COSMETIC PRODUCT

SAFETY REPORT

ESMALTE SEMIPERMANENTE

Product colour versions:

BLANC0 1000, NEGRO 900, ROJO 420, ROJO 412, ROJO 426, NUDE 101, NUDE 110, MORADO 601, MARRON 307, MARRON 308, AZUL 701, VERDE 800, FULL GLITTER 1, FULL GLITTER 3, GLITTER 01, GLITTER 02, ROSA 521, ROSA 505, PASTEL SHAKE BANANA 4, PASTEL SHAKE ICE 5, PASTEL SHALE RASPBERRY 1, PASTEL SHAKE MINT 3, PASTEL SHAKE PEACH 2, PASTEL SHAKE BLUEBERRY 6, GRIS 213, ROJO 406, NUDE 102, NUDE 107, VERDE 805, MORADO 621

Product description:

Product name:	ESMALTE SEMIPERMANENTE
Product destination:	Hybrid nail polish
State of aggregation:	Liquid
Nominal content:	5 g
Type of a packaging:	Glass bottle with a plastic cork and nylon brush

Product name / identifier	BLANC0 1000, NEGRO 900, ROJO 420, ROJO 412, ROJO 426, NUDE 101, NUDE 110, MORADO 601, MARRON 307, MARRON 308, AZUL 701, VERDE 800, FULL GLITTER 1, FULL GLITTER 3, GLITTER 01, GLITTER 02, ROSA 521, ROSA 505, PASTEL SHAKE BANANA 4, PASTEL SHAKE ICE 5, PASTEL SHALE RASPBERRY 1, PASTEL SHAKE MINT 3, PASTEL SHAKE PEACH 2, PASTEL SHAKE BLUEBERRY 6, GRIS 213, ROJO 406, NUDE 102, NUDE 107, VERDE 805, MORADO 621
Data of a responsible entity	Postquam Cosmetic, S.L. Ctra. Burgos –Portugal Km.115. 47270 Cigales – (Valladolid) Espańa

Safety report for the product was drawn up in accordance with the Regulation of the European Parliament and of the Council (EC) no. 1223/2009 of November 30, 2009 on cosmetic products.

*This assessment is based solely on the list of ingredients and cosmetic product safety information submitted for toxicological risk assessment, and assumes that this list is accurate and there are no additional ingredients present or intentionally added or data which are not listed.

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A list of potential abbreviations:

ADI- accepted daily intake

FDA- Food and Drug Administration

IARC- International Agency for Research on Cancer

LOAEL- the lowest possible level of substance that harmful effects are observed in

LD_{50}- the lowest dose that death of 50% of examined organisms is observed in

LC50- the lowest concentration that death of 50% of examined organisms is observed in

MoS- margin of safety

NOISH- National Institute for Occupational Safety and Health

NOAEL- the level of substances without observed harmful effects

NOEL- the level of substances that no effects are observed at

NTP- National Toxicology Program

OSHA- Occupational Safety and Health Administration

SED- Systemic Exposure Dosage

PART A: INFORMATION ABOUT SAFETY OF A COSMETIC PRODUCT

1. Quantitative and qualitative composition of a cosmetic product

Chemical composition	CAS	EINECS	% max	Function
Di-Hema Trimethylhexyl Dicarbamate	41137-60-4	255-239-5	45	Film-making agent
Hema	868-77-9	212-782-2	25	Film-making agent
Hydroxypropyl Methacrylate	27813-02-1	248-666-3	25	Film-making agent
Ethyl Trimethylbenzoyl Phenylphosphinate	84434-11-7	282-810-6	2,5	Cross-linking agent
Hydroxycyclohexyl Phenyl Ketone	947-19-3	213-426-9	2,5	Stabilizer
+/- (May contain)				
CI 77266	1333-86-4	215-609-9	1	Dye
CI 77891	13463-67-7	236-675-5	5	Dye
CI 73360	2379-74-0	219-163-6	2	Dye
CI 15880	6417-83-0	229-142-3	2	Dye
CI 74160	147-14-8	205-685-1	2	Dye
CI 74260	1328-53-6	215-524-7	1	Dye
CI 19140	1934-21-0	217-699-5	1	Dye
CI 60725	81-48-1	201-353-5	1	Dye
CI 77007	57455-37-5	215-111-1	4	Dye
CI 77000	7420-90-5	231-072-3	8	Dye
Mica	12001-26-2	215-479-3	10	Filler

The product does not contain fragrance composition.

