ]
Percutane Permeation [%]	1 [default] [50% skinpermeation according to TTC concept]	1 [%] [skin permeation 50%, acc. to TTC concept]
Percutane Permeation [%] calc.	N/A [semi QSAR (KP, tlag)/QSAR]	n/a [QSAR]
Permeation Coefficient KP	[cm/h] []	[cm/h] []
Lag Time (tlag)	[h] []	[h] []
Dermal Irritation (rabbit, OECD 404)	negative [LIT0001]	
Mucosal irritation (rabbit, OECD 405)	positive [LIT0001]	
Sensitization (guinea pig, OECD 406)	positive [LIT0001]	
Mutagenicity (Ames Test, OECD 471)	positive [LIT0001]	
Carcinogenicity (OECD 451,452,453)	no data available	
Reproductive toxicity (OECD 415,416,421,422)	NOAEL > 250 mg/kg [LIT0001]	
Developmental toxicity (OECD 414)	NOAEL > 250 mg/kg [LIT0001]	
Log POW	2 [LIT0001]	[]
Assessment:	There is no limitation regarding the Cosmetics Regulation. The substance is considered to be safe in the preceding application concentration.	

commodity #8		
commodity name:	(confidential)	
product code:	(confidential)	
product code (manufacturer):	(confidential)	
concentration:	(confidential)	
Manufacturer:	(confidential)	
specification:	(confidential)	
Formulation component (substance)	1-Hydroxy-4-(p-toluidino)anthraquinone	
structure		
CAS-No.	81-48-1	
EINECS-No.	201-353-5	
Reach-No.		
INCI	CI 60725	
MW (g/mol)	431 (g/mol)	(g/mol)
Acute oral toxicity LD50 rat	> 4640 mg/kg [LIT0326]	mg/kg []
Acute dermal toxicity LD50, rabbit		
Subchronic toxicity (90d, OECD 408), NOAEL	109 mg/kg [LIT0326]	mg/ kg []
Dermal Absorption DA	mg/cm^2 [ ]	mg/cm^2 [ ]
Percutane Permeation [%]	1 [%] [skin permeation 50%, acc. to TTC concept]	1 [%] [skin permeation 50%, acc. to TTC concept]
Percutane Permeation [%] calc.	n/a [QSAR]	n/a [QSAR]
Permeation Coefficient KP	[cm/h]	[cm/h] []
Lag Time (tlag)	[h] []	[h] []
Dermal Irritation (rabbit, OECD 404)	negative [LIT0001]	
Mucosal irritation (rabbit, OECD 405)	mostly classified as non-irritating [C&L Inv.]	
Sensitization (guinea pig, OECD 406)	negative [LIT0001]	
Mutagenicity (Ames Test, OECD 471)	partially positive / negative in vitro [LIT0326] negative in vivo [LIT0326]	
Carcinogenicity (OECD 451,452,453)	no data available	
Reproductive toxicity (OECD 415,416,421,422)	no data available	
Developmental toxicity (OECD 414)	NOAEL > 435,2 mg/kg [LIT0326]	
Log POW	3,1 [calc.]	[]
Assessment:	There is no limitation regarding the Cosmetics Regulation. The substance is considered to be safe in the preceding application concentration.	

Full Profiles of colorants and carrier materials available in the full version.

b) ingredients interactions:

Interactions between individual components of the formula are not known or expected.

5.3 Nanomaterials

Product does not contain any materials with these properties.

(acc. to definition EC 1223/2009 §2 (k) -*nanomaterial means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm)*

6 Adverse effects and serious undesirable effects

a) Complaints

Complaints	Date	Medical certificate	(possible) cause	Review**	Quote [%]*	Measures
So far there are no complaints.	-	-	-	-	-	-

* Number of products concerned by complaint / action in relation to the total number of products

A serious adverse effect ** = B = Adverse effect, C = general complaint

b)Reports

Report initiated from:	Category of report	Date	Description	Measures
-	-	-	-	-

Part B: Safety assessment of cosmetic product

1 Conclusions of the evaluation

The formulation **"PRO BIO FIBERBOND"** is harmless to health, in light of the general toxicological profile and of the ingredients, chemical structure and the degree of exposure in compliance with the warnings and conditions of use under normal and foreseeable purpose of use.

