Cosmetic Product Safety Report

Pro Base

Responsible person:

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This document has been prepared in compliance with:

- Regulation (EC) No 1223/2009 regarding cosmetic products
- COMMISSION IMPLEMENTING DECISION of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products.
- SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation - 12th revision – SCCS/1647/22

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LIST OF ABBREVIATIONS

NOEL – (Non Observed Effect Level). Greatest concentration or amount of a substance, found by experiment or observation, that causes no alteration of morphology, functional capacity, growth, development, or lifespan of the target organism distinguishable from those observed in normal (control) organisms of the same species and strain under the same defined conditions of exposure.

NOAEL – (Non Observed Adverse Effect Level). Greatest concentration or amount of a substance, found by experiment or observation, that causes no detectable adverse alteration of morphology, functional capacity, growth, development, or lifespan of the target organism under defined conditions of exposure.

LOEL – (Lowest Observed Adverse Effect Level). Lowest concentration or amount of a substance, found by experiment or observation, there is still observed alteration of morphology, functional capacity, growth, development, or lifespan of the target organism distinguishable from those observed in normal (control) organisms of the same species and strain under the same defined conditions of exposure.

LOAEL – (Lowest Observed Adverse Effect Level). Lowest concentration or amount of a substance, found by experiment or observation, that is still observed detectable adverse alteration of morphology, functional capacity, growth, development, or lifespan of the target organism under defined conditions of exposure.

DNEL - (Derived No Effect Level). Is the level of exposure to a substance above which humans should not be exposed

LD50 - The amount of a chemical that is lethal to one-half (50%) of the experimental animals exposed to it.

SED – systemic exposure dose

POD – point of departure – is defined as the point on a toxicological dose-response curve established from experimental data or observational data generally corresponding to an estimated low effect level or no effect level.

Fret – dermal retention factor specific for a given type of cosmetic product

MOS – margin of safety

PART A – COSMETIC PRODUCT SAFETY INFORMATION

1. Qualitative and quantitative composition of the cosmetic product

1.1. Qualitative composition

Ingredients: Acrylates Copolymer, Hydroxypropyl Methacrylate, Isobornyl Acrylate, Dimethylacrylamide, Bis-(Methacryloyloxyethyl) Phosphate, Ethyl Trimethylbenzoyl Phenylphosphinate, Hydroxycyclohexyl Phenyl Ketone, Phosphoric Acid, Citronellol, Dimethicone

1.2. The quantitative composition of the cosmetic product, including chemical identity of the substances (INCI, CAS, EINECS/ELINCS, where possible) and their intended function.

Trade name	INCI	Function	Concentration [%]	CAS NO	Annex/ Ref
Acrylates Copolymer	Acrylates Copolymer	Film forming	45-60	25035-69-2	-
Hydroxypropyl Methacrylate	Hydroxypropyl Methacrylate	Film forming	5-15	27813-02-1	-
Isobornyl Acrylate	Isobornyl Acrylate	Nail Sculpting	1-10	5888-33-5	-
N, N-dimethylacrylamide	Dimethylacrylamide	Stabilizer	1-10	2680-03-7	-
Phosphoric Acid	Phosphoric Acid	Buffering	0-1	7664-38-2	-
Bis(methacryloyloxyethyl) hydrogen phosphate	Bis-(Methacryloyloxyethyl) Phosphate	Nail Sculpting	2-6	32435-46-4	-
Citronellol	Citronellol	Perfuming	0-1	106-22-9	III/86
Dimethicone	Dimethicone	Conditioning	0-1	9006-65-9	-
Hydroxycyclohexyl Phenyl Ketone	Hydroxycyclohexyl Phenyl Ketone	Binding	1-3	947-19-3	-
Ethyl Trimethylbenzoyl Phenylphosphinate	Ethyl Trimethylbenzoyl Phenylphosphinate	UV Absorber	1-5	84434-11-7	-

1.3. Description of the name and code number of the composition and the identity of the supplier.

This formulation does not contain a synthetic fragrance and therefore a fragrance safety evaluation as per IFRA code of practice is not applicable to this product.

