

PART B — COSMETIC PRODUCT SAFETY ASSESSMENT

1. Assessment Conclusion

Assessment conclusions have been reached by taking into account the information and documents provided by the Responsible Person (presented in Part A - Cosmetic Product Safety Information). As a result, based on references to the Cosmetics Directive EU 1223/2009/EC and the 12th Revision Notes of Guidance of the SCCS on the Testing and Safety Assessment of Cosmetic Ingredients, it was concluded that for the product **“CariSpray Kids Cavity Protection Oral Spray Strawberry”** is safe for human health and does not pose any health hazard when used under normal or reasonably foreseeable conditions of use.

Reviews of this assessment will be made as and when new information becomes available.

In order to ensure that the cosmetic product safety report is kept up to date as required by Article 10(1)(c) of Cosmetics Regulations EU 1223/2009/EC, the safety of the finished product should be reassessed regularly.

When changes in the legal requirements occur (e.g. restrictions of one of the substances included in the formulation), it should be checked, amongst others (e.g. labelling), whether the formulation still complies with the law, and the safety assessment should be reviewed and, if necessary, updated.

The safety assessment should also be reviewed and, if necessary, updated, where one or more of the following circumstances apply:

- (a) new scientific findings and toxicological data on the substances are available which could modify the result of the existing safety assessment;
- (b) changes occurring in the formulation or specifications of raw materials;
- (c) changes occurring in the conditions of use;
- (d) a rising trend in terms of the nature, severity and frequency of undesirable effects, both under reasonably foreseeable conditions of use and in the case of misuse

Structures and processes should be established to ensure that the information relevant for the update of the cosmetic product safety report is efficiently exchanged between the responsible person and the safety assessor, and that the safety assessor is in a position to intervene where an update is necessary. The safety assessment was issued personally and is not transferable.

2. Labelled Warnings and Instructions of Use

The final label artworks provided below have been reviewed and are held by the safety assessor.



The product label has been assessed and found to be compliant with with Cosmetics Regulation (EC) No 1223/2009 and applicable national requirements. Based on the composition of the cosmetic product, no specific precautionary measures are required under the restrictions listed in Annexes III to VI of Regulation (EC) No 1223/2009. The currently labelled warnings and instructions for use have been assessed and are considered adequate and appropriate, complying with the requirements of the Regulation and aligning with industry best practices.

3. Reasoning

In accordance with Cosmetics Regulation (EC) No 1223/2009, a Product Information File (PIF) must be prepared for each cosmetic product before it is placed on the market. The PIF must be updated as necessary and kept readily accessible, either in electronic or physical format, at the address of the Responsible Person indicated on the product label. It must be made available to competent authorities upon request for market surveillance purposes and retained for a period of ten years following the date the last batch of the product was placed on the market.

The Regulation also stipulates that cosmetic products made available to consumers must be safe for human health when used under normal or reasonably foreseeable conditions. To ensure this, each cosmetic product must undergo a safety assessment, the results of which form a core component of the Product Information File. This assessment serves to verify that the product, as formulated and intended for use, presents no risk to human health.

Quantitative and Qualitative Composition of the Cosmetic Product

All ingredients are controlled in accordance with Cosmetics Regulation (EC) No 1223/2009. The ingredients used in the formulation are present at safe and legally permitted concentrations. The composition of the product is fully compliant with the requirements set out in Regulation (EC) No 1223/2009.

Physical/Chemical Characteristics and Stability of the Cosmetic Product

The physical and chemical properties of all raw materials have been verified through supplier documentation (e.g., CoAs, technical and safety data sheets), which are included in the Product Information File (PIF). The finished product's characteristics, appearance, color, odor were reviewed via the Certificate of Analysis and found to align with its intended function as a oral spray. Accelerated stability testing for 3 months in final packaging confirmed that all parameters remained within acceptable limits, supporting the product's stability under normal storage conditions.

The Period After Opening (PAO) is established as 12 months, indicated on the label with the standard open jar symbol, in accordance with Article 19 of Regulation (EC) No 1223/2009. Overall, the product is physically and chemically stable and remains safe and effective throughout its shelf life and PAO under normal and reasonably foreseeable conditions of use.

