Cosmetic Product Safety Report

CPSR No. 2026 04 00157/1

Product name:	Cleaner Steady 2
Responsible person:	Kohana LTD Suite 10182, 77 Sir John Rogerson's Quay, Dublin 2, Ireland
Date of report preparation:	28.03.2026
Version	First

This document hasbeenprepared in compliance with:

- Regulation(EC)No1223/2009 of the European Parliament and of the Council of 30 November2009oncosmetic products (Official Journal of the European Union L 342 of 22.12.2009,p.59),applicable since 11 July 2013, as amended;
- CommissionImplementing Decision of 25 November 2013 on guidelines for Annex I to Regulation(EC)No1223/2009 of the European Parliament and of the Council on cosmetic products
- Act of 4 October2018on cosmetic products (Journal of Laws 2018, item 2227)
- SCCS Notes ofGuidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, 12threvision, 15 May 2023, SCCS/1647/22

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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
Isopropyl Alcohol	Solvent	80-100	67-63-0	-
Aqua	Solvent	0-20	7732-18-5	-

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.

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.

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

Category	INCI name	CAS No.	Max. Concentration in the finished product [%]
Nanomaterials	-	-	-
Preservative (annex V)	-	-	-
UV Filters	-	-	-
Other - colorant	-	-	-

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 ofthe 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	liquid
Color	colorless
Smell	Light specific alcohol like
pH 20℃	Not applicable
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: 14.02.2024
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
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

Criteria in accordance with PN-ISO 17516:2014	
Microbiological requirements	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 ≤ 10^2 cfu/g Yeasts and moulds ≤ 10^2 cfu/g Pathogens – absent in 1 g CATEGORY II: Other products: Total aerobic mesophilic microorganisms ≤ 10^3 cfu/g Yeasts and moulds ≤ 10^3 cfu/g Pathogens – absent in 1 g

Result of microbiological test:

Microbiological quality of the finished cosmetic product	
Product category:	II
Report No.:	Not applicable

Results of preservation challenge test:

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. 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.

Based on the raw material documentation provided by the manufacturer, the presence of the following impurities in the raw materials listed in the table below has been identified.

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

All packaging components (type Bottle: 150ml, 500ml

of material)	Bottle Material: HD-PE Cup material: 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. KohanaProfessional LTD, date:14.02.2024
Test reportNo.	

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: nail cleaner

Application: Using a lint-free cotton swab or applicator (depending on the volume of the product), spread the cleaner evenly over the entire nail plate

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

DERMAL EXPOSURE The site of application: The surface area of application: The amount of product applied: Duration and frequency of use: Body weight [kg] Retention factor R: The targeted populations: Type of exposure: The normal and reasonably foreseeable exposure route:	Product is applied on the nail plate 4,0 cm^3 according to SCCS and RiVM 5 g/day (Ficheux et al., 2014) 1,17 per week (Ficheux et al., 2014) 60 0,1 Adult Female & Adult Males Leave-on Nail plate
Predictable wrong use:	~~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 m^3
Area of exposure	25 cm^2
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=1,36 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	Max. Concentration [%]	DA [%]	SED	POD [mg/kg/d]	MOS
Isopropyl Alcohol	100	50	0,68000	120	176
Aqua	20	Does notpose a systemicrisk			

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.

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: 14.02.2024	Positive result

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”
Composition	Ingredients: Isopropyl Alcohol, Aqua
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

Cleaner Steady 2 - 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:

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.

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 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