

Cosmetic Product Safety Report

CPSR No. 2026 03 0096/1

Product name: HAND CREAM PARADISE

Responsible person: Kohana LTD
Address: Suite 10182
77 Sir John Rogersons Quay Dublin 2

Date of report preparation: 06.03.2026

Version First

This document has been prepared in compliance with:

- Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (Official Journal of the European Union L 342 of 22.12.2009, p. 59), applicable since 11 July 2013, as amended;
- Commission Implementing Decision of 25 November 2013 on guidelines for Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products
- Act of 4 October 2018 on cosmetic products (Journal of Laws 2018, item 2227)
- SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, 12th revision, 15 May 2023, SCCS/1647/22

Table of contents

LIST OF ABBREVIATIONS	4
1. QUALITATIVE AND QUANTITATIVE COMPOSITION	5
1.1. Description of the name and code number of the composition and the identity of the supplier.	6
1.2. List of other restricted substances (excluding allergens) listed in Annexes III–VI	6
2. Physical/chemical characteristics and stability of the cosmetic product	6
2.1. Physicochemical properties of substances or mixtures	6
2.2. Physicochemical properties of the finished cosmetic product	7
2.3. The stability of the cosmetics product under reasonably foreseeable storage conditions	7
2.4. Product shelf life	7
3. Microbiological quality	7
3.1. The microbiological specifications of the raw materials	7
3.2. The microbiological specifications of the final product	8
4. Impurities, traces, information about the packaging material	9
4.1. The purity of the raw materials	9
4.2. The relevant characteristics of packaging material, in particular purity and stability	9
5. Normal and reasonably foreseeable use	10
6. Exposure to the cosmetic product	10
7. Exposure to the substances	10
8. Toxicological profile of the substances	11
9. Undesirable effects and serious undesirable effects	12
10. Information on the cosmetic product	12
10.1. Cosmetic product label design	12
PART B – COSMETIC PRODUCT SAFETY ASSESSMENT	14
1. Assessment conclusion	14
2. Labelled warnings and instruction of use	14
3. Reasoning	15
4. Assessor’s credentials and approval of Part B	16

This Cosmetic Product Safety Report is protected under the Act of 4 February 1994 on Copyright and Related Rights. Reproduction, modification, or alteration of this document or any part thereof without the author's consent is prohibited.

The original document is provided exclusively in electronic form and bears a qualified electronic signature. Therefore, any printouts, unless certified as true copies of the original, are considered copies.

This document has been prepared in accordance with the legal status applicable on the date of its issue.

In accordance with Article 10(1)(c) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, the Responsible Person is obliged to update this document with any additional information obtained after the product has been placed on the market, in particular information concerning undesirable effects. The manufacturer is responsible for providing and confirming the qualitative and quantitative composition of the cosmetic product, prepared in accordance with the submitted documentation.

The INCI nomenclature used should comply with Commission Implementing Decision (EU) 2022/677 of 31 March 2022 laying down rules for the application of Regulation (EC) No 1223/2009 as regards the glossary of common ingredient names for use in the labelling of cosmetic products.

The contents of this Safety Report, supplemented by the Safety Assessor preparing the safety assessment of the cosmetic product described in formula Part A, item 1 “Qualitative and quantitative composition”, have been prepared based on information provided by the Responsible Person.

All toxicological calculation results refer exclusively to the formula composition specified in Part A of the document.

This assessment does not cover individuals showing hypersensitivity or allergy to any of the ingredients of the described product.

