

# Product Information File (PIF)

European Union Law  
art. 7a / Council Directive 93/35/EEC (of 14 June 2022)  
amending for the sixth time Directive 76/768/EEC  
on the approximation of the laws of the Member States  
relating to cosmetic products /

## Confidential Document

Bulk Ref.	F442	Comm. Ref.	4106
Trade Name of the product	Makari		
Name of the product	RETINOL CONTROL LINE SMOOTHING EYE CREAM		
Product Category Annex I	Cream for the skin		
Responsible Person	VICTORIA ALBI INTERNATIONAL INC.		
Address	1178 Broadway NY NY 1001		
Market Address	Mr. Michael Ackerman		
Contact	+ 2126892601		
Phone	makari@makari.com		
E-mail	<a href="http://www.makari.com/">http://www.makari.com/</a>		
Web-Site			

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# VICTORIA ALBI

BRAND: MAKARI DE SUISSE

PRODUCT REF CODE: 4106 RETINOL CONTROL LINE SMOOTHING EYE CREAM

Ingredients INCI Names	Wt.% age	Function	Active %age	CASR Number
Water	59.56%	Solvent	100%	7732-18-5
Glycerin	4.75%	Humectants	100%	3539-43-3
Lactose	3.98%	Emulsifying Agent	100%	67701-33-1
C12-15 Alkyl	3.50%	Humectants	99.70%	56-81-5
Benzoate	3.05%	Emollient	100%	8042-47-5
Cetearyl Ethylhexanoate	2.55%	Solvent	44.950%	127-51-5
Sodium hyaluronate	2.31%	Solvent	98.00%	5466-77-3
Glyceryl	2.30%	Humectants	100%	57-55-6
PEG-8 Stearate	2.25%	Emollient	98.00%	67762-27-0
Oryza Sativa (Rice) Bran extract	2.00%	Emollient	100%	131-57-7
Terminalia Chebula Fruit Extract	1.83%	Emollient	100%	3687-46-5
Glycine Soja (Soybean) Extract	1.50%	Emollient	60%	63148-62-9
PEG-100 Stearate	1.50%	Emollient	100%	68439-49-6
Stearyl Alcohol	1.00%	Emollient	100%	8007-69-0
Sodium PCA	1.00%	Emollient	100%	110-27-0
Allantoin	1.50%	Emollient	100%	7732-18-5
BHT	0.30%	Botanical	100%	84929-31-7
Acetyl Hexapeptide-8	0.50%	Antioxidant	100%	77-92-9
Panthenol	0.60%	Emollient	100%	50-81-7
Tromethamine	0.52%	Emollient	100%	9004-82-4
Carbomer	0.50%	Moisturizer	100%	312-86-6
Isopropyl	1.50%	Solvent	100%	7732-18-5
Myristate	0.55%	Perfume	100%	
Vitamin-E	0.45%	Preservative	100%	94-13-3
Disodium EDTA	0.25%	Preservative	100%	99-76-3
Retinol	0.15%	Antioxidant	100%	78-81-2
Phenoxyethanol	0.10%	Antioxidant	100%	50-81-7
<b>Total INCI</b>	<b>100 %</b>			

DATE: 9/9/2022

SIGNED

*Michael Ackerman*

MICHAEL ACKERMAN  
QC TECHNICAL MANAGER

VICTORIA A LLC 1178 BROADWAY 5<sup>TH</sup> FLOOR NEW YORK, NY 10001

b) PHYSICO-CHEMICAL AND MICROBIOLOGICAL SPECIFICATIONS  
OF THE INGREDIENTS

The company Cosmotech Inc., as manufacturer of the product herein believes that the trade names of ingredients used as raw materials to manufacture this product is its strictly know how and has to be considered a trade secrecy. As a consequence this information belongs to Cosmotech Inc.

Apart from this statement we are aware of the great impact of purity, microbiological and toxicological profile of such ingredients on the quality of the finished product.

As a support to this statement we state that the standards adopted at our company reflect international regulatory (mainly Pharmacopea) requirements and are generally accepted by industry practice.

More detailed information is kept by our company and stored at two different secure locations.

This detailed information is readily accessible and will be made available to the competent authority upon request and within a reasonable period of time.

## Identification of persons with ultimate responsibility

Operation	Forname / Last Name	Qualifications
Bulk Manufacturing (Compounding)	Mr. Lazaro Carvajal	Cosmetic Operator
Bulk Release	Mr. Lazaro Carvajal	Laboratory Technician
Packing	Mr. Lazaro Carvajal	Packing Technician
Finished product release	Mr. Lazaro Carvajal	Director of production

The method of manufacture, packing and storage used at Cosmotech Inc. complies with international manufacturing standards and

### **CGMP (Cosmetic Good Manufacturing Practices)**

laid down by:

Swiss Federal Office of Public Health, Bern Switzerland

Cantonal Laboratory, Lausanne, Switzerland

Community law (European Council Directive 76/768/EEC)

Colipa (The European Cosmetic and Toiletry Association), Bruxelles, Belgium

IKW (Industrie Körperpflege und Waschmittel), Frankfurt am Main, Deutschland.

