Cosmetic product safety report

It is essential that cosmetic product made available on the Union market be safe for human health when used under normal and reasonably foreseeable conditions of use. To that end, Regulation (EC) No 1223/2009 requires that, in order to establish that a cosmetic product is safe under those conditions, cosmetic product undergo a safety assessment.

Manufacturer:	
Name:	Limited Liability Company
Address:	Oktiabrskaya Str., Krasnodar
Country:	Russian Federation
E-mail:	
Phone:	

Responsible person:	
Name:	P.C.
Address:	Korydallos, TK 18120
Country:	Greece
E-mail:	
Phone:	

Product:	
Class:	Name:
Nail care	VNA professional Top coat

INTRODUCTION

Every cosmetic product has to be assessed according Regulation (EC) No 1223/2009. Safety assessment report considers safety for human health under normal or reasonably foreseeable conditions of use. It includes the evaluation of toxicological profile of single substances and also of the cosmetic product itself. Dose, frequency of use and all known information that is available at the time of assessment is taken into account.

Literature sources:

- certificates and safety data sheets of the raw material producers
- Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products
- Commission implementing decision (2013/674/EU) on Guidelines on Annex I to Regulation (EC) No 1223/2009
- Opinions and Statements of SCCS (Scientific Committee on Consumer Safety),
- European Commission database Cosing for information on cosmetic substances
- Council Directive 76/768/EEC
- Commission Decision amending Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products
- Sigma-Aldrich database,
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
- Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- cosmetic product test reports
- z SCCS notes of guidance for the testing of cosmetic ingredients and their safety evaluation, 9th revision (SCCS/1564/15),
- other related literature and www pages.

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Part A, Annex I, Regulation (EC) No 1223/2009

1. Quantitative and qualitative composition of the cosmetic product

(exact quantitative and qualitative composition of the finished product, starting from raw materials)

No	Name (INCI)	Name (IUPAC)	CAS No EC No	Substance %	Intended function	Active ingredient %
1.1	Polysilicone 13	-	158451-77-5 -	30	conditioning	30
1.2	HEMA	2-Hydroxyethyl Methacrylate	868-77-9 212-782-2	30	film forming	30
1.3	Trimethylpropane trimethacrylate	Propylidyne-trimethyl trimethacrylate; 2,2-bis({[(2-methylprop-2-enoyl)oxy]methyl})butyl 2-methylprop-2-enoate	3290-92-4 221-950-4	10	film forming	10
1.4	Butyl methacrylate	n-butyl methacrylate, butyl 2-methylprop-2-enoate	97-88-1 202-615-1	10	film forming, masking, viscosity controlling	10
1.5	Acrylates copolymer	(Meta)acrylic ester co-polymer 2-propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate	25133-97-5 25035-69-2 25212-88-8 607-492-1	10	antistatic, binding, film forming	10
1.6	Trimethylbenzoyl diphenylphosphine oxide	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8 278-355-8	5	skin conditioning	5
1.7	Hydroxycyclohexyl phenyl ketone	(1-hydroxycyclohexyl) phenylmethanone	947-19-3 213-426-9	4.5	binding	4.5
1.8	CI 60725	1-Hydroxy-4-(p-toluidino)anthraquinone	81-48-1 201-353-3	0.5	cosmetic colorant	0.5

2. Physical/chemical characteristic and stability of the cosmetic product

(*relevant physical and chemical specifications of the substances or mixtures used and the cosmetic product itself)*

Substances:

