

# PRODUCT INFORMATION FILE\*

RegimA

Instant Facial Lifting Wonder  
Serum and O2 Purifyer Face  
+ Body Enhancing Serum

Prepared: August 2018  
(Label & packaging update August 2021)

\*As required under Article 11 of the European Cosmetics Regulation EC No. 1223/2009

# TABLE OF CONTENTS

## Contents

INTRODUCTION .....	3
PRODUCT DESCRIPTION .....	3
COSMETIC PRODUCT SAFETY REPORT .....	7
Part A: Cosmetic Product Safety Information.....	7
A.1 Quantitative and qualitative composition of the cosmetic product:.....	7
A.2 Physical /chemical characteristics and stability of the cosmetic product .....	11
A.3 Microbiological Quality.....	13
A.4 Impurities, traces, information about the packaging material .....	13
A.5 Normal and reasonably foreseeable use.....	13
A.6 Exposure to the Cosmetic Product .....	13
A.7 Exposure to the Substances .....	14
A.8 Toxicological Profile of the Substances .....	16
A.9 Undesirable Effects and Serious Undesirable Effects.....	20
A.10 Information on the Cosmetic Product .....	20
B: Part Cosmetic Product Safety Assessment .....	21
B.1 Assessment Conclusion .....	21
B.2 Label Warnings and Instructions for Use .....	21
B.3 Reasoning .....	23
B.4 Assessors Credentials and Approval of Part B.....	23
List of References.....	23
METHOD OF MANUFACTURE / GMP CERTIFICATION.....	24
PROOF OF EFFECT CLAIMED .....	25
ANIMAL TESTING STATEMENT.....	25
Appendix 1: Safety Data Sheets or Ingredient Specifications .....	27
Appendix 2: Microbial Challenge Test .....	28
Appendix 3: Certificates of Allergen Content .....	29
Appendix 4: Miscellaneous .....	32

## **INTRODUCTION**

### **PRODUCT DESCRIPTION**

**Product Names:** Instant Facial Lifting Wonder Serum and O2 Purifyer Face + Body Enhancing Serum\*

Product type	Serum to help with firming and purifying
Form	Gel
Colour	Slightly hazy brown
Pack size	50 ml (Instant Facial Lifting Wonder Serum), 200ml (O2 Purifyer Face + Body Enhancing Serum)
Pack type	Airless container
Dispenser type	Pump
Part of a set	No
Manufacturer code	PBP 003
Normal use	<p><u>Instant Facial Lifting Wonder Serum</u></p> <p>AM: Cleanse with RegimA. Apply eye care products. Apply a few drops of Lifting Serum to face, neck and decollete. Allow Serum to dry to a film before applying other desired RegimA serums and daily care.</p> <p><u>O2 Purifyer Face + Body Enhancing Serum</u></p> <p>To be used as part of a RegimA Peel or facial, apply eye care then a layer of O2 Purifyer Face + Body Enhancing Serum to all treated areas. Allow to dry to a film, one may then, if desired, also apply a thin layer of Marine Replenish Masque with fingertips to face and neck, avoiding the eye area, to finalise a purifying, hydrating, replenishing treatment</p>

\*This PIF contains two products with differing names, with the exact same formulation. The Instant Facial Wonder Serum is a take home product, while the O2 Purifyer Face + Body Enhancing Serum is a salon use product.

**Pictures of the Item: On following page**

## Container label

### Instant Facial Lifting Wonder Serum



### O2 Purifyer Face + Body Enhancing Serum



## Carton label

## Instant Facial Lifting Wonder Serum



## O2 Purifyer Face + Body Enhancing Serum



**Batch code:** The batch number is printed onto the underside of the carton and the container at the point of manufacturing and filling, therefore it is not visible on the label as represented in this PIF. The batching is automated, so the batch code and date is printed onto the carton and container as they are filled and boxed.

**Product claims:**

This product claims to help with firming and purifying and provide firming and immediate long-lasting hydration.

