

Cosmetic Product Safety Report – CPSR Part B

1. Assessment conclusion

Evaluated product: CARISpray

This assessment is based on information supplied by the customer, product manufacturer, raw material manufacturers and from published information in recognized authoritative sources. Whilst best endeavors have been used to check the accuracy of this information, the undersigned cannot be held responsible for any erroneous information supplied and used for preparing this assessment.

All statements in this safety assessment are elaborated on the recent level of knowledge. Any change or changes in the formulation and/or additional information on relevant data, respectively, will require an immediate re-evaluation of this safety assessment. This assessment is conditional on the Responsible Person complying with the conditions in the notes and any other purity restrictions listed.

The evaluation of the available data on the product and the information about the ingredients for the claimed use does not indicate a significant risk to users that outweighs the benefits of use. Concerning skin tolerance, the final product is expected to be well-tolerated and to have good cosmetic acceptability. Based on the information provided, the cosmetic product detailed in this report is assessed as **safe** when used under normal or reasonably foreseeable use in accordance with the European Cosmetics Regulation (EC) No 1223/2009.

2. Labelled warnings and instructions of use

The labelling must comply with the requirements of Article 19 of Regulation (EC) 1223/2009. Any claims made on the packaging must be substantiated with valid data for the formulation, which must be kept on file.

Instructions for use to be written on the label, provided by the responsible person:

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Recommended instructions of use to be written on the label:

No additional instructions are required for this product as long as it is clear from the product's function on the presented label.

Warnings

Warnings to be written on the label, provided by manufacturer:

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Recommended warnings to be written on the label:

For oral use only. Do not inhale or spray into eyes. In case of eye contact, rinse thoroughly with water and seek medical advice. Use in addition to brushing and flossing. For adults only. Keep out of reach of children. Avoid unnecessary swallowing; any excess may be expelled from the mouth after use. If irritation occurs, discontinue use. Store at room temperature.

3. Reasoning

Based on the formulation of this cosmetic product, its qualitative and quantitative composition according to its INCI ingredients, basic physical and chemical characteristics, and microbiology, Preservation Challenge Test performed – if applicable, classification of the cosmetic product type, including its purpose and method of application, and available toxicological information and safety sheets of the ingredients used; the cosmetic product's safety has been assessed for the consumer by assessing the toxicological profile of all ingredients, their chemical structure, exposure level and Margin of Safety (MoS) depending on the purpose of use in this cosmetic product.

The cosmetic product contains only the allowed ingredients in the allowed concentrations. For ingredients with safety limits as specified in Annexes to Cosmetic Regulation (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit; therefore, it is a **safe** concentration in these cosmetic products.

The evaluation of the entire composition and applied ingredient concentrations indicates that the cosmetic product's composition complies with the requirements of Cosmetic Regulation (EC) No. 1223/2009 of the European Parliament and of the Council.

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The final product would not be considered an irritant or a potential skin sensitiser.

Due to the eye's sensitivity, adding any foreign matter to the eye is expected to cause a degree of irritation. Although, if the toxicology data show that there are substances that are irritating by themselves, this feature must be minimised after their incorporation into the formula and by the type of product application.

The product does not contain any known photosensitising ingredients.

The packaging of the product is designed to protect it during its shelf life and use, and to ensure the safe use of the product. No interaction with the packaging material is expected, as the packaging is compatible with the formulation. Based on that, the packaging is rated suitable and safe for this specific product type. This package does not contain hazardous materials that require special markings or labelling on the shipper.

Justification of the hazard identification data:

Alternative methods have been developed over the years to evaluate ingredient and product safety. However, most cosmetic ingredients still lack sufficient data. To establish cosmetic ingredients and product safety without animal study, New Approach Methodologies (NAMs) have been started to be used. NAMs may include in vitro, ex vivo, in chemico, in silico methods, grouping, Read Across, and combinations thereof. This risk assessment may have used computational tools to gather, compare and utilise the hazard identification data for toxicological endpoints.

4. Assessor's Credential and approval of Part B

Safety Assessor Qualifications/Credentials:

Cisem Bahar Al-Jamal, Cosmetic Safety Assessor, MBTS, MRSB



Prepared and signed by:

Cisem Bahar Al-Jamal

Academic Qualifications

- 2024, Vrije Universiteit Brussels, Belgium / Safety Assessment of Cosmetics in the EU - Training Course – 2024, Grade: Pass 2022,
- Karma Grup, Istanbul, Turkey / Cosmetic Product Safety Evaluation Training, Grade: Pass 2011,
- Hacettepe University, Ankara, Turkey / Bachelor of Science Degree in Biology

Memberships

- Member of the Royal Society of Biology (MRSB) – Membership number: P0146577
- Member of the Society of Cosmetic Scientists (MSCS) – Membership number: 5939
- Member of the British Toxicology Society (MBTS) – Membership number: 1080116

Relevant Experience

- Over 10 years of extensive industry expertise in manufacturing, testing, and regulatory affairs of pharmaceuticals and cosmetics.
- Transitioned to the toxicology and risk assessment area in the cosmetics industry.
- Background in manufacturing and qualitative & quantitative testing of pharmaceuticals, cosmetics, and food supplements with a strong foundation in GMP applications.
- Expert in regulatory compliance of personal care products and cosmetics with a deep understanding of industry practices and regulations. Experienced in sourcing technical documents and compiling PIFs. Managing the projects to ensure products are developed to specified standards to meet customer and company requirements, ensuring that all relevant technical standards are applied.

30/04/2026

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

Cisem Bahar Al-Jamal

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

"Safety Assessment of Cosmetics in the EU – Training Course 2024"

from Monday the 5th of February to Saturday the 10th of February 2024
organized at the Vrije Universiteit Brussel

Brussels, 8 March 2024

DocuSigned by:
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