The chemical names presented above refer to raw ingredients used for formulation of this product. The identity of raw ingredients is not necessarily based on the International Nomenclature of Cosmetic Ingredients (INCI) and does not represent INCI that says that components must be presented on the product label. Given names are used to make a safety assessment.

2. Physical/chemical properties and stability of a cosmetic product

Physical and chemical properties of substances or mixtures are shown in the specification of particular raw ingredients used during production of a finished product.

Finished cosmetic product has the following properties:

Parameter	Requirements
Appearance	Viscous liquid, uniform colour, no delamination and impurities
Colour	Compatible with a pattern
Smell	Characteristic smell of acrylic
Density in 20°C	1,0-1,1 [g/cm^3]
Solubility in water	Insoluble
Ignition temperature	>87°C

The cosmetic product underwent stability tests, in which sample was kept for 8 weeks in temperature of +40°C. Every week, the product was observed in terms of polymerization, settlement of pigments and potential visual changes in the product. Mass is compatible with the packaging and no reactions occur between the mass of a product and walls of the bottle and brush immersed in it.

3. Microbiological quality

The cosmetic product, due to its qualitative composition (content of solvents /alcohol/acrylic) is not a product susceptible to microbiological infections, therefore, there is no need to conduct tests of the presence of micro-organisms.

Referring to PN-EN ISO 29621:2011, there is no need to conduct a load test because this product is anhydrous, it is a product of low microbiological risk. Its correct use ensures no growth of micro-organisms during application of the cosmetic.

4. Impurities, trace amounts, information about material that the packaging was made of

Finished cosmetic product may contain trace amounts of inhibitors of polymerization: hydroquinone (HQ) and p-hydroxyanisole (hydroquinone monomethyl aether MeHQ). The product works based on polymerization. After this process, trace impurities are trapped in the structure of polymer and there is nearly zero possibility of migration. In accordance with data contained in the documents made available by the producer for specific raw ingredients applied in the composition, the presence of trace amounts of prohibited substances, of which concentration may arouse fear of safety of a finished product was not observed. The substances subject to quantitative limitations in the cosmetic products were used in accordance with SCCS recommendations.

The packaging of the product consists of 5 g glass bottle and plastic top and a brush made of synthetic fibre. External walls of the bottle were painted black to protect against UV radiation. Packaging and stored mass are stable, no negative effects of contact of mass of the product with the packaging were observed. There were also no complaints about changes of packaging or product for the whole shelf life. The packaging has been regarded as appropriate.

5. Normal and foreseeable application

The cosmetic product is intended for decorating the nails of hands and feet. Frequency of use is usually once every three or four weeks. After application of one foundation layer of the product, it is hardened using UV lamp for 2-3 minutes or LED lamp for 30 seconds. An excess from the edge of a nail must be removed before hardening of the product. The packaging, along with information about what the product is intended for on, shows the method of application. The product name and instructions for use saying what this product is intended for and recommended method of use of the product can be found on the packaging. Moreover, information that the product is intended only for professional use can be found on the product label.