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

INCI	Function	Concentration [%]	CAS NO	Annex/Ref
Aqua	Base, solvent	70,0–85,0	7732-18-5	-
Cetearyl Alcohol	Emollient / Emulsifier / Viscosity controlling	5,0–10,0	67762-27-0	-
Cetareth-20	Consistency component	1,0–5,0	68439-49-6	-
Glycerin	Humectant / Moisturizer	1,0–5,0	56-81-5	-
Urea	Humectant /Moisturizer	1,0–5,0	57-13-6	-
Izopropyl Myristate	Emollient / Conditioning component	1,0–5,0	110-27-0	-
Parfum	Fragrance	0,1–5,0	N/E	-
Prunus Amygdalus Dulcis (Sweet Almond) Oil	Skin conditioning	1,0 – 5,0	8007-69-0	-
Cyclopentasiloxane	Emollient / Consistency component	1,0 – 3,0	541-02-6	-
Sorbitan Oleate	Humectant / Moisturizer	1,0 – 3,0	1338-43-8	-
Phenoxyethanol	Preservative	0,1 – 1,0	122-99-6	V/29
Ethylhexylglycerin	Preservative		70445-33-9	-
Tocopheryl Acetate	Preservative / Antioxidant	0,1 – 1,0	7695-91-2 / 58-95-7	-
DMDM Hydantoin	Preservative	0,1 – 0,5	6440-58-0	V/33
Tetrasodium EDTA	Sequestrant	0,01 – 0,1	64-02-8	-
Citric Acid	Preservative /Antioxidant	0,01 – 0,1	77-92-9	-

Parfum Delicious K813/M Supplier: FSZ “Pollena – Aroma” Sp. z o.o.				
Substances which cosmetic products must not contain except subject to the restrictions laid down	CAS Number	Annex/Ref	Percent concentration % in Parfum	Percent concentration % in Product
Hexyl cinnamal	101-86-0	III/87	5,0000	0,25
Alpha-isomethyl ionone	127-51-5	III/90	4,5997	0,07
Citronellol	106-22-9	III/86	3,2363	0,16
Linalool	78-70-6	III/84	2,0668	0,10

Geraniol	106-24-1	III/78	0,7159	0,04
Eugenol	97-53-0	III/71	0,5022	0,03

The qualitative and quantitative composition has been prepared based on data provided by the Responsible Person.

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

Trade name:	Parfum Delicious K813/M
Code:	K813/M
Supplier:	FSZ "Pollena – Aroma" Sp. z o.o.
IFRA Category:	5C
IFRA compliance	Compliant with IFRA

1.2. List of other restricted substances (excluding allergens) listed in Annexes III–VI

Category	INCI name	CAS No.	Concentration in the finished product [%]
Nanomaterials	-	-	-
Preservative (annex V)	Phenoxyethanol	122-99-6	1,0
	DMDM Hydantoin	6440-58-0	0,5
UV Filters	-	-	-
Other	-	-	-

Substances used in permitted concentrations.

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

2.1. Physicochemical properties of substances or mixtures

Physicochemical properties of substances or mixtures	
The physicochemical properties of the raw materials comply with the information provided in the respective specifications and Safety Data Sheets (SDS).	The physicochemical properties of the raw materials used are satisfactory. No formulation incompatibilities were identified.

2.2. Physicochemical properties of the finished cosmetic product

Properties	Requirements
Appearance	Homogeneous emulsion
Color	Cream
Smell	Pleasant, characteristic for the fragrance composition
pH 20°C	6,24
Mechanical impurities	No mechanical impurities

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

Cosmetic product stability – stability testing	
Physicochemical stability test	The test was conducted by storing product samples at temperatures of -5°C, 4°C, 25°C, 37°C, 45°C.
Report no.	Kohana Professional LTD, date: 25.02.2026
Tested parameters	Appearance, colour, odour, viscosity
Stability test results	The physicochemical stability test confirmed that the product maintains its stability under varying temperature conditions.

2.4. Product shelf life

The stability of the cosmetic product has been demonstrated under reasonably foreseeable storage conditions.