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

2.1. Product specification

No.	Properties	Requirements
1	Appearance	liquid
2	Color	characteristic of the raw materials used
3	Smell	characteristic of the raw materials used
4	Mechanical impurities	doesn't contain

2.2. Safety Data Sheets and Technical Data Sheets for raw materials

Safety Data Sheets and Technical Data Sheets were provided by the responsible person/entity that developed the recipe.

2.3. The stability of the cosmetics product under reasonably foreseeable storage conditions

The results of the stability and compatibility tests of the mass with the packaging: Stability and packaging compatibility tests have been carried out (plastic tube 30g, 60g). Based on the stability and compatibility tests of the mass with the packaging, it can be concluded that the final product is stable in storage conditions during the declared shelf life.

3. Microbiological quality

3.1. The microbiological specifications of the raw materials

Information on the microbiological purity of raw materials is included in the Quality Certificates provided by the raw material manufacturer. Requirements for microbiological purity depend on the type of raw material and its susceptibility to microbial contamination. Many raw materials, such as preservatives and oil components, are not susceptible to microbial contamination. The raw materials used do not raise any objections from the point of view of microbiological purity. In the case of raw materials of low microbiological risk, the assessment of microbiological purity was not carried out.

Based on PN-EN ISO 29621:2017-04 Cosmetics-Microbiology-Guidelines for the risk assessment and identification of microbiologically low-risk products challenge testing is not performed. To comply with "Guidelines on Microbiological Quality of the Finished Cosmetic Product" under SCCS's Notes of Guidance, the following limits apply to this product:

Test	Method	Unit	Criteria
Total Aerobic Mesophilic Microorganisms (Bacteria + yeast and mould)	PN-EN ISO 21149:2017-07 PN-EN ISO 16212:2017-08	tk/1g	≤2x 103
Pseudomonas aeruginosa	PN-EN ISO 22717:2016-01	tk/1g	Not detectable in 1g
Staphylococcus aureus	PN-EN ISO 22718:2016-01	tk/1g	Not detectable in 1g
Escherichia coli	PN-EN ISO 21150:2016-01	tk/1g	Not detectable in 1g
Candida albicans	PN-EN ISO 18416:20016-01	tk/1g	Not detectable in 1g

The shelf life has been set at > 30 months from the date of production. The shelf life was established on the basis of microbiological tests, preservation test and compatibility tests.

4. Impurities, traces, information about the packaging material

4.1. The purity of the raw materials

The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence poses no risk to human health. A detailed document sustaining this unavoidability must be provided to satisfy this requirement.

4.2. The relevant characteristics of packaging material, in particular purity and stability

It is considered there is no signs of reactions between the product and packaging materials at least until the end of the minimum durability of the product. Cosmetic product is packaged in packages intended for this use. According to the presentation and the formula of the product, package is considered unlikely to affect its purity and stability.

5. Normal and reasonably foreseeable use

Product: nail cosmetics for professional use only (base)

Application: nail plate

6. Exposure to the cosmetic product

DERMAL EXPOSURE The site of application: The surface area of application: The amount of product applied: Duration and frequency of use:	Product is applied on the nail plate
Body weight [kg] Retention factor R: The targeted populations: Type of exposure: The normal and reasonably foreseeable exposure route:	4,0 cm3 according to SCCS and RiVM
	0,6 g/day (Ficheux et al., 2014)
	1,17 per week (Ficheux et al., 2014)
	60
Predictable wrong use:	1,0
	Adult Female & Adult Males
	Leave-on
	Nail plate
	Product occasionally might have contact with cuticles but skin contact should be avoided. Contact with eyes should be minimized. If product accidentally enters the mucosa membrane around the eyes, wash out with plenty of water and seek medical assistance if the condition persists. Stop using this product if you develop redness or itching.
INHALATION EXPOSURE	
Time of exposure	5 min
Average product quantity	0,5 g
Room Volume	1 m3
Area of exposure	25 cm2
Speed of inhalation	23,1/1min