6. Exposure to the cosmetic product

Exposure to the product (SED) depends on the amount of applied product. The amount sufficient for one nail is on average 0,04 g, maximally up to 0,05 g. To calculate the exposure to the product, the following factors must be taken into account:

- type of a product - product remaining on the nail

- target exposed population - people at the age of above 18

- normal path of exposure - dermal (around nail plate and nail) - in accordance with recommendations, the product should not have contact with the skin, inhalation (5min/23,1 l/min)

- surface area of application - 20cm^3 surface area of the nail

- the amount of applied product for 10 nails is maximum 0,2g

- absorption for dermal exposure: 10% of applied amount (0,2g*10%=0,02g)

- the amount of applied product daily per unit of skin surface: 5mg/cm^3 per day- for consultation

- frequency of use – once every three/four weeks

- duration of exposure - 2-3 minutes (max. 5 minutes)

- calculated daily exposure – exposure to the product SED=0,333mg/kg month/ day

Because the process of polymerization is quick, and nail plate is a natural barrier penetration of the substances, exposure to the product is slight.

7. Exposure to the substances

For the components of considered formulation that NOAEL values were not identified for, other scientific information about safety of applied substances were used for the assessment. Safe substance is the one having MoS value at least 100. Taking quantitative composition of the cosmetic product into account, SED value (for maximum concentration values) was

calculated. For the substances that NOAEL values are available for, the value of MoS was calculated.

Chemical composition	SED	NOAEL	MoS
Di-Hema Trimethylhexyl Dicarbamate	0,1485	30	202
Hema	0,0825	30	364
Hydroxypropyl Methacrylate	0,0825	150	1818
Ethyl Trimethylbenzoyl Phenylphosphinate	0,0083	500	60606
Hydroxycyclohexyl Phenyl Ketone	0,0083	100	12121
+/- (May contain)			
CI 77266	0,0033	none	none
CI 77891	0,0165	375	22727
CI 73360	0,0066	125	18939
CI 15880	0,0066	none	none
CI 74160	0,0066	60	9091
CI 74260	0,0033	60	9091
CI 19140	0,0033	750	227273
CI 60725	0,0033	none	none
CI 77007	0,0132	100	7576
CI 77000	0,0264	16	606
Mica	0,1485	30	202

8. Toxicological profile of substances

Based on the Regulation of the European Parliament and of the Council (EC) no. 1223/2009 of November 30, 2009 on cosmetic products and the Regulation of the Minister of Health of March 30, 2005 on the lists of prohibited or substances permitted with the limitations for use in the cosmetics and graphic signs placed on the packaging of cosmetics (Dz. U. [Journal of Laws] of 2005, no. 72, item 642, as amended), the composition of the cosmetic product was verified and it was found that:

- it does not contain substances prohibited in the cosmetics (substances of Annex II, Reg. 1223/2009)

- it does not contain substances subject to limitations (Annex III, Reg. 1223/2009)

- it contains dyes approved for use in the cosmetics (Annex IV, Reg. 1223/2009)

Toxicological description of the substances used for production of a cosmetic product was developed based on data obtained in the course of reviewing toxicological databases and information from data sheets of specific components made available by the producer of a finished cosmetic product.

DI-HEMA TRIMETHYLHEXYL DICARBAMATE

It is a monomer of methacrylate esters. It is applied in nail products as a film-forming factor. This substance quickly polymerizes creating hard layer, which makes potential migration to the body impossible. The substance was not tested toxicologically well, however, its application in the products was tested by CIR. Data for some methacrylate esters show acute oral, dermal and intraperitoneal toxicity. 28-day inhalation using butyl methacrylate caused irritation of upper respiratory tract, however, neither any long-term harmful effects, nor lesions in organs were observed. NOAEL value was 1801mg/m3. During 28-week test of oral toxicity in rats, t-butyl methacrylate, NOAEL was determined as 20mg/kg month/day. During tests on beagle dogs for 13 weeks, animals were fed orally 0,2 , 0,6 or 1,0g/kg month/day with methacrylate monomer (C12 to C18). The effects were observed only in the group with the highest dose: weight loss, vomiting, diarrhoea, mucoid feces or salivation (NOAEL: 600mg/kg month/day). None of examined monomers of methacrylate ester have shown activity disturbing hormonal processes. These esters were usually not mutagenic in tests on bacteria, however, slight mutagenic reactions were observed in different test systems (non-bacterial). Some groups of these compounds may cause skin irritation, but there is no information about specific component. Due to the possibility of skin irritation, CIR Expert Panel has found the discussed components safe, provided that contact is limited to nail plate (avoid contact with the skin). This material is regarded as safe in current cosmetic use. CIR recommendations: avoid contact with the skin. It is not on the list Annex XVII (EU regulations, Reach, 1907/2009 and CLP 1272/2008. Classification of carcinogenicity – not classified.