Estimated minimum durability	> 30 months
PAO (Period After Opening)	12 months
Recommended storage conditions:	Standard, reasonably foreseeable storage conditions

The stability of the cosmetic product was determined based on the analysis of the finished product composition and the physicochemical properties of the raw materials used, the results of stability tests performed using a method appropriate to the type and intended use of the product, the results of packaging stability tests, the results of compatibility tests between the product mass and the packaging material, as well as other available data, in particular those concerning the method of use and the expected period of use of the product by the consumer.

3. Microbiological quality

3.1. The microbiological specifications of the raw materials

Information regarding the microbiological purity of the raw materials used is included in the Certificates of Analysis provided by the raw material manufacturers. Microbiological purity requirements depend on the type of raw material and its susceptibility to microbiological contamination. Many raw materials, such as preservatives or oil-based ingredients, are not

susceptible to microbiological contamination. In the case of raw materials with low microbiological risk, microbiological purity testing was not performed.

3.2. The microbiological specifications of the final product

Test	Method	Unit	Results
Total Aerobic Mesophilic Microorganisms	PN-EN ISO 21149:2017-07	cfu/1g	$\leq 1 \times 10^1$
Total Yeast and mould	PN-EN ISO 16212:2017-08	cfu/1g	$\leq 1 \times 10^1$
<i>Pseudomonas aeruginosa</i>	PN-EN ISO 22717:2016-01	cfu/1g	Absent in 1g
<i>Staphylococcus aureus</i>	PN-EN ISO 22718:2016-01	cfu/1g	Absent in 1g
<i>Escherichia coli</i>	PN-EN ISO 21150:2016-01	cfu/1g	Absent in 1g
<i>Candida albicans</i>	PN-EN ISO 18416:20016-01	cfu/1g	Absent in 1g

Criteria in accordance with PN-ISO 17516:2014	
Microbiological requirements	<p>CATEGORY I: Products for children under 3 years of age, products intended for use in the eye area, and products intended for use on mucous membranes: Total aerobic mesophilic microorganisms $\leq 10^2$ cfu/g Yeasts and moulds $\leq 10^2$ cfu/g Pathogens – absent in 1 g</p> <p>CATEGORY II: Other products: Total aerobic mesophilic microorganisms $\leq 10^3$ cfu/g Yeasts and moulds $\leq 10^3$ cfu/g Pathogens – absent in 1 g</p>

Result of microbiological test:

Microbiological quality of the finished cosmetic product	
Product category:	II
Report No.:	safety report, date: 15.11.2023
Test results:	Microbiological testing did not demonstrate the presence of <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Escherichia coli</i> , or <i>Candida albicans</i> in the finished product. The total count of aerobic mesophilic microorganisms (total aerobic mesophilic bacteria, yeasts, and moulds) was $< 1 \times 10^3$ cfu/g.

Results of preservation challenge test:

The efficacy of the preservation system has been confirmed (the preservative efficacy test was performed in accordance with PN-EN ISO 11930:2019). The preservative efficacy test results demonstrate that the preservation system of the tested product meets the requirements of Criterion A. The results are presented in the test report: safety report, date: 15.11.2023.

The manufacturer is responsible for ensuring an appropriate level of microbiological purity of each batch of raw materials and the finished cosmetic product.

4. Impurities, traces, information about the packaging material

4.1. The purity of the raw materials

Possible impurities 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 30 November 2009 on cosmetic products are permitted only in trace amounts, provided that their presence is technically unavoidable under good manufacturing practice.

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

All packaging components (type Bottle: PP

of material)	Cap: PP
Declarations of compliance	REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC Substances classified as CMR or skin irritants, category 1A, 1B or 2 in accordance with Annex VI to REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labeling and packaging of substances and mixtures Substances prohibited or allowed for use with restrictions included in Annex ii or iii to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of November 30, 2009 on cosmetic products Presence of heavy metals SVHC substances (Substances of Very High Concern) in accordance with the REACH Regulation: 1907/2006 (Article 33) Potential migration of substances contained in the packaging to the cosmetic mass.
Possible interactions between the product and the packaging	Compatibility testing confirmed no interaction between the product and the packaging material.
Compatibility of the packaging with the product	Compatible according to the performed tests.