There are possibility of inhalation exposure to this product due to content of volatile substances, however time of exposure is very short (around 5 min) and the risk low. Moreover nails surface and fingers area are exposure for dermal exposure to the product. It is also secondary way of exposure during product application. Eyes, mucosal and consumption. Risk is assessed as very low. In case of contact with eyes it is necessary to rinse with big amount of water and doctor contact.

7. Exposure to the substances

There are no nanoparticles to be used in this formulation. Systematic Exposure Dose (SED) is derived for each substance, taking into account 50%
bioavailability as default value for oral and dermal absorption, and 100% bioavailability for inhalation, unless otherwise specified. Margin of Safety (MOS) is calculated by dividing Point of Departure POD (~NOAEL) by the SED.

Estimated daily exposure:

A=1,67 mg/kg/day

SED (Systemic Exposure Dosage) was calculated:

SED = A (mg/kg/d) x C(%)/100 x DAp (%)/100

with:
A (mg/kg mc/d) – Estimated daily exposure to a cosmetic,
C (%) – concentration of the substance under study in the finished cosmetic product,
DA (%) – Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real life conditions

The Margin of Safety (MOS) was calculated:

MOS= POD/SED

INCI	Concentration [%]	DA [%]	SED	POD [mg/kg/d]	MOS
Acrylates Copolymer	60	50	0,501	333	665
Hydroxypropyl Methacrylate	15	50	0,12525	50	399
Isobornyl Acrylate	10	50	0,0835	50	599
Dimethylacrylamide	10	50	0,0835	15	180
Phosphoric Acid	1	50	0,00835	52,5	6287
Bis-(Methacryloyloxyethyl) Phosphate	6	50	0,0501	Does not pose a systemic risk	
Citronellol	1	4,7	0,0007849	1000	1274048
Dimethicone	1	50	0,00835	166	19880
Hydroxycyclohexyl Phenyl Ketone	3	50	0,02505	150	5988
Ethyl Trimethylbenzoyl Phenylphosphinate	5	50	0,04175	13	311

8. Toxicological profile of the substances

The assessment is performed according to the European Cosmetics Regulation (EC) No 1223/2009.

Physicochemical properties and toxicological data of the substances used in the cosmetic product were developed on the basis of data obtained as a result of the review of toxicological databases: National Library of Medicine, NIH, EDETOX, ECHA, RTECS, HERA and the review of opinions and scientific papers on public and independent, private and private cosmetic ingredients organizations such as: CIR (Cosmetic Ingredient Review), SCCS (The Scentific Committee on Consumer Safety), COSING, as well as data contained in points 9 and 11 of the Material Safety Data Sheet of the raw materials used in the product and other publications made available by manufacturers of cosmetic raw materials used in the product included in the product the composition of the evaluated cosmetic product (see Annex 1).

9. Undesirable effects and serious undesirable effects

Pro Base is a product placed on the market. In accordance with the requirements set out in Art. 23 of Regulation EC 1223/2009, the responsible person is obliged to document and report an adverse reaction caused by a cosmetic product. Information on the adverse reaction must be kept up to date and made available to the safety assessor for possible changes to the safety report.

10. Information on the cosmetic product

Test	Report	Conclusion
Stability test	Kohana Professional LTD, report no.: 04.08.2025	Positive results

PART B – COSMETIC PRODUCT SAFETY ASSESSMENT

1. Assessment conclusion

Pro Base is safe when used in accordance with the regulations, in accordance with the application procedure and in predictable situations does not pose a threat to health. The product poses no identifiable risk to human health when used in an intended and gender-compatible manner.

The safety assessment was made on the basis of the quantitative and qualitative composition declared by the manufacturer and in the list of data on ingredients and product.