Source: CIR Expert Panel Final Report of the Safety Assessment of Methacrylate Ester Monomers Used in Nail Enhancement Products. International Journal of Toxicology, 24: 52-100,2005

HEMA

2-Hydroxyethyl Methacrylate, Skin Irrit. 2, H315, Eye Irrit. 2, H319, Skin Seans. 1, H317.

Monomers of methacrylate ester are applied as artificial nail fillers in the nail strengthening products. They accelerate polymerization and/or create mutual connections. Available data showed slight acute toxicity orally, dermally. Methacrylate esters should be limited only to contact with nails and may not come into contact with the skin. LD50>4000mg/kg (orally); LD50>3000mg/kg (dermally). HEMA is caustic upon inoculation to the rabbit eye. In guinea pigs, HEMA is a strong sensitizer. Hema can be toxic for development in high doses (1000mg/kg/day). None of examined monomers of methacrylate esters have shown any disorders of endocrinological functions. These methacrylate esters are usually not mutagenic in the tests on bacteria, however, slight mutagenic reactions were observed in test systems of mammalian cells. Esters of methacrylate monomers applied in nail strengthening products. CIR Expert Panel assessed scientific data and has found that HEMA is safe in application in nail strengthening products with proper labelling and avoiding contact with the skin. NOAEL: 30mg/kg/month/day.

HYDROXYPROPYL METHACRYLATE

Classification: Skin Irrit. 2, H315, Skin Sens. 1 , H317, Eye Irrir. 2 , H319, STOT SE 3, H335. Monomers of methacrylate ester are applied as artificial nail fillers in the nail strengthening products. They accelerate polymerization and/or create mutual connections. Available data showed slight acute oral, dermal and intraperitoneal toxicity. Methacrylate esters should be limited only to contact with nails and may not come into contact with the skin. Esters of methacrylate monomer applied in nail strengthening products, during 28-day inhalation test in rats, this compound caused irritation of the respiratory tract. NOAEL was 1801 mg/m3. During 28-week test of, t-butyl methacrylate was NOAEL in the dose of 20 mg/kg/day. In Beagle dogs administered between 0,2 and 2,0g/kg/ day monomers C12 to C18 for 13 weeks showed effects only in the highest dosage group: loss of weight, vomiting, diarrhoea, salivation. Butyl methacrylate (0,1M) and isobutyl methacrylate (0,1M) mildly irritate the rabbit eye. HEMA is caustic upon inoculation to the rabbit eye, and PEG-4 dimethacrylate and trimethylolpropane trimethacrylate show minimal eye irritating effects. Skin irritation caused by methacrylate has recorded in guinea pigs and rabbits. In guinea pigs, HEMA, isopropylidenediphenol methacrylate, lauryl methacrylate and trimethylolpropane trimethacrylate are strong sensitizers. Butyl methacrylate, cyclohexyl methacrylate, hexyl methacrylate and urethane methacrylate are moderate sensitizers.
Hydroxypropylmethacrylate is a weak sensitizer; both PEG-4 dimethacrylate and dimethacrylate of triethylene glycol do not cause allergies. Dimethacrylate of ethylene glycol did not show allergic properties in one test on a guinea pig, but showed features of strong allergic product in a different test. In some allergy test, cross-reactivity between various methacrylate esters occurs. Methacrylate can be toxic for development in high doses (100 mg/kg/day). None of examined monomers of methacrylate esters have shown any disorders of endocrinological functions. Methacrylate esters are usually not mutagenic in the tests on bacteria, however, slight mutagenic reactions were observed in test systems of mammalian cells. Chronic dermal exposure by the mouses to PEG-4 dimethacrylate did not cause increased frequency of occurrence of skin cancers or cancers of internal organs. Carcinogenicity of dimethacrylate of triethylene glycol (5, 25 or 50%) was assessed in an imaging examination of mouses (50 microns for 5 days/week for 78 weeks), but was not carcinogenic in any examined range of the dose. A team of experts was worried about strong allergy and possibility of co-reactive secretion of methacrylate ester in this report. However, data showed that the degrees of polymerization of methacrylate were similar to ethyl polymer, which would limit the exposure of monomer activity to the skin. NOAEL: 150mg/kg/month/day.
CIR Expert Panel assessed scientific data and has found that component is safe in application in nail strengthening products in accordance with instructions for use, avoiding contact with the skin.