Above mentioned guidelines cover:

Documentation

Qualifications of Management and staff

Internal audit

Complaints and recalls

Buildings and Facilities

Equipment

Raw materials selection, quality control and storage

Bulk Processing

Quality Control

Packing

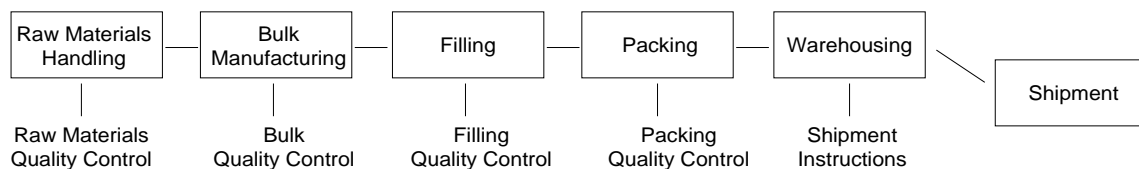
Storage of finished products

Deviations

Shipment procedures.

These guidelines apply to all the products manufactured at Cosmotech Inc. facilities which are regularly inspected by Swiss Authorities (Chemist of Canton Vaud).

### **Production Flow Chart**



Quality Assurance and Quality Control Operations are settled out according to ISO 9001 and ISO 9004 Standards.

# *COSMOTECH INC.*

## Certificate of compliance with Cosmetic Directive 76/768/EEC

We, Cosmotech Inc. hereby confirm that the product mentioned herein complies with above mentioned regulation.

More specifically it does not contain:

Any substance listed in annex II;

Any substance listed in annex III beyond the limits and outside the conditions laid down;

Any coloring agent other than those listed in annex IV;

Any substance listed in annex V beyond the limits and outside the conditions laid down;

Any substance listed in annex VI beyond the limits and outside the conditions laid down.

## Certificate of non-infection (BSE Free)

We hereby certify that the product described herein does not contain ingredients derived from animals. As a consequence it is free from bovine spongiform encephalopathy (BSE).

## Certificate of Heavy Metals Content

Despite Good Manufacturing Practices traces of heavy metals are technically unavoidable in cosmetic products as they are usually found all around.

To the best of our knowledge and belief, the products listed herein do not contain detectable traces of heavy metals.

This product has been manufactured according to all decisions made by the World Health Organization, EU and Swiss Cosmetic Directives, all applicable U.S. federal state and local laws and regulations, and all necessary adjustments and controls are applied to minimize any risks for humans.

Shelf Life / Period After Opening (PAO) / Expiration Date

The product mentioned herein as been stability tested at the below conditions.

1 month at 50 °C

3 months at 40 °C

1 week thermal shock (4 °C - 40 °C)

The product successfully passed these tests. Therefore, we may assume that when stored at normal conditions (as long as the product has not suffered from important and repeated thermal shocks and is stored in appropriate and dry area),

a shelf life of

36

Months

is predicted for it.

Furthermore we may assume that

a period of time of

6

Months

after opening (PAO) is predictable.

d) Assessment of the safety for human health

## Safety Assessment

I, the undersigned, Lazaro Carvajal, have examined the herein mentioned product and the following documents:

- Intended and foreseeable use (area of the body exposed to the product and frequency of use);
- Historical use and experience of the product;
- Number of pieces sold (if applicable);
- Master formula (quali-quantitative formula showing level of content and commercial names of ingredients);
- General toxicological profile and chemical structure of the ingredients;
- Physico-chemical and microbiological specifications of the ingredients;
- Stability tests results.

Based on results of above exams and according to Good Laboratory Practice laid down in Council Directive 87/18/EEC of December 18th, 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and verification of their application for tests on chemical substances, I conclude that:

**the product herein does not present any danger for human health when it is used under the normal operating conditions.**

### Safety Assessor Details

Name : Lazaro  
Last name : Carvajal  
Date of birth : June 5th, 1979  
Marital status : Married, two children  
Qualifications : Chemical Engineer (ITIS / High School for Industrial Chemistry / Italy)  
  
Post qualifications : Cosmetic Chemist / "A" Member of Swiss SCC  
(Swiss Society of Cosmetics Chemists)

e) Undesirable Effects on Human Health

To the best of our knowledge no undesirable effects on Human Health have been recorded in relation with the product herein.

Approximate number of pieces sold to date: > 200'000  
f) Proof of Effect

As a support to the claimed effects of the product herein we may provide the following information:

- Data from suppliers on raw materials
- Reference to the literature
- In-use efficacy reports