

# COSMETICS LAB

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## **COSMETIC PRODUCT SAFETY REPORT EU REGULATION (EC) NO. 1223/2009**

This document addresses the requirements of Article 3 and Annex 1 of Regulation (EC)1223/2009 and in particular the required statement on the safety of the cosmetic product before it is placed on the market.

## **KLEEM ORGANICS® JEUNESSE PROFESSIONAL AGE-DEFYING VITAMIN C SERUM**

Kleem Organics®  
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# COSMETIC PRODUCT SAFETY REPORT

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## IDENTIFICATION OF THE PRODUCT AND CLAIMS

<b>CL Project number</b>	R15599
<b>Product name</b>	Professional Age-Defying Vitamin C Serum
<b>Product Formula</b>	SP4156
<b>Product Type</b>	Face Serum
<b>Consumer Type</b>	Adults
<b>Site of Application</b>	Face
<b>CMR Content</b>	Nil Reported
<b>Nano Material Content</b>	Nil Reported
<b>Claims</b>	Nil

# PROFESSIONAL AGE-DEFYING VITAMIN C COSMETIC PRODUCT SAFETY ASSESSMENT

## 1. ASSESSMENT CONCLUSION

We have independently assessed the product declared above and confirm that a Product Information File has been completed and summarised in this document. A full evaluation of the product has been made and our Cosmetic Product Safety Report has been compiled.

This product is a Cosmetic Product as defined in Article 6 of the EU Regulation 1223/2009 and complies with the appropriate requirements of the Regulation as amended at the date of this assessment.

All points of EU Regulation 1223/2009 Annex 1 have been fully expounded in a reasonable fashion with no deviation.

The product fully complies with the legislation and with the various Annex's relating to banned substances, CMRs, restricted substances, colours, preservatives, perfumes and sunscreens.

The Cosmetic Product Safety Report is based on information supplied by the Brand Owner, Importer, Substance Manufacturers and from published information in recognized authoritative sources and, whilst best endeavours have been made to check the accuracy of this information, the undersigned cannot be held responsible for any erroneous information supplied to it and used for preparing this assessment.

No evidence of harm to human health has been presented.

The product should give consumers the level of safety they can reasonably expect.

Under normal or reasonably foreseeable conditions of use, a product made to this formulation is unlikely to produce an abnormally high number of adverse reactions.

Substances, mixtures, ingredients should be bought from reputable suppliers.

The product should be produced by a manufacturer working to GMP (Good Manufacturing Practice) and tested to ensure good microbiological quality.

This report is considered appropriate at the time of its publication.

This report only remains valid if no material change is made to the substances used to make the product remain the same.

# PROFESSIONAL AGE-DEFYING VITAMIN C

## COSMETIC PRODUCT SAFETY ASSESSMENT

### 2. LABELLED INSTRUCTIONS, ADVICE, CAUTIONS AND WARNINGS

#### Directions of Use

Gently press pump. Apply a small amount with fingertips to a freshly cleansed and toned face, neck and decollete areas (avoid direct contact with eyes). Allow time to absorb prior to moisturiser application.

#### Advice

Nil

#### Caution

Avoid contact with eyes.  
If eye contact occurs, rinse thoroughly with water.  
For external use only.  
Keep out of reach of children.

### 3. REASONING

#### Scientific Reasoning for the Cosmetic Product Safety Report conclusion

In arriving at our conclusions we have taken into consideration the general toxicological profile of each ingredient used, the chemical structure, the CIR panel evaluation where available, the level of exposure (full technical data and/or toxicology files are held for each ingredient) and a total daily exposure has been calculated along with the margin of safety for each ingredient.

A reasonable margin of safety of the cosmetic product has been established by reviewing the results of the historical tests in the light of their validity to the relevant Material Safety Data Sheet (MSDS).