p.č.	Name (INCI)	Name (IUPAC)	CAS No EC No	Conc. in product %	Classification	Physical characteristics	NOAEL LD_{50}
2.1	Polysilicone 13	-	158451-77-5 -	30	still not clasified	no data available	no data available
2.2	HEMA	2-Hydroxyethyl Methacrylate	868-77-9 212-782-2	30	Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens.1 H317	Clear colorless liquid Melting/freezing point: - 11.99 °C Initial boiling point and boiling range 67 °C at 4.7 hPa Flash point 106 °C Vapor pressure 0.08 hPa at 20 °C - OECD Test Guideline 104 Solubility in water 100 g/l při 20 °C Partition coeff. n-octanol/water log Pow: 0.42 at 25 °C - OECD Test Guideline 107 Self-ignition temperature 375 °C at 1.024 hPa Viscosity 6.36 mm^2/s at 20 °C - 3.42 mm^2/s at 40 °C This substance wasn´t identified by the IARC at levels greater than or equal to 0.1% as probable, potential or confirmed carcinogen.	LD_{50}, oral, rat: 5.564 mg/kg LD_{50}, dermal., rabbit male - > 5000 g/kg Eye irritating, can cause sensitization by skin contact. (OECD Test Guideline 429)
2.3.	Trimethylpropane trimethacrylate	Propylidyne-trimethyl trimethacrylate; 2,2-bis({[(2-methylprop-2-enoyl)oxy]methyl})butyl 2-methylprop-2-enoate	3290-92-4 221-950-4	10	Aquatic chronic 2 H411	slightly yellow liquid Melting point: ≥-41.6-≤-29.5 °C Boiling point: 161.3°C - 166.9 °C Density: 1.066 g/cm^3 Flash point: > 130°C Self ignition point: > 130°C non-flammable Viscosity: 65.725 mPa Solubility in water: 20.1 mg/l (20°C)	LD_{50}: >2000 mg/kg
2.4	Butyl methacrylate	n-butyl methacrylate, butyl 2-methylprop-2-enoate	97-88-1 202-615-1	10	Flam. Liq. 3 H226 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1 H317 Stot Se 3 H335	Colorless liquid Melting point: -50 °C Boiling point: 163°C Density: 0.89 g/cm^3 at 20°C Vapor pressure: 2.12 hPa at 20°C Flash point: 48.5°C Self ignition point: 294°C Solubility in water: 360 mg/l at 25°C	LD_{50}: >2000 mg/kg

2.5	Acrylates copolymer	(Meta)acrylic ester co-polymer 2-propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate	25133-97-5 25035-69-2 25212-88-8 607-492-1	10	Skin Irrit.2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	Milk liquid of sour smell, pH (25 °C, 10% water solution): 2.1 -3.5 Density: 1.1 – 1.2 g/cm^3 při 20 °C	No toxicological data available, used as cosmetic ingredient for long time. This substance wasn´t identified by the IARC at levels greater than or equal to 0.1% as probable, potential or confirmed carcinogen.
2.6	Trimethylbenzoyl diphenylphosphine oxide	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8 278-355-8	5	Skin Sens.1 H317 Repr. 2 H361f Aquatic Chronic 2 H411	Yellow powder Melting point/range: 88 - 92 °C Initial boiing point/range: > 200 °C Solublity in water: 0.0001 g/l (OECD Test Guideline 105) slightly soluble substance Partition coeff. n-octanol/water log Pow: 3,1 at 23 °C Self ignition temperature: > 400 °C at 1.01325 hPa	LD_{50}, oral, rat: > 5.000 mg/kg (OECD Test Guideline 401) LD_{50}, dermal., rat: > 2.000 mg/kg (OECD Test Guideline 402)
2.7	Hydroxycyclohexyl phenyl ketone	(1-hydroxycyclohexyl) phenylmethanone	947-19-3 213-426-9	4.5	Eye Irrit. 2 H319	Powder Melting point/range: 47-50 °C Initial boiling point: 175 °C at 20 hPa Flash point: 164 °C Relative density: 1.182 g/cm^3 at 20 °C Partition coeff. n-octanol/water log Pow: 2.81 at 25 °C Self ignition temperature: 424 °C Surface tension: 60.2 mN/m at 20 °C	LD_{50}, oral, rat: > 2.500 mg/kg LC_{50}, inhal., rat, 4 h: > 1 mg/l (OECD Test Guideline 403) LD_{50}, dermal., rat: > 5.000 mg/kg (OECD Test Guideline 402)
2.8	CI 60725	1-Hydroxy-4-(p-toluidino) anthraquinone	81-48-1 201-353-3	0.5	Skin Sens.1 H317	Purple to violet powder without odour Mw: 329.37 g / mol Melting point: 189°C Non-soluble in cold water Density: 1.35 g / cm^3 Flash point: > 200°C Decomposition point: >300°C	LD_{50} (rat): 8160 mg / kg

Physical/chemical characteristic of the cosmetic product:

Appearance:	viscous liquid
Color:	transparent, colorless
Scent:	pungent according used substances
pH:	4.5 – 9.0

Stability of the cosmetic product:

It isn´t possible to perform the stability testing due to rapid polymerization of this product.
The expected product stability is conditioned by the physical conditions of the storage environment.

3. Microbiological quality of the finished cosmetic product

Microbiological quality:

Microbiological examination can´t be performed. Considering the composition, no conditions for bacterial growth are created and therefore it is a high presumption of microbiological purity.