Microbiological Quality

To ensure microbiological quality, all raw materials are carefully selected, stored, and managed in compliance with Good Manufacturing Practices (GMP). The manufacturer has demonstrated through the product's composition and finished product specifications that the formulation meets microbiological safety requirements. The product has undergone microbiological testing and preservative efficacy testing (challenge test), both of which have successfully met the acceptance criteria. Therefore, the CariSpray Kids Cavity Protection Oral Spray Strawberry is considered microbiologically safe and stable for its intended use.

Impurities, Traces, Information About the Packaging Material

Packaging material means the container (or primary packaging) that is in direct contact with the cosmetic formulation. The relevant characteristics of packaging materials in direct contact with the final product are important for the safety of the cosmetic product. Since the substances may migrate from the packaging to the formulation, the relevant characteristics of the packaging material are to be considered. The selected primary packaging is PET bottle with HDPE sprayer.

Depending on available information it must be considered that impurities resulting from the packaging and / or the raw materials, do not pose a risk to the health of the consumer nor can influence the suitability of the product for its intended use. Compatibility test provided by packaging supplier and declared by the manufacturer, showed that the no interaction between product and the packaging, no change or distribution was observed at the level of packaging and the packaging remained intact therefore packaging-product combination is adequate.

Normal and Reasonably Foreseeable Use

The product is an oral spray, marketed as *CariSpray Kids Cavity Protection Oral Spray Strawberry*. The product label, as provided in the packaging artwork, clearly communicates usage instructions and warnings: the product is not intended to be rinsed off, excess product may be expelled if needed, and it should not be swallowed, being for oral care use only. Children are instructed to use the product only under adult supervision.

The formulation is a leave-on oral spray designed for topical daily application to the teeth and oral mucosa. It is specifically targeted for children from birth through 12 years of age, including sensitive users such as those with sensory sensitivities. The intended benefits include cavity protection, maintaining strong teeth, and convenient oral care when brushing is not possible.

The application pattern is consistent with foreseeable cosmetic use: 2–3 sprays into the mouth after meals or before bed, without rinsing. Foreseeable use scenarios include bedtime when brushing was missed, after snacks, during school/daycare, or while traveling. The label provides clear directions and warnings, reducing the risk of misuse.

The exposure profile is appropriate for the pediatric target group, and no high-risk application areas or unsafe foreseeable misuse scenarios were identified. Therefore, the product may be considered safe for its intended cosmetic use in children (0–12 years), provided it is used under adult supervision and in accordance with the labeling

Toxicological Profile of the Substances

The raw materials used in the product are sourced from reliable suppliers and should be classified as cosmetic grade ingredients. The toxicological profiles of all ingredients used are described in the section “**8. Toxicological Profile of the Substances**”. It has been concluded that all raw materials are non-toxic at the concentrations used in this product under normal or unforeseeable conditions of use.

Exposure to the Cosmetic Product

Human exposure to cosmetic products can occur via dermal, oral, or inhalation routes; however, for this product, dermal exposure is the primary relevant route. To evaluate the potential risk of each ingredient, exposure was estimated based on their concentrations in the final formulation. (Exposure data can be found in Part A – Section 6: Exposure to the Cosmetic Product.)

Using information provided by the manufacturer, the Systemic Exposure Dose (SED) and Margin of Safety (MoS) for all ingredients were calculated with ToxTool®. The exposure levels and risk assessments for each substance are summarized in Table 5,6 and 7.

Undesirable Effects and Serious Undesirable Effects

Any adverse reactions and serious adverse reactions have not been reported.

Information on the Cosmetic Product

The dermatological study on CariSpray Kids Cavity Protection Oral Spray Strawberry supports the product's safety for its intended use. Patch testing on 20 healthy adults with sensitive skin demonstrated that the product is non-irritant and does not induce local skin reactions when used as recommended.

These results align with the overall toxicological assessment. Considering formulation review, toxicological profiles, exposure assessment, and microbiological data, the product meets human skin tolerance requirements and may be considered safe for its intended leave-on oral application in the target population, provided users are not allergic to any ingredient.

Other Information Complying Regulation No. 1223/2009 and ISO 22716 (Article 8)

Provided certificate confirms that the product is manufactured in compliance with the ISO 22716 guidelines for Good Manufacturing Practices (GMP) for cosmetic products.

Manufacturer declared that the raw materials used to manufacture the product are not from animal origin and no animal testing was conducted on any of the cosmetic products after September 11th, 2004 for the purpose of compliance with the European legislation on cosmetic products.