Where necessary an alternative Chemical Abstract Service registry number MSDS has been used to find relevant verified toxicity data. This data is the most verifiable to the actual product used, is catalogued by internal reference and is held by Cosmetics Laboratory Limited.

Where possible the use of a REACH ready MSDS containing a No Observed Adverse Effect Level (NOAEL) has been used.

Where no NOAEL is directly available from a REACH ready MSDS the route of possible administration of the substance has been considered in the choice of the LD50 used in the order Dermal, Oral, Acute. In the case of an LOAEL being used this is fully justified in the text accompanying the toxicological profile.

Mathematical operations to calculate NOAEL from established LD50 values have been used according to Layton *et al* 1987. Mathematical operations have been used to calculate mass from values of specific gravity and volume where required for LD50.

# PROFESSIONAL AGE-DEFYING VITAMIN C COSMETIC PRODUCT SAFETY ASSESSMENT

## 3. REASONING Cont/d

Where possible the Scientific Committee on Cosmetic Safety (SCCS) Notes of guidance 7<sup>th</sup> Revision, SCCS/1416/11 have been followed for the calculation of SED. When a specific dermal absorption factor has been used this has been justified in the text accompanying the compound.

The SCCS guidelines have also been used to calculate the MoS where possible but where not possible further justification has been given within the toxicological profile.

At the time of writing no reasonable QSAR or toxicological databases have been mandated by legislation nor can be used to substantiate the findings of this report which makes the consideration of interactions in the product impossible.

All allergens have been declared by IFRA statement and all suppliers of all chemicals are noted within the body of the report.

Where no data exists from an available MSDS, the Open tox database, European Commission Health and Consumers (Cosing) and European Chemicals Agency (ECHA) may have been used to check for mutagenicity, skin sensitization and carcinogenicity data that can be inferred from the structure of the constituent chemicals.

No attempt has been made to have a complete knowledge of the compatibility with other skin products or their interactions with the completed product as the technology does not exist and further animal studies are prohibited by law.

### **Margins of safety**

The Margins of Safety for this product are either all over 100 or those which are less are judged not to affect the overall safety of the product.

### **Product assessment for use by children under 3 or for use exclusively in external intimate hygiene**

This product has not been assessed for the above use.

### **An assessment of the possible interactions of the substances contained in the cosmetic product**

Substances have interacted to make a stable cosmetic product. It is impossible to know what the substances will do with other substances without further testing using a relevant *in vitro* toxicological model which does not exist. Warnings about specific reported interactions, if any, are stated in Section 2 Part B.

### **Justification of the consideration and non-consideration of different toxicological profiles shall be duly justified**

A toxicological profile is the historical test that has been used to determine the toxicity of a product to a human or animal. Data is collated by websites such as ECHA under the REACH program and is being continually verified.

# PROFESSIONAL AGE-DEFYING VITAMIN C COSMETIC PRODUCT SAFETY ASSESSMENT

## 3. REASONING Cont/d

This report takes into account only

- 1) The profile available from the suppliers MSDS
- 2) The profile available from the collection of MSDS used by Cosmetics Laboratory Limited, or
- 3) The profiles available from ECHA.

Should no data be available but a structure is available the QSAR database 'Open tox' has been used to predict chemical domains that may cause toxicity. In some cases, this is not possible to ascertain.

All profiles are fully expounded within section 16.

The product is not used exclusively as a UV screen and no claim is made on the potential to protect from the effects of the ultra violet waveband.


No chemical substance in the formulation has documentary evidence that photo-toxicity occurs with the compound.

**Impacts of the stability on the safety of the cosmetic product shall be duly considered.**

Should the product disassociate over time, the margin of safety is such that no expected harm will come to the user.

No evidence is presented to be of harm to human health.

## 4. ASSESSOR'S CREDENTIALS AND APPROVAL

  
Signed: Dr Vanessa Crawley, PhD., M.Chem (Hons.)  
For and on behalf of Cosmetics Laboratory Limited

Date: 09 November 2015