

Cosmetic Product Safety Report

Conforming to

REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of
30 November 2009 on Cosmetic Products and SCHEDULE 34 OF THE PRODUCT SAFETY AND
METROLOGY ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019 By

Cosmetic Safety Solutions Ltd on behalf of the named manufacturer below

CSC Reference	PP071117SRMCPSRv1.1
Product name	Sense Deep Repairing Treatment Rejuvenating Mask
Product category	Cosmetic emulsion - hair care – Rinse-off
Responsible organization / contact details	Vitak Hair Cosmetics Carlisle Building 51 Bracken Road D18 CV48 Dublin Ireland

Safety Report Part B

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Product category	Cosmetic emulsion - hair care - Rinse-off
Responsible organization / contact details	Vitak Hair Cosmetics Carlisle Building 51 Bracken Road D18 CV48 Dublin Ireland

1. Assessment Conclusion

This product meets the criteria for safety specified by the requirements of Article 3 of REGULATION (EC) No 1223/2009 and SCHEDULE 34 OF THE PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019.

2. Labelled Warnings and Instructions for Use

No specific warnings required other than standard product usage instructions – for external use only - not to be used around the eyes, mucous membranes or on broken skin. If irritation occurs discontinue use.

If the product is used around the eye area, warning must be given to avoid direct eye contact. No other specific instructions for use are prescribed.

Allergen declaration

In a rinse off product, any of the 26 fragrance allergens detailed in Annex III of Regulation (EC) No 1223/2009 - List Of Substances Which Cosmetic Products Must Not Contain Except Subject To The Restrictions Laid Down, that are present in the final product at a concentration greater than or equal to 0.01% must be declared on the product labeling.

Declarable allergens Hexyl Cinnamal, Citronellol, Alpha-isomethylionone, Geraniol, Limonene, Linalool

3. Reasoning

Appropriate data were available for all components and a full review of this information has been made. The following information was reviewed as a minimum requirement

Relating to the final product -

Physical and Chemical Properties
Stability and Reactivity
Microbiological Purity
Packaging
Normal and reasonably foreseeable use
Target Population

And specifically

The general toxicological profile of each ingredient used:

The chemical structure of each ingredient:

The level of exposure of each ingredient;

The specific exposure characteristics of the areas on which the cosmetic product will be applied;

The specific exposure characteristics of the class of individuals for whom the cosmetic product is intended.

Margins of safety have been calculated for all components, with additional safety factors applied where appropriate due to the use of data from structurally related compounds.

CALCULATION OF THE MARGIN OF SAFETY

Maximum amount of ingredient applied (mg) **I**

Typical body weight of human (kg) **60**

Maximum absorption through the skin (%) **A**

Systemic Exposure Dose (mg/Kg/Bw) $SED = I \times A / 60$

Margin of Safety **NOAEL / SED**

Where NOAEL equals no observed adverse effect level in mg/kg/bw from appropriate repeated dose studies.

MOS values for all toxicologically significant components (other than those whose presence is governed / prescribed specifically by the Annexes of Regulation (EC) No 1223/2009) have been calculated and are satisfactory (MOS >100)

Local toxicity – Phototoxic materials are not included in this formulation at levels of concern

CMRs – not included in this formulation

Nano materials – not included in this formulation

Dermal irritants / sensitizers – No significant exposure. Compatibility testing is generally advised if the product formulation uses ingredients at concentrations significantly greater than in previously well tolerated formulations. This formulation is very similar to other formulations that have been marketed previously, over a number of years without report of adverse reaction.

Interaction of substances

No significant interactions expected, based on a review of the chemical properties of the species included in this formulation. There are no components present that are likely to undergo spontaneous reaction – no species are present that have structural alerts with regard to carcinogenic activity.

4. Assessor's credentials and approval of part B

Approved - This product meets the criteria for safety specified by the requirements of Article 3 of REGULATION (EC) No 1223/2009 and SCHEDULE 34 OF THE PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019.

13/04/2022

 Joanne Priestley CBiol MRSB Managing Director, Safety Assessor ☒	 Simas Kazlauskas CBiol MRSB Safety Assessor ☒
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