2. Labelled warnings and instruction of use

It is not necessary to indicate other precautions to be followed during use, resulting from the substances listed in Annexes III-VI to Regulation (EC) No 1223/2009 and any other information on precautionary measures required for cosmetic products for professional use.

Composition: Ingredients: Acrylates Copolymer, Hydroxypropyl Methacrylate, Isobornyl Acrylate,
Dimethylacrylamide, Bis-(Methacryloyloxyethyl) Phosphate, Ethyl Trimethylbenzoyl Phenylphosphinate, Hydroxycyclohexyl Phenyl Ketone, Phosphoric Acid, Citronellol, Dimethicone

Recommended labelled warnings and instructions of 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.

The packaging should include markings in accordance with Regulation (EC) No. 1223/2009 of the European Parliament and of the Council, Art. 19., including:

- •name and address of the responsible person,
- •nominal content of the product,
- •expiration date,
- •special precautions,
- •markings allowing for product identification,
- •list of ingredients (Ingredients) and the function of the cosmetic.

3. Reasoning

The evaluation conclusion was drawn up on the basis of:

ü risk assessment of ingredients, which include:

a) hazard analysis - toxicological data for ingredients, including data on local and systemic toxicity, taking into account the reliability of these data,
b) analysis of systemic exposure to product components,
c) risk assessment - in justified cases, safety margins have been determined,

ü test results of the finished product.

In addition, the assessment was made on the basis of applicable law, taking into account international recommendations of authorities and associations and own professional experience, taking into account the compatibility of the raw materials used, their toxicological profile, structure, physico-chemical properties, testing of the finished cosmetic product and considering the level of exposure.

The raw materials used in the evaluated product are commonly used in the cosmetics industry.

The lack of complete data and scientific progress impose the obligation of constant analysis and review of literature information and possible verification of toxicological data. All ingredients are used as intended and in the correct amounts.

The analysis of the product composition showed that the substances were used in accordance with the restrictions on use (Annex III), the preservatives used are approved for use in cosmetic products and were used in permitted concentrations (Annex V).

The purity of the raw materials used in the product does not raise any objections. Contamination with prohibited substances or residues of prohibited substances listed in Annex II of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of November 30, 2009 may only be present in trace amounts, provided that their amount is unavoidable from a technological point of view.

The toxicological data of the ingredients was analyzed. On the basis of the collected data, endpoints relevant in terms of safety assessment were determined. The reasoning takes into account the exposure to the cosmetic product and to the individual ingredients of the preparation. For this purpose, 50% of the permeation of the substance has been taken into account in the calculation of the systemic exposure to the components. Quantitative data from adult use are included in the calculations, as the MoS (Margin of Safety) value, which is assumed to be > 100, also takes into account intra-species differences. For the components for which the NOAEL value was determined, a safety margin was calculated. For raw materials for which the calculation of the safety margin is impossible, to confirm their safety, we use scientific information on safe use, as well as opinions of public and independent private organizations, such as: CIR (Cosmetic Ingredient Review), ECHA (European Chemicals Agency), RTECS (The Registry of Toxic Effects of Chemical Substances database), SCCS (The Scentific Committee on Consumer Safety). Taking into account the available data on the product and the intended use, the potential risk
does not exist. However, the occurrence of adverse reactions in hypersensitivity to any component of the preparation cannot be ruled out.

NOTE:

- Any change in chemical composition, scope and manner of use or trade name of the product should be re-examined by an safety assessor.

- The opinion does not apply to people who are allergic to any ingredient in this product.
- This assessment relates only to the cosmetic products assessed; their composition, properties, information for customers and other materials essential for assessment shall agree with the documents submitted for this assessment. The evaluation of the functional properties of the product declared by the manufacturer is not part of this assessment.

4. Assessor's credentials and approval of Part B

Safety report prepared by the Safety Assessor:

Sylwia Dąbrowska