The listed materials are suitable for use as primary packaging of the cosmetic product. The selected packaging does not negatively affect the product stability.

5. Normal and reasonably foreseeable use

Product: hand cream Application: apply to the skin of the hands; leave-on product

Exposure assumptions are based on normal and reasonably foreseeable use of the product. The product should be used in accordance with the method of use indicated on the label. Warnings and other explanations on labels should be consistent with identified normal and reasonably foreseeable uses.

6. Exposure to the cosmetic product

The site of application: The surface area of

application: The amount of product applied:	Skin of the hand
Duration and frequency of use: Body weight	860 cm ³ (total body area, SCCS and RiVM)
[kg] Retention factor R: The targeted	2,16 g/d (SCCS)
populations: Type of exposure:	2 applications per day
	60
	1,0
	Adults
	Leave-on
The normal and reasonably foreseeable exposure route:	Skin of the hand
Secondary exposure route:	Eyes - not intended. Mucous membranes - not intended. Ingestion - not intended

7. Exposure to the substances

In order to assess the exposure to the individual components of the preparation, the concentration of the substance and the data on epidermal absorption should be taken into account in the calculations. The MoS (Margin Of Safety) value was calculated for substances for which NOAEL (~POD) was determined, based on exposure to a cosmetic product, in accordance with the SCCS/1628/21 guidelines and using data from substance manufacturers, opinions of scientific committees of SCCS, EFSA, toxicology databases. To define a substance as safe, the safety margin must be at least 100.

Estimated daily exposure:

$$A=32,70\text{mg/kg/day}$$

SED (Systemic Exposure Dosage) was calculated:

$$SED = A \text{ (mg/kg/d)} \times C(\%)/100 \times DAp (\%)/100$$

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:

$$\text{MOS} = \text{POD} / \text{SED}$$

INCI	Max. Concentration [%]	DA [%]	SED	POD [mg/kg/d]	MOS
Aqua	Ad 100				
Cetearyl Alcohol	10	1	0,03270	375	11468
Ceteareth-20	5	0,02	0,00033	500	1529052
Glycerin	5	7,34	0,12001	800	6666
Urea	5	0,1	0,00164	1125	688073
Izopropyl Myristate	5	50	0,81750		Does not pose a systemic risk
Parfum	5				
Prunus Amygdalus					Does not pose a systemic risk
Dulcis (Sweet Almond) Oil	3	50	0,81750		Does not pose a systemic risk
Cyclopentasiloxane	3				
Sorbitan Oleate	1	0,17	0,00167	50	29981
Phenoxyethanol	0,1	50	0,49050	500	1019
Ethylhexylglycerin	1	85	0,27795	184,5	664
Tocopheryl Acetate	0,5	50	0,01635	8,3	508
DMDM Hydantoin	0,1	12,2	0,03989	133	3334
Tetrasodium EDTA	0,1	50	0,08175	100	1223
Citric Acid	0,25	50	0,01635	250	15291
Hexyl cinnamal	0,07	50	0,01635	700	42813
Alpha-isomethyl ionone	0,16	50	0,0409	75	1835
Citronellol	0,1	50	0,0114	15	1311
Linalool	0,04	4,7	0,0025	1000	406663
Geraniol	0,03	14,7	0,0048	125	26004
Eugenol		7	0,0010	150	157094
		50	0,0049	150	30581

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 Scientific 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.

9. Undesirable effects and serious undesirable effects

No undesirable effects or serious undesirable effects are known for the product. In accordance with the requirements set out in Article 23 of Regulation (EC) No 1223/2009, the Responsible Person is obliged to document and report any undesirable effects caused by the cosmetic product. Information on undesirable effects must be updated and made available to the Safety Assessor in order to amend the safety report if necessary.