2 Calculation margins of safety (MoS) and justifications

a) Calculation of: nail polish / gel (intended use)

The calculation of MoS (margin of safety) is carried out with formula (3)

(3) MoS = NOAEL/SED

Each safety margin MoS of a formulation substance of the cosmetic raw material must be at least 100.

Substance	CAS-No.	Dermal Absorption DA [mg/cm2]	Percutane Permeation P [%]	NOAEL [mg/kg]	MoS
Benzylmethacrylate	2495-37-6		1	500,00	**>100**
Ethylphenyl(2,4,6-trimethylbenzoyl)phosphinate	84434-11-7		1	100,00	**>100**
1-Hydroxycyclohexyl phenyl keton	947-19-3		1	300,00	**>100**
Calcium Natrium Phosphosilikat	65997-17-3		1	497,00	**>100**
Urethane Methacrylate	n/a		1	30,00	**>100**
4-Methoxyphenol	150-76-5		1	50,00	**>100**
3,5-Bis(1,1-dimethylethyl)-4-hydroxytoluene	128-37-0		1	5,00	**>100**
Acrylnitrilpolymerisate	26658-88-8		1	40,00	**>100**
Urethane Acrylate	n/a		1	40,00	**>100**
Tripropylene glykol diacrylate	42978-66-5		1	250,00	**>100**
1-Hydroxy-4-(p-toluidino)anthraquinone	81-48-1		1	109,00	**>100**

Result: All substances evaluated have now a sufficient margin of safety (MoS) to the NOAEL (No Observed Adverse Effect Level) of >100

b)) Calculation of: - (misuse)

none known

c) other expositions

none known

d) other

Inhalational exposure to the solvent is negligible.

By working on the nail gels, abrasion dust can arise. The home application is not considered, as manual files produced no relevant amount of dust. If no ventilation system exists, the exposure is: 2.5 / week with 1 g of product, which produces max. 10% of dust due to handling and max. 10% absorption of the product by breathing air.

A maximum of 25 mg of product per 25 m^3 room area = 1 mg / m^3

Extrapolating from toxicity values of the principal component shows no concern regarding inhalation. If the respirable fraction is assumed to be less than 5%, an adequate margin of safety is achieved when inhaled. The margin of safety (MoS) regarding inhalation is sufficient (> 100).

The toxicological profile results are according to (EC) No. 1272/2008 neither in acute toxicity nor in a harmful classification. The raw materials used are considered to be microbiologically harmless. The preparation may be classified as irritating to eyes and skin according to (EC) No. 1272/2008.

3 Warning notices, Safety instructions and Application instructions

Instructions for use, application conditions:	*see label*
Warning notices	*- Avoid skin contact* *(- Avoid eye contact)* *- Read directions for use carefully* *(- Avoid exposure to dust)* *- For professional use only*

4 Qualification of the safety assessor and approval for Part B

First assessor:

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approved:

Name/signature:

(safety assessor) *Andreas Rau* *Holger Rabuske*

Proof of qualification: see Annex.

5 Validation

All information and statements given in this safety assessment has been made under the current state of knowledge. Any subsequent change to the recipe or the change / addition of relevant data for the safety assessment leads to Invalidity of this assessment.

6 Documents and declarations provided to the safety assessor, Appendix

- Documents relating to annex I, EC 1223/2009 requirements for the safety assessor Qualifications (certificates and curriculum vitae)
- specifications of the raw materials and finished product
- Information on Packaging and manufacturing
- labelling information

7 Literature

LIT0001 ECHA Datenbank der registrierten Stoffe (Europäische Chemikalienagentur) https://echa.europa.eu/de/information-on-chemicals/registered-substances

LIT0002 IUCLID Datenbank (International Uniform ChemicaL Information Database)

LIT0003 Gestis-Stoffdatenbank (Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung); https://gestis.dguv.de/

LIT0004 Toxicology and Applied Pharmacology. Vol. 16, Pg. 718, 1970

LIT0005 Japan Chemical Industry Ecology-Toxicology & Information Center, SIAM 19, 19-22 October 2004

LIT0006 Rath Birgit, Baumann Michael A., Permeationsverhalten verschiedener Handschuhe bei Einwirkung eines alkoholischen Händedesinfizienz, Int Poster J Dent Oral Med 1999, Vol 1 No 3, Poster 22