ETHYL TRIMETHYLBENZOYL PHENYLPHOSPHINATE

Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate, Phosphine oxid, Acylphosphine. Skin Seas. 1B, H317, Aquatic Chronic 3, H413.
Liquid photoinitiator for nail polishes hardened in UV. It can cause allergic dermal reaction.
Oral LD50>5000 mg/kg (rat, orally) (OECD 401)
LD50>2000 mg/kg (rat, dermally) (OECD 402)

Exposure by dermal route: DNEL (Derived No Effect Level) 5,88mg/m3
Exposure by inhalation route: DNE: 1,7mg/kg bw/day, AF=300, Dnel NOAEL=500
No mutagenic effects: OECD 471 AMES (bacteria)/OECD 476 Mammalian Cell Gene Mutation
Test (ML): negative

HYDROXYCYCLOHEXYL PHENYL KETONE

Hydroxycyclohexyl phenyl ketone is a photoinitiator of the processes of hardening for the resins based on acrylates and methacrylate hardened with UV rays. It has been used for years in body care and for different purposes. The studies on rats showed low oral toxicity LD50: 2800mg/lg. The product was assessed as moderately irritating for the rabbit eyes. During 28-day test on rats with oral administration using a tube, the level that no effects (NOEL) were observed was 50mg/kg, and considered level of NOAEL of 300mg/kg (the highest examined dose). High safety assessment of application of this component in the products for professional nail care is based on historical data that show long safe application of this ketone in nail products. UE-REACH Regulation, an annex XVII(no. 1907/2009). Registered as controlled substance. EU Regulation on cosmetic products (no. 1223/2009). Not listed as a controlled substance. EU Regulation on Regulation of CLP (no. 1272/2008). Registered as a controlled substance. Carcinogenic classification (IARC 2013): Not listed.

CI 77266

IV/126. Carbon black / Charcoal powder. It is a vegetable charcoal obtained as a result of carbonization of organic, plant raw materials such as wood, remains of cellulose, peat, coconut shells and others. Raw material is carbonized in high temperature. E153- food additive. Permissible dosage: 50-500mg/kg. Component of nacreous pigments. EFSA claimed that the component, in reported levels of use in food, is not a threat to health. ADI-Not determined.

CI 73360

IV/100. Colouring of category 1 of an annex (approved for all cosmetics). LD50 (rat)=4170mg/kg. No mutagenic effects. (Ames Test: TA98, TA1537, TA100, TA1535; +/- S9 mixD&C Red No. 30:negative) Carcinogenicity: not mentioned as carcinogenic in the following bases: ACGIH, IARC, NTP. No carcinogenic/teratogenic effects. It shows negative impact on reproductive ability ADI=1,25mg/kg; NOEL of 125mg/kg-bw/day. (US FDA 1982a)

CI 60725

Purple dye approved for use in all cosmetic products in accordance with the EU Cosmetic Directive. Listed in the Directive on Cosmetics (Annex IV/1) without any additional conditions, regarded as safe in the products for nail care. It was accepted as a cosmetic dye in the United States in 1976.