Confirmed reports of undesirable effects: None reported

Confirmed reports of serious undesirable effects: None reported

10. Information on the cosmetic product

Test	Report	Conclusion
Stability of the cosmetic product and compatibility with the packaging	Kohana Professional LTD, date: 25.02.2026 Silcare sp. z o.o. sp. k., ul.	Positive result
Microbiological test	Kostrzyńska 1, 66-400 Gorzów Wlkp., safety report, date: 15.11.2023 Silcare sp. z o.o. sp. k., ul.	The result complies with the standard.
Challenge test	Kostrzyńska 1, 66-400 Gorzów Wlkp., safety report, date: 15.11.2023 Silcare sp. z o.o. sp. k., ul.	The effectiveness of the preservation system was demonstrated. The product meets internal standards
Dermatological test	Kostrzyńska 1, 66-400 Gorzów Wlkp., safety report, date: 15.11.2023	No positive reactions were observed

The requirements concerning claims for cosmetic products are defined in Article 20 of Regulation (EC) No 1223/2009 on cosmetic products and Commission Regulation (EU) No 655/2013 establishing common criteria for the justification of claims used in relation to cosmetic products. Furthermore, horizontal legislation also applies to cosmetic claims, including provisions relating to competition law, unfair commercial practices, advertising, consumer sales, and language requirements.

10.1. Cosmetic product label design

Labelling	Name and address of the Responsible Person (full name or registered company name and address)
	Nominal content at the time of packaging, expressed in units of mass or volume
	The date until which the cosmetic product, stored under appropriate conditions, will continue to fulfil its initial function (the date or details of its location on the packaging shall be preceded by the hourglass symbol or the phrase “Best before end”; where applicable, the Period After Opening (PAO) symbol shall be indicated)

	Particular precautions for use, including at least those listed in Annexes III–VI, and any other precautionary information required for cosmetic products intended for professional use Batch number or reference allowing identification of the cosmetic product Function of the cosmetic product, unless it is clear from its presentation List of ingredients preceded by the word “Ingredients” Ingredients: Aqua, Cetearyl Alcohol, Cetareth-20,
Composition	Glycerin, Urea, Isopropyl Myristate, Parfum, Prunus Amygdalus Dulcis (Sweet Almond) Phenoxyethanol, Dimethylsiloxane, Sorbitan Oleate, Ethylhexylglycerin, Tocopheryl Acetate, DMDM Hydantoin, Tetrasodium EDTA, Citric Acid, Hexyl cinnamal, Alpha-isomethyl ionone, Citronellol, Linalool, Geraniol, Eugenol
Precautions	Precautions resulting from the presence of substances listed in Annexes III–VI: Not applicable. Taking into account the provisions of Article 19 of Regulation (EC) No 1223/2009, no additional warnings are required on the product label due to the presence of specific ingredients.

PART B – COSMETIC PRODUCT SAFETY ASSESSMENT

1. Assessment conclusion

HAND CREAM PARADISE – The cosmetic product is safe and does not pose a risk to human health under normal and reasonably foreseeable conditions of use, taking into account the instructions for use and the current state of knowledge.

The ingredients used in the product and their concentrations are permitted for use in cosmetic products in accordance with Regulation (EC) No 1223/2009 on cosmetic products (Official Journal of the European Union L 342 of 22 December 2009, pp. 59–209). Pursuant to Article 3 of Regulation (EC) No 1223/2009, it is declared that the product does not pose a foreseeable risk to human health when used under the intended conditions of use, in accordance with the instructions for use and warnings, and taking into account the current state of knowledge.

The safety assessment was performed based on the qualitative and quantitative composition declared by the manufacturer and on the data provided for the ingredients and the finished product.

2. Labelled warnings and instruction of use

Taking into account the provisions of Regulation (EC) No 1223/2009 on cosmetic products (Articles 19 and 20) and Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products, the cosmetic product must be labelled in a visible, legible, and indelible manner, ensuring that the labelling cannot be easily removed.

