

PROFESSIONAL AGE-DEFYING VITAMIN C

COSMETICS LAB 

Cosmetics Laboratory Limited

Unit 6 Lawson Hunt Industrial Park
Broadbridge Heath Horsham RH12 3JR
United Kingdom

Tel: +44 (0) 1403 261500

Fax: +44 (0) 1403 254493

www.cosmeticslab.co.uk

compliance@cosmeticslab.co.uk

**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®
21A, Princess Margaret Street,
Msida MSD1331,
Malta

PROFESSIONAL AGE-DEFYING VITAMIN C

COSMETIC PRODUCT SAFETY REPORT

CONTENTS

IDENTIFICATION OF PRODUCT AND CLAIMS

COSMETIC PRODUCT SAFETY INFORMATION

Product

1. Calculations to be used
2. Physical and chemical characteristics
3. Stability and test results
4. Microbiological quality and Challenge test results
5. Impurities and trace elements in the product
6. Fragrances
7. Product toxicological profile
8. Normal and reasonable foreseeable use
9. Areas for attention
10. Exposure to the Cosmetic Product
11. Toxicological Profiles, Exposure Data, Margins of Safety
12. Assessors credentials

PROFESSIONAL AGE-DEFYING VITAMIN C SERUM
COSMETIC PRODUCT SAFETY INFORMATION

IDENTIFICATION OF THE PRODUCT AND CLAIMS

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

PROFESSIONAL AGE-DEFYING VITAMIN C SERUM
COSMETIC PRODUCT SAFETY INFORMATION

1. CALCULATIONS TO BE USED

- Margin of Safety = $\frac{\text{NOAEL}}{\text{SED}}$ (No Observed Adverse Effect Level)
(Systematic Exposure Dosage)
- Systematic Exposure Dosage = $\frac{A \times C \times \text{Dap}}{100 \times 100 \times \text{Bw}}$
- Where A = amount of the cosmetic product in grams applied daily.
C = concentration of the ingredient under study in the finished product on the application site.
Dap = dermal absorption (retention factor) expressed as a percentage of the test dose assumed to be applied in real life conditions.
Bw = default human whole body weight assumed by SCCS to be 60kg for an average female, 70kg for an average male and 15kg for an average child.

2. PHYSICAL / CHEMICAL CHARACTERISTICS

TEST	SPECIFICATION
pH @ 25°C	7.6 – 8.2
Viscosity	NA
Appearance @ 20°C	Clear, semi viscous aloe serum, free of foreign matter
Odour @ 20°C	Orange
Colour @ 20°C	Clear to light amber yellow
S.G. @ 20°C (g/ml)	0.93 – 1.00

PROFESSIONAL AGE-DEFYING VITAMIN C SERUM

COSMETIC PRODUCT SAFETY INFORMATION

3. STABILITY AND TEST RESULTS

This product has passed the necessary Stability Test, results given below/over.

The test results indicate that under reasonably foreseeable storage conditions the product will not deteriorate to the extent of being unsafe to human health within 30 months of opening.

A PAO label symbol has to be printed on the packaging and we suggest a 12 month period indication is appropriate but this may be varied by the Brand Owner from 1 to 30 months.

FULL TEST RESULTS

PROFESSIONAL AGE-DEFYING VITAMIN C SERUM

COSMETIC PRODUCT SAFETY INFORMATION

4. MICROBIOLOGICAL QUALITY AND CHALLENGE TEST RESULTS

This Cosmetic Product Safety Report is only valid if the product is adequately preserved.

A Challenge test should be conducted to evaluate the preservative efficiency.

Should it not be adequately preserved, there will be a potential for microbial growth which may cause a health hazard.

This product has passed the necessary Challenge test, full results given below/over.

Total Viable Count of Bacteria <10 cfu/g

Total Viable Count of Yeasts and Moulds <10 cfu/g

FULL TEST RESULTS

PROFESSIONAL AGE-DEFYING VITAMIN C SERUM

COSMETIC PRODUCT SAFETY INFORMATION

5. IMPURITIES AND TRACE ELEMENTS IN THE PRODUCT

Impurities are periodic table elements present in the composition of the substance and further information can be found from the [Periodic table of the elements](#)

Most substances are sourced from suppliers who supply individual MSDS (Material Safety Data Sheets) issued under REACH regulations for each substance and from which most data is taken.

Changes of supplier may impact on the levels of impurities and traces in the cosmetic product.

6. FRAGRANCES

Any perfume, essential oil or flavour added to this product must comply with the most recent IFRA guidelines at its level of use in this product type or the Cosmetic Product Safety Report will become invalid.