LIT0007 Beskitt JL, Sun JD. In vitro skin penetration characteristics of ethanol in the rabbit, mouse, rat and human. J Toxicol - Cut & Occular Toxicol 1997; 16(1): 61-75

LIT0008 Scott RC, Corrigan MA, Smith F, Mason H. The influence of skin structure on permeability: an intersite and interspecies comparison with hydrophilic penetrants. J Invest Dermatol 1991; 96(6): 921-925

LIT0009 International Journal of Toxicology 2010 29: 84S

LIT0010 ChemIDplus Datenbank

LIT0200 RTECS-Datenbank (Registry of Toxic Effects of Chemical Substances) - The Canadian Centre for Occupational Health and Safety (CCOHS)

LIT0201 The SCCS Notes Of Guidance For The Testing Of Cosmetic Ingredients And Their Safety Evaluation, 11th Revision

LIT0202 DGK-Vorschlag zu Kernelementen einer Sicherheitsbewertung, SÖFW-Journal | 131 | 8-2005

LIT0203 Guidance for Industry Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers, Center for Drug Evaluation and Research Food and Drug Administration

LIT0204 Casarett & Doull's Toxicology: The Basic Science of Poisons

LIT0205 Regulatory Toxicology and Pharmacology 53 (2009) 16–19

LIT0206 Draft OPINION ON Use of the Threshold of Toxicological Concern (TTC) Approach for the Safety Assessment of Chemical Substances, SCCP/1171/08

LIT0207 Guidance Document on Dermal Absorption, Sanco/222/2000 rev. 7 , 19 March 2004, EUROPEAN COMMISSION HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

LIT0208 Regulatory Toxicology and Pharmacology 57 (2010) 200–209

LIT0209 European Journal of Pharmaceutical Sciences 21 (2004) 471–477

LIT0210 Information zum Schweizer Chemikalienrecht, Merkblatt D05, Version 2.1, www.afu.llv.li Survey and health assessment of chemical substances in essential oils and fragrance oils, Survey of Chemical Substances in Consumer Products, No. 92 2008, Danish Environmental Protection Agency

LIT0299 International Journal of Toxicology 24(Suppl 5):53-100 2005

LIT0307 SIDS Initial Assessment Report for SIAM 25 Berlin, Germany, 25-22 October 2004

LIT0417 SIDS Initial Assessment Report 2,6-di-tert-butyl-p-cresol (BHT)

LIT0431 Kodak Company Reports. Vol. 21MAY1971

LIT1122 Kroes R., Greim H. et al.: Application of the threshold of toxicological concern (TTC) to the safety evaluation of cosmetic ingredients. Food Chem Toxicol. 2007 Dec;45(12):2533-62

LIT1163 International Journal of Toxicology 30(Supplement I) 54S-65S, 2011

LIT1164 Amended Safety Assessment of Acrylates Copolymers as Used in Cosmetics, Cosmetic Ingredient Review (CIR), 01/2019

LIT1281 Safety Assessment of Borosilicate Glasses as Used in Cosmetics; Int. J. Toxicol. 32 (Suppl. 3), 65-72, 2013 (CIR)

c) method of manufacturing

Description of the manufacturing:

see manufacturer documents

d) proof of the effect claimed for the cosmetic product

Claim	**Study**	**Date**	**Institute**
-	-	-	-
Result			
not relevant			

There are no known claims available.

e) data on animal experiments

During the development and safety assessment of the cosmetic product no animal experiments were carried out by us or in our mission with this product. We have no information that the starting materials used might not be suitable for use in cosmetics. From the suppliers of the raw material it is confirmed that the raw materials delivered are in compliance with the current Cosmetics directive.

see attached documents (if applicable)

d) other

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3.) Disclaimer: This document is not equivalent to a certificate of marketability. Only product safety is assessed on the basis of current data and to the best of our knowledge.

4.) Both the presentation and the labelling of the finished cosmetic product were not fully checked. If the draft label is available, the clients will be informed in writing form in case of major violations against the Cosmetics Regulation (EC 1223/2009) and the so-called claims regulation (EU 655/2013). It is generally recommended to have the labelling of the product checked separately, as this report does not cover all details, but only existing safety-relevant points.