Acute toxicity	Orally, LD50:>2000 mg/kg
Caustic/irritating effects on the skin	No irritating effects

Serious eye damage/irritating effects	No irritating effects
Allergic effects on the respiratory tract or skin	No data
Mutagenic effects on germ cells	No data
Carcinogenicity	No data
Harmful effects on reproductiveness	No data
Toxic effects on target organs - single / repeated exposure	No data
Hazard caused by aspiration	No data
Other data	*RTECS no. CB7700000/FDA-EEC-JAPAN-CHINA: positive list

MICA

As a result of long-term exposure to dust, irritation of the respiratory tract and initiation of inflammatory processes were observed, and after many years, nodular fibrosis, lung scarring and pneumoconiosis were observed.

Acute toxicity	No data
Caustic/irritating effects on the skin	No data
Serious eye damage/irritating effects	Exposure to concentrations in air higher than required or recommended permissible concentrations may cause eye irritation or reddening.
Allergic effects on the respiratory tract or skin	No significant allergenic effects
Mutagenic effects on germ cells	No reports of adverse effects
Carcinogenicity	No reports of adverse effects
Harmful effects on reproductiveness	No reports of adverse effects
Toxic effects on target organs - single / repeated exposure	Repeated or long-term inhalation of dust may cause chronic irritation of respiratory tracts
Hazard caused by aspiration	Exposure to concentrations in air higher than required or recommended permissible concentrations may cause irritation of nose, throat and lungs.
Other data	No data

CI 74160

The substance regarded generally as safe. LD_{50} (rat, orally)>10000mg/kg month/day; LD_{50}(mammals >5g/kg; LD_{50} (rabbits, orally): 16000mg/kg month/day. Chronic toxicity upon intake - the symptoms occur in concentration of >0,2 g/kg. During tests of chronic and subchronic toxicity in rats in oral administration, NOAEL was determined: 200 mg/kg month/day. It may cause irritation of eyes, skin and respiratory tracts in children. However,

during tests on acute toxicity in rabbits, no irritating or allergenic properties were observed. No carcinogenic, teratogenic and genotoxic properties.

CI 19140

IV/44. During tests on acute toxicity in laboratory animals, LD_{50} in oral exposure in mouses was 12750 mg.kg month/day and in rats: 12956 mg/kg month/day. LD_{50} (mouses, inhalation): 7477 mg/l 4h. It shows no acute toxicity in dermal administration (in humans). It shows no irritating effects on rabbit eyes and skin. No allergenic properties in tests both on animals and humans were observed. During tests of chronic and subchronic toxicity, in tests on mouses, NOAEL value was 8103 mg/kg month/day for females and 9735 mg/kg month/day for females. The substance shows no genotoxic, toxic impact on fertility, and during tests of teratogenic properties, NOAEL was 1000 mgkg month/day. LD_{50} rat, orally >2000 mg/kg. Irritating effects: skin, eye - no irritating effects. Food colouring E 102. ADI=7,5 mg/kg.

Acute toxicity			Rat, orally, LD50:>2000 mg/kg
Acute toxicity			No irritating effects
Caustic/irritating effects on the skin			No irritating effects
Serious eye damage/irritating effects			No data
Allergic effects on the respiratory tract or skin			No data
Mutagenic effects on germ cells			No data
Carcinogenicity			No data
Harmful effects on reproductiveness			No data

CI 77007

Ultramarine, Lazurite. In tests on animals, toxicity of aluminium was defined as slight both in oral and inhalation administration. Absorption from alimentary canal was assessed as less than 1%. To a large extent, it shows the ability of accumulation, mainly in bones and lungs. As a result of dermal exposure, the frequency of occurrence of allergic reactions was low. No significant allergenic effects on the eyes and respiratory tracts were observed. No genotoxic and carcinogenic properties, as well as no toxic impact on reproductiveness. In tests on neurotoxicity of aluminium, it was observed that in some examined animals, neurological disorders along with epileptic seizures occurred. Osteomalacia was observed in larger species of animals. Approved for use in cosmetic products without limitations.