In accordance with Commission Regulation (EU) No 655/2013, all marketing claims must be supported by adequate and verifiable evidence, including appropriate application or instrumental studies.

The following information must appear on the cosmetic product packaging:

- Name or registered business name and address of the Responsible Person. In the case of imported cosmetic products, the country of origin must also be indicated;
- Nominal content at the time of packaging, expressed in units of mass or volume;
- The date until which the cosmetic product, stored under appropriate conditions, will continue to fulfil its initial function (the date or details of its location shall be preceded by the hourglass symbol or the phrase “Best before end”; where applicable, the Period After Opening (PAO) symbol shall be indicated);
- Particular precautions for use, including at least those listed in Annexes III–VI, and any other precautionary information required for cosmetic products intended for professional use;
- Batch number or reference allowing identification of the cosmetic product;

- Function of the cosmetic product, unless it is clear from its presentation;
- List of ingredients preceded by the word “Ingredients”;
- Where applicable, an indication that the product is intended for professional use.

3. Reasoning

The evaluation conclusion was drawn up on the basis of:

- 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,
- test results of the finished product.

The safety assessment of the cosmetic product took into account the opinions and evaluations of the SCCS, EFSA, FDA, CIR reports and EPA, as well as Safety Data Sheets and technical specifications of raw materials, and information from ECHA, PubMed databases, and scientific publications. Furthermore, the assessment was carried out in accordance with applicable legislation, taking into account international recommendations of authorities and professional bodies, as well as professional experience, considering the compliance of the raw materials used, their toxicological profile, structure, physicochemical properties, results of studies performed on the finished cosmetic product, and the level of exposure.

According to the manufacturer’s declaration, the cosmetic product is manufactured in compliance with Good Manufacturing Practice (GMP). The finished product and its ingredients have not been tested on animals in accordance with Article 18 of Regulation (EC) No 1223/2009.

The raw materials used in the assessed product are commonly used in the cosmetic industry. Due to scientific progress and possible data gaps, continuous review of scientific literature and toxicological data is required.

The analysis of the product composition confirmed that the substances were used in accordance with the restrictions set out in Annexes III–VI of Regulation (EC) No 1223/2009. The preservatives used are permitted in cosmetic products and were applied within the allowed concentrations (Annex V).

The purity of the raw materials used does not raise any concerns. Impurities with prohibited substances listed in Annex II may be present only in trace amounts, provided that they are technically unavoidable.

The safety assessment of substances and mixtures was performed based on available toxicological and physicochemical data, including molecular weight, log P o/w, and their long history of safe use in cosmetic and food products.

The risk of interaction between ingredients was assessed based on physicochemical, toxicological, and literature data, as well as dermatological testing of the finished product. No interactions or negative impact on human health were identified.

The risk assessment was performed based on exposure to the product and its ingredients, taking into account dermal exposure.

Margins of Safety (MoS) were calculated where systemic toxicity data (PODsys) were available. NOAEL values were derived from repeated-dose toxicity studies, including chronic, carcinogenicity, and reproductive toxicity studies. Where NOAEL was not available, alternative reference values such as NOEL, LOAEL, or LOEL were used.

In all cases, the Margin of Safety exceeded 100, confirming the safe use of the substances. Where MoS could not be calculated, safety was confirmed based on scientific data and opinions of recognized authorities including CIR, SCCS, ECHA, RTECS, EFSA, and FDA.

According to available data, the packaging materials are suitable and safe for cosmetic use. No migration or instability affecting product safety is expected.

Based on the overall risk assessment, the cosmetic product is considered safe for human health under normal and reasonably foreseeable conditions of use.

The safety assessment was prepared based on the composition declared by the manufacturer and the data provided for the raw materials and the finished product. The manufacturer is responsible for confirming the product composition.

Adverse reactions in hypersensitive individuals cannot be excluded. This assessment does not cover individuals allergic to specific ingredients.

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