Characteristic of packaging material:

Glass bottles for perfume and beauty products „DOUBLE STAR“, manufacturer GUANGZHOU STAR GLASSWARE CO., LTD, China, 1405, No. 3, Tingyuan Road, Haizhu District, Guangzhou, Guangdong, China
Packaging fulfils the legislative requirements for cosmetic products, heavy metal concentrations are well below permitted limits. – test report of laboratory Limited Liability Company „Helios“ No. DR5P1KN from 3.11.2017

4. Normal and reasonably foreseeable use:

Text on the packaging:

Ingredients (INCI): Polysilicone 13, HEMA, trimethylopropane trimethacrylate, butyl methacrylate, acrylates copolymer, trimethylbenzoyl diphenylphosphine oxide, hydroxycyclohexyl phenyl ketone, CI 60725

We recommend to introduce the date of manufacture on the packaging.

5. Exposure to the cosmetic product:

(the toxicological profile of individual substances is given in section 2)

For cosmetic substances (ingredients) of toxicological importance it must be the systemic exposure dose (SED) calculated. It is the amount of the substance that can enter the bloodstream and act systemically. This amount depends on dermal absorption. If there is no data on the absorption of the substance, its full (100%) absorption is assumed.

Formula:

- $SED_{ingr.derm.}$ = $SED_{product}$ (mg/kg bw/day) x ingredient concentration (%) x dermal absorption (%)

For all toxicologicaly relevant ingredients it is required the Margin of Safety (MOS). MOS value is recommended (The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their safety evaluation, 9th Revision, SCCS/1564/15) for assessing risk of cosmetic substances in long-term and regular administration of the dose. It tells us with which certainity it can be argued that the Systemic Exposure Dose (SED) of a particular cosmetic raw material is safe at a given exposure. For calculation of the Margin of Safety (MOS) the relevant data must be used. Dose values with No Observed Adverse Effect (NOAEL) are used. If these data aren´t available, it can be used the other applicable regulations, which define the toxicological profile of substances
(Regulation (EC) No 1907/2006; Regulation (EC) No 1272/2008). It is assumed that the NOAEL value is 1% of the oral LD_{50} value. If the substance is not classified as toxic or harmful, then it is according the classification criteria for hazardous chemicals the value of LD_{50} > 2000 mg/kg and NOAEL value is 20 mg/kg/day.

Formula:

- $MOS_{ingredient} = NOAEL_{ingredient} / SED_{ingredient}$

Site of application and exposition to the product: nails
Surface area involved: 1.6 cm^2
Amount of single dose application: 0.5 g, retention factor 0.1;
leave-on product.
Frequency of application: about once in 30 days.
Target group: adult woman
Calculated exposure in case of one application: 0.83 mg/kg bw
Mean relative daily exposure within 30 days: 0.027 mg/kg bw/day

6. Exposure to the substances

(the toxicological profile of individual substances is given in section 2)

Polysilicone 13

$SED_{product}$	0.027 mg/kg bw/day
$SED_{ingr.} = SED_{product}$ (mg/kg bw/day) x ingr. conc. (%) x dermal absorption (%)	0.027 x 0.30 x 0.1 = 0.00081 mg/kg
$MOS_{ingr.} = NOAEL_{ingr.} / SED_{ingr.}$	20 / 0.00081 = 24691.36= >100

Substance is at normal and reasonably foresseable use safe.

HEMA :

$SED_{product}$	0.027 mg/kg bw/day
$SED_{ingr.} = SED_{product}$ (mg/kg bw/day) x ingr. conc. (%) x dermal absorption (%)	0.027 x 0.30 x 0.1 = 0.00081 mg/kg
$MOS_{ingr.} = NOAEL_{ingr.} / SED_{ingr.}$	20 / 0.00081 = 24691.36= >100

Substance is at normal and reasonably foresseable use safe.

Trimethylopropane trimethacrylate:

$SED_{product}$	0.027 mg/kg bw/day
$SED_{ingr.} = SED_{product}$ (mg/kg bw/day) x ingr. conc. (%) x dermal absorption (%)	0.027 x 0.10 x 0.1 = 0.00027 mg/kg
$MOS_{ingr.} = NOAEL_{ingr.} / SED_{ingr.}$	20 / 0.00027 = 74074.07= >100

Substance is at normal and reasonably foresseable use safe.