Acute toxicity	Rat for pigment blue29 LD50: 10 g/kg
Caustic/irritating effects on the skin	No data
Serious eye damage/irritating effects	It may cause eye irritation and reddening, irritation of nose, throat and lungs

Allergic effects on the respiratory tract or skin	No allergic effects
Mutagenic effects on germ cells	No data
Carcinogenicity	No data
Harmful effects on reproductiveness	No data
Toxic effects on target organs - single / repeated exposure	Repeated or long-term inhalation of dust may cause chronic irritation of respiratory tracts

CI 74260

Green colouring of an annex IV, item 107. Do not apply in the region of the eyes. Practically non-toxic upon single intake (among others, used in toothpastes). Rat, orally LD50: >5000 mg/kg. Rat, dermally LD50: >5000 mg/kg. Irritating effects: Draize test. Rabbit, skin - no irritating effects. Rabbit, eyes – no irritating effects on eyes (Draize test). Allergenic effects: guinea pig, no allergenic properties. Mutagenicity: no data – it is not expected. Toxicity for single/repeated dose. No impact on reproductiveness, reproduction or development of fetus was observed. (Based on the products of similar structure) Not listed by NTP, IARC, ACGIH, OSHA as a carcinogenic substance.

CI 77891

Titanium Dioxide. Colouring of category 1 of an annex IV (approved for all cosmetics). IV/143. Purity criteria are defined by the Directive 95/45/EC (E171). The substance regarded as harmless for human health. It has been used for years as a food colouring (in concentrations up to 3%). According to WHO data, no fears when it comes to safety of application in food. Titanium dioxide is not absorbed by human skin. Epidemiological data show that there are no carcinogenic effects connected with the effects of dust of titanium dioxide. Chronic toxicity test for titanium dioxide covered with mica in concentrations of 0,1 , 2 and 5% administered rats for up to 130 weeks did not show toxicological or carcinogenic effects. (Bernard et al. 1990). The effects of inhalation of dust are limited to local adverse effects in lungs. Data on acute toxicity: LD_{50} (rat, orally) >24 g/kg. LD50 (rabbit, dermally) >10 g/m3. NOEL 24000 mg/kg. ADI- no limit.

Acute toxicity	LD_{50} (rat, orally) > 10000 mg/kg LD_{50} (rabbit, dermally) > 10000 mg/kg LC_{50} (rat, inhalation) > 6,82 mg/l/4h
Caustic/irritating effects on the skin	No caustic properties
Serious eye damage/irritating effects	It may cause slight eye irritation
Allergic effects on the respiratory tract or skin	No data

Mutagenic effects on germ cells	No data
Carcinogenicity	No data
Harmful effects on reproductiveness	No data
Toxic effects on target organs - single / repeated exposure	No data

CI 15880

LD_{50} Rat, orally >5000 mg/kg. No irritating effects on the skin. It has no irritating effects on eyes. No carcinogenic, mutagenic, allergenic and teratogenic effects were observed.