Manufacturer declared that they are not using any CMR substances of category 1A or 1B as ingredients / raw materials in any of the cosmetic products.

Manufacturer declared that they are not using any nanomaterials as ingredients/raw materials in any of the cosmetic products.

4. Assessor's Credentials and Approval of Part B

Safety Assessor Name-Surname:

Ilke Kildaci Usa, M.Sc.

Address

Buyuk Tur Yolu 19, Maltepe, 34841,
Istanbul, Turkiye

E-mail

ikildaci@gmail.com

**Diploma or other evidence of formal
qualifications**

Attached at the end of this report

Signature & Date

Disclaimer:

This safety report for human health has been prepared based on the information provided by the manufacturer at the time of issue. I, as the safety assessor, do not accept any responsibility for any changes or updates to the product that may occur after the report's issue date. It is the responsibility of the manufacturer to inform me of any modifications, formulation changes, or new safety data that may impact the findings of this report. This disclaimer applies to all aspects of the safety assessment and its conclusions.

REFERENCES

[REGULATION \(EC\) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products](#)

[The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation 12th Revision](#)

[Regulation \(EC\) No 1223/2009 - Annex I on the Cosmetic Product Safety Report](#)

[ISO 22716:2007 Cosmetics — Good Manufacturing Practices \(GMP\) — Guidelines on Good Manufacturing Practices](#)

[Recommandations Relatives a L'estimation De La Periode Apres Ouverture \(PAO\)](#)

[ISO 17516:2014 Cosmetics — Microbiology — Microbiological limits](#)

[ISO 29621:2017 Cosmetics — Microbiology — Guidelines for the risk assessment and identification of microbiologically low-risk products](#)

[Scientific Committee on Consumer Safety \(SCCS\)](#)

[Cosmetic Ingredients Review – CIR](#)

[European Chemicals Agency \(ECHA\)](#)

[The European Food Safety Authority \(EFSA\)](#)

[Pubchem](#)



DIPLOMAWAARDERING

Naam : mevrouw İlke Kıldacı Uşa
Naam op document : İlke Kıldacı
Geboortedatum : 21 september 1996
Land van opleiding : Turkije
Naam onderwijsinstelling : *Yıldız Teknik Üniversitesi (Yildiz Technical University)*
Studierichting : *Biyomühendislik (Bioengineering)*
Nominale studieduur : 2 jaar
Jaar van afstuderen : 2021
Behaalde graad/diploma : *Yüksek Lisans Derecesi (Master of Science)*

Waardering

Hierdoor heeft betrokkene een niveau bereikt dat in Nederlandse termen overeenkomt met dat van de graad van master in het wetenschappelijk onderwijs in de richting *biotechnology*.

Deze waardering is afgegeven te Den Haag door Nuffic op 25 oktober 2024.



BIJLAGE BIJ DE DIPLOMAWAARDERING

Naam : mevrouw İlke Kıldacı Uşa
Naam op document : İlke Kıldacı
Geboortedatum : 21 september 1996

Overige getuigschriften

Betrokkene behaalde voorafgaand in 2019 een *Lisans Diploması (Bachelor's Degree)* na een nominaal 4-jarige opleiding aan dezelfde instelling in de richting *Biyomühendislik (Bioengineering)*.

Opmerkingen

Betrokkene heeft officiële documentatie overgelegd waaruit blijkt dat zij de naam van haar partner heeft aangenomen.

Afgegeven te Den Haag door Nuffic op 25 oktober 2024.

European Credit Transfer and Accumulation System ECTS: 6 credit points
ERT-accredited course: taken into consideration for the recognition as European Registered Toxicologist

CERTIFICATE

The Undersigned declare that

Ilke Kildaci Usa

has followed the lessons and has successfully passed the exam of the

"Safety Assessment of Cosmetics in the EU – Training Course 2025"

from Monday the 3rd of February to Saturday the 8th of February 2025
organized at the Vrije Universiteit Brussel

Brussels, 21 February 2025

Ondertekend door:

Vera Rogiers
35B7CBB0EBE34AC...

Em. Prof. Dr. Pharm. V. Rogiers
Course organizer

DocuSigned by:

Jan Danckaert
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Prof. Dr. Jan Danckaert
Rector of Vrije Universiteit Brussel