Butyl methacrylate:

$SED_{product}$	0.027 mg/kg bw/day
$SED_{ingr.} = SED_{product}$ (mg/kg bw/day) x ingr. conc. (%) x dermal absorption (%)	0.027 x 0.10 x 0.1 = 0.00027 mg/kg
$MOS_{ingr.} = NOAEL_{ingr.} / SED_{ingr.}$	20 / 0.00027 = 74074.07= >100

Substance is at normal and reasonably foresseable use safe.

Acrylates copolymer:

$SED_{product}$	0.027 mg/kg bw/day
$SED_{ingr.} = SED_{product}$ (mg/kg bw/day) x ingr. conc. (%) x dermal absorption (%)	0.027 x 0.10 x 0.1 = 0.00027 mg/kg
$MOS_{ingr.} = NOAEL_{ingr.} / SED_{ingr.}$	20 / 0.00027 = 74074.07 = >100

Substance is at normal and reasonably foresseable use safe.

Trimethylbenzoyl Diphenylphosphine Oxide:

$SED_{product}$	0.027 mg/kg bw/day
$SED_{ingr.} = SED_{product}$ (mg/kg bw/day) x ingr. conc. (%) x dermal absorption (%)	0.027 x 0.05 x 0.1 = 0.000135 mg/kg
$MOS_{ingr.} = NOAEL_{ingr.} / SED_{ingr.}$	50 / 0.000135 = 370370.37 = >100

Substance is at normal and reasonably foresseable use safe.

Hydroxycyclohexyl phenyl ketone:

$SED_{product}$	0.027 mg/kg bw/day
$SED_{ingr.} = SED_{product}$ (mg/kg bw/day) x ingr. conc. (%) x dermal absorption (%)	0.027 x 0.045 x 0.1 = 0.0001215 mg/kg
$MOS_{ingr.} = NOAEL_{ingr.} / SED_{ingr.}$	50 / 0.0001215 = 164609.05 = >100

Substance is at normal and reasonably foresseable use safe.

CI 60725 (1-hydroxy-4-(p-toluidino)anthraquinone):

This is a dye allowed under Regulation 1223/2009, Annex IV. It has no limitations. It does not pose a health risk.

7. Undesirable effects and serious undesirable effects

The manufacturer has a system of evidence and reporting of undesirable effects. This is a new product, but no adverse effects have been reported with a similar product type.

8. Information on the cosmetic product

It is an acrylic nail gel containing 80% of acrylic hardening component. The product is intended for professional use. This eliminates the potential risks. In addition, the MOS calculation for individual components confirms that substances are safe when used under normal and reasonably foreseeable conditions.

The product does not contain synthetically produced perfumes, petroleum substances such as mineral oil, paraffin or petrolatum, synthetic preservatives, synthetic dyes, animal ingredients, GMOs or alergenic substances.

Part B, Annex I, Regulation (EC) No 1223/2009

1. Assessment conclusion

Based on all available information mentioned in the introduction, toxicological evaluation of ingredients, knowledge of Margin of Safety (MOS) and compliance with the requirements of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), **the product VNA professional Top coat, can be assessed as safe**. It is required to keep the declared instruction of use and to comply with the current regulations valid for cosmetics and also chemical products regarding the mandatory labeling on packaging. This conclusion applies only to those products whose composition and properties correspond to the dossiers submitted and to the results of the laboratory trials.

2. Labelled warnings and instruction of use

In accordance with the Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products it is required no specific warning on the label. The purpose of use and instructions for proper application are given on the label. We recommend to introduce the date of manufacture on the packaging.

Ingredients (INCI) on the label: Polysilicone 13, HEMA, trimethylopropane trimethacrylate, butyl methacrylate, acrylates copolymer, trimethylbenzoyl diphenylphosphine oxide, hydroxycyclohexyl phenyl ketone, CI 60725

3. Reasoning

The manufacturer provided a safety data sheet and the certificate of quality of the packaging. Product ingredients are from the toxicological point of view at a given concentration safe and by keeping the normal and foreseeable use they do not pose the risk of irritation, sensibilisation and another systemic or toxicological undesirable effects to healthy persons. Margins of Safety (MOS) are well above the value 100.

Safety assessment report No: KP-18-002 from 18.1.2018

This report is issued according to the requirements of valid and binding regulations for cosmetic products and classification of chemical preparations.
It serves solely to assess the safety of the product for human health. It is processed according to the current state of legislative, scientific and technical knowledge. If a recipe or legislative requirements will be changed, a reassessment of product safety and a new report issuing will be required.