CI 77000

Aluminium. Oral acute toxicity of these aluminium compounds that data are available for (bromine, nitrate, chloride and sulphate) is between moderate and low, of the value between LD50 162 and 750 mg Al/kg of body mass in rats and between 1164 and 980 mg Al / kg of body mass of the mouses, depending of aluminium compound (EFSA, 2008). Based on tests on neurodevelopmental toxicity of aluminium citrate added to drinking water in rats, Joint FAO/WHO Expert Committee on Food Additives (JECFA) has established PTWI (provisional tolerable daily intake) of 2 food additives. Toxicity for reproduction and development: LOAEL=100 mg/kg month/day and harmful effects (NOAEL was 30 mg/kg month/day) were not observed. Bioavailability of aluminium chloride, sulphate and ammonium nitrate and aluminium hydroxide was much lower than of aluminium citrate (Poirier et al. 2011). This test was used by JECFA as a key test to obtain PTWI. Genotoxicity: SCCS agrees with conclusions of the EFSA Panel. Aluminium compounds do not cause gene mutation for bacteria or cells of mammals. Exposure to aluminium compounds causes chromosomal structural and numerical aberrations, both in in-vitro and in-vivo in mutagenicity tests. SCCS also agrees that DNA damage is probably a result of indirect mechanism. DNA damage was observed only for high levels of concentration. Carcinogenicity: no carcinogenic effects in large feed intakes (up to 850 mg/kg, Al. month/day) in tests on animals, SCCS said that no carcinogenic effects at the levels of exposure reached by the cosmetic products are expected. To determine precise exposure to aluminium upon application on the skin, the level of exposure under conditions of product use should be determined.

9. Adverse effects and heavy adverse effects

The main adverse effect that the use of the product may cause is sensitivity or skin irritation. However, if the product is applied in accordance with the instructions for use, potential risk of such reactions is minimal and possible only for liquid form of the gel. After hardening, the cosmetic product is no longer a subject of deliberations about adverse effects. Up to now, no serious adverse effects connected with using this product were observed.

There are no reports of adverse effects or heavy adverse effects, analysed also in the aspect of complaints upon application of the discussed cosmetic product.

10. Information about cosmetic product

Finished product was not tested on animals.

PART B: COSMETIC PRODUCT SAFETY ASSESSMENT

1. Assessment conclusion

In accordance with the Regulation of the European Parliament and of the Council (EC) no. 1223/2009 of November 30, 2009 on cosmetic products, on the basis of a safety assessment conducted in the point A of the cosmetic product intended for nail design, I declare that discussed product can be regarded as safe for human health under normal or foreseeable conditions of use. The assessment was conducted on the basis of declared composition and available data on finished product.

2. Labelled warnings and instructions for use

The product allows to cover natural nail plate within 2-3 minutes in UV lamp, or within 30 minutes in a LED lamp. The product is safe provided that it is used by the professionals, in accordance with the producer's recommendations. Safety level is provided that can be realistically expected from such products. Due to the product composition, its purpose and due to the fact that it belongs to the group of products for professional use, I hereby declare that there is necessity to place specific precautions and instructions for use for special group of cosmetics on the packaging (in accordance with Art. 19 (1) (d) of EC Regulation, no. 1223/2009)

Cosmetic product packaging must have appropriate product description, guaranteeing expected conditions of use and purpose. Label text should contain:

-required information about components (INCI)

-data on batch number and period after opening/PAO

-information that this is the product only for professional use along with its instructions for use and warnings

The warnings must include the following expressions:

- only for professional use

- it may cause allergic reaction

It is recommended to place additional warnings:

- avoid contact with the skin

- read instructions for use carefully

3. Reasoning

The conclusion described in the point 1 is a result of data analysis conducted in part A, that is:

- quantitative and qualitative product composition

- physical and chemical properties of substances and stability of a finished product

- toxicological data of specific components

- observed information or potential adverse effects

The components that were described in the EC Regulation 1223/2009 that are subject to limitations were used in permissible concentrations and conditions of use.

For the components that NOAEL values were available for, the margins of safety (MoS) were determined. In all cases, they were higher than 100. For remaining components that no toxicological data are available for, it was found that substances would be applied in the product in recommended concentration and conditions of use. Moreover, the assessment considered:

- purity of substances

- purity and stability of a packaging material

- interactions of product components and interactions with a packaging material

-the way of product marking

NOTES:

This assessment will have to be updated in the event of:

-modification of a prescription by the producer

-the change of a component specification

- the change of current state of the art

- the change of legal regulations

-the growth of the cases of adverse effects

4. Assessor's credentials and approval of part

Assessor's CV available on request.