The following Orange Fragrance has been used at 1% in the formulation and the following allergens are to be declared:

Benzyl Alcohol and Limonene.

Limonene and Linalool

Natural products containing substantial amounts of Limonene and/or Linalool should only be used when the level of peroxides is kept to the lowest practical level, for instance by adding antioxidants at the time of production. Such products should have a peroxide value of less than 20 millimoles peroxides per litre, determined according to the FMA method.

Photosensitive citrus essential oils may increase skin sensitivity to sunlight.

PROFESSIONAL AGE-DEFYING VITAMIN C SERUM

COSMETIC PRODUCT SAFETY INFORMATION

7. PRODUCT TOXICOLOGICAL PROFILE

The product is a Face Serum and has therefore been analyzed as a Face Cream.

The product is targeted at the female population and therefore the average body weight used will be 60kg.

Percentage of the amount of substance applied (no compound was tested in this way).

C (%)	A (mg/kg bw/day)	DAP (%)
Per material	24.14	100

Scientific Committee on Consumer Safety (SCCS) Notes of Guidance, 7th revision SCCS/1416/11.

Estimated Daily Amount Applied	Retention factor	Calculated daily exposure (g/day)	Calculated relative daily exposure (mg/kg bw/day)	Relative amount applied (mg/kg bw/day)
1.54g	1.0	1.54	24.14	24.14

Daily amount applied estimated from dropper size/product literature.

Particle sizes are defined by the structure of the chemical and the formula weight FW / MW / Weight in Daltons.

Impurities of the substances are at the best grade possible from the MSDS and are defined in Section 4.

PROFESSIONAL AGE-DEFYING VITAMIN C SERUM

COSMETIC PRODUCT SAFETY INFORMATION

8. NORMAL AND REASONABLY FORESEEABLE USE

The normal use of this product is to modify appearance of the face.

The method of use stated on the packaging is:

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 moisturizer application.

No other use is foreseen.

9. AREAS FOR ATTENTION

The following areas may need particular attention:

Eyes:	Unlikely
Mucous Membranes:	Unlikely
Damaged skin:	Unlikely
Elderly People:	Unlikely
Children under 3:	Unlikely
Immune-compromised:	Unlikely

10. EXPOSURE TO THE COSMETIC PRODUCT

Adult/Child	Adults
Where Product Used	Face
Amount of substance applied per use	1.54g
Rinse Off or Leave On	Leave On
Frequency of use	Daily

Possibility of secondary exposure	Unlikely
Route of secondary exposure	Not expected
Possibility of unintended route into body	None
Nano-materials in product	None

PROFESSIONAL AGE-DEFYING VITAMIN C SERUM

COSMETIC PRODUCT SAFETY INFORMATION


11. TOXICOLOGICAL PROFILES, EXPOSURE DATA, MARGINS OF SAFETY

1. The Regulation 1223/2009 requires a Margin of Safety to be calculated for each ingredient in a product.
2. To calculate the Margin of Safety (MoS) we must first calculate the Systemic Exposure Dose (SED) and obtain the No Observed Adverse Effect Level (NOAEL) or the Lethal Dose 50 number (LD50).
3. Where necessary we have used a Layton empirical factor. Layton reviewed published data regarding LD50 values and NOAELs from longer term studies for small mammals. Using these ratios for a large number of chemicals Layton recommended using a factor to convert an LD50 to an ADI (acceptable daily intake).
4. Data bases used to obtain the relevant information for an ingredient are: EWG'S Skin Deep Cosmetics Database, Innovadex, Cosing, Chembook, Open Tox, ECHA, SCCS notes of guidance 7th revision SCCS/1416/11, Dweck Handbooks of Cosmetic Ingredients and of Natural Ingredients, CLL Compliance data base, MSDS database.
5. A Margin of Safety greater than 100 is fully acceptable.
6. Some ingredients (substances and mixtures) are known to interact and a specific warning on their use is given in Section B2 under the labelled warnings to the ingredients.
7. No remote QSAR database can accurately predict the interaction of the ingredients in this formula and animal testing of the product and ingredients is totally banned as from 13th March 2013 by Regulation 1223/2009.
8. Prediction of the interaction of the ingredients using Toxicological methods is therefore not possible.
9. The report is made taking into Account the Margin of Safety of all the ingredients and other available data which is source verified. The report therefore is only as good as the data available.

PROFESSIONAL AGE-DEFYING VITAMIN C SERUM

COSMETIC PRODUCT SAFETY INFORMATION

12. 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