## **COSMETIC PRODUCT SAFETY REPORT**

### **Part A: Cosmetic Product Safety Information**

#### **A.1 Quantitative and qualitative composition of the cosmetic product:**

**Instant Facial Lifting Wonder Serum and O2 Purifyer Face + Body Enhancing Serum Base formula**

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Aqua	5	5	7732-18-5	231-791-2	Solvent	In-House Croda Chemicals	Water Crovil A-70
2	Almond Oil PEG-6 Esters	5		124046-50-0	#			
3	Sodium Lactate	3	5	72-17-3 / 867-56-1	200-772-0 / 212-762-3	Emollient/ Emulsifying Buffering/ Humectat/ Keratolyic/ Solvent	Purac (Chempure)	Purasal S
	Aqua	2		7732-18-5	231-791-2			
4	Butylene Glycol	2	4	107-88-0	203-529-7	Humectant/ Skin Conditioning/ Solvent/ Viscosity Controlling/ Skin Protecting	Silab (Meganede)	Detoxyl
	Aqua	1.91		7732-18-5	231-791-2			
	Butyrospermum Parkii Seedcake Extract	0.092		91080-23-8	293-515-7			
5	Aqua	2.87	3	7732-18-5	231-791-2	Solvent/ Skin Conditioning/ Skin Protecting/ Preservative	Silab (Meganede)	Celldetox
	Hydrolyzed Candida Saitoana Extract	0.11		#	#			
	Phenoxyethanol	0.015		122-99-6	204-589-7			
	Ethylhexylglycerin	0.006		70445-33-9	408-080-2			
6	Glycerin	2	2	122-99-6	204-589-7	Humectant/ Perfuming/ Skin protecting/ Viscosity Controlling	Various	Glycerine CP
7	Phenoxyethanol	0.9	1	1117-86-8	214-254-7	Preservative/ Emollient/	Vestatil PC	Dr. Straetmans (Meganede)
	Caprylyl Glycol	0.1		7732-18-5	231-791-2			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
						Humectant/ Skin Conditioning		
8	Aqua	0.8	1	1310-73-2	215-185-5	Solvent/ Buffering/ Denaturant	Various	Sodium Hydroxide 20% Solution
	Sodium Hydroxide	0.2		93686-22-7	297-672-2			
9	Citrus bergamia peel oil expressed (also known as the perfuming name: Citrus Reticulata, X C. Sinensis Peel Extract)	1	1	93686-22-7	203-806-2	Perfuming	FD Copeland (CJP Chemicals)	Bergamot Oil
10	Cyclohexane	0.009	1	9007-20-9 / 9003-01-4 / 76050-42-5 / 9062-04-8 / 9007-16-3 / 9007-17-4	#	Solvent/ Emulsion Stabilizing/ Gel Forming/ Viscosity Controlling	Noveon (Carst & Walker)	Carbopol Ultrez 30 Polymer
	Carbomer	0.99		#	#			
11	Kappaphycus Alvarezii Extract	0.2375	0.5	39300-88-4	254-409-6	Hair Conditioning/ Solvent/ Skin Conditioning/	Silab (Meganede)	Filmexel
	Caesalpinia Spinosa Fruit Pod Extract	0.2375		7732-18-5	231-791-2			
	Aqua	0.025		11138-66-2	234-394-2			
12	Xanthan Gum	0.35	71.5	7732-18-5	231-791-2	Binding/ Emulsifying/ Emulsion Stabilizing/ Gel Forming/ Skin Conditioning/	CP Kelco (Tranarc)	Keltol T Plus

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
						Surfactant/ Viscosity Controlling		
13	Aqua	71.15	71.5	7732-18-5	231-791-2	Solvent	In-House	Water

# not assigned

Ingredient order for the label: Aqua (Water), Almond Oil PEG-6 Esters, Sodium Lactate, Butylene Glycol, Glycerin, Citrus Bergamia Peel Oil Expressed, Carbomer, Phenoxyethanol, Xanthan Gum, Limonene, Caesalpinia Spinosa Fruit Pod Extract, Kappaphycus Alvarezii Extract, Sodium Hydroxide, Hydrolyzed Candida Saitoana Extract, Linalool, Caprylyl Glycol, Butyrospermum Parkii Seedcake Extract, Citral, Cyclohexane, Ethylhexylglycerin.

Red font denotes ingredients present at less than 1% which may be listed in any order.

Below are the allergens and their respective concentrations in the fragrance that are required to be listed in Article 19 Paragraph 1(d) & (g (ii)) of EC 1223/2009 when present at levels >0.001% in a leave-on product.

**Fragrance allergens\***

<b>INCI (EU) Name</b>	<b>CAS number</b>	<b>EC number</b>	<b>Concentration % w/w</b>	<b>IFRA Standard</b>	<b>Comment</b>
Citral	5392-40-5	226-394-6	0.0301		Above 0.001% limit for leave on product
Limonene	5989-27-5	227-813-5	0.2735	d-, l- and dl-limonene and natural products containing substantial amounts of it, 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 liter, determined according to the FMA method.	Entire product has less than 20 mmoles/L. The product also contains antioxidants tocopherol and tocopheryl acetate and the preservative phenoxyethanol.  Above 0.001% limit for leave on product
Linalool	78-70-6	201-134-4	0.1005		Above 0.001% limit for leave on product

#### **A.2 Physical /chemical characteristics and stability of the cosmetic product**

Physical and chemical characteristics of the ingredients have been listed in the safety data sheets which are maintained electronically by the Responsible Person and are available on request. A cross reference to the SDS tradename and electronic reference number has been shown in the base formula table.

#### **Physical and Chemical Characterization of the product**

1 Physical state	Gel
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	o/w
3 organoleptic properties (colour, odour, whenever relevant)	Slight hazy gel, characteristic odour
4 pH (at 25°C)	4.6
5 viscosity (at 25°C)	360000 cPs
6 thermal stability (glass bottle)	2 weeks @ 40°C
7 Specific gravity	1 g/ml

### Stability of the product

A shelf-life of 6 months after opening has been allocated to this product.

An on-going stability study of the product in the packaging will be available to support the shelf-life. A stability test of the product in glass jars has confirmed stability at 40°C and 50°C for 2 weeks, at which point the appearance was slightly darker in both samples and the viscosity decreased by 14% and 12%, respectively.

A 12 week stability test of the product in glass jars at room temperature has confirmed the stability of the product as formulated, at which point the products appearance was slightly darker on top. No other significant changes were noted during the 12 week period.

An accelerated aging rate of 475 days was calculated which confirmed the 6 month shelf life for the product after opening. Presented below is how the accelerated aging rate was calculated. An industry standard of 2 was used for Q10 with 84 real time testing days.

$Q10^{((\text{Accelerated Aging temperature} - \text{Ambient Temperature})/10)} \times \text{real time testing days}$

$$2^{((50-25)/10)} = 5.66$$

$$5.66 \times 84 \text{ real time testing days} = 475 \text{ days}$$

### **A.3 Microbiological Quality**

A PET test has been performed according to USP method 38 and confirms the effectiveness of the preservative for a period of 28 days. The certificate has been presented in Appendix 2.

### **A.4 Impurities, traces, information about the packaging material**

None of the ingredients of this product contained impurities at a level which would require notification.

A statement on the suitability of the product packaging is shown below.

The Chubby Chunky Airless container is made from Polypropylene, light density polyethylene (LDPE) and high density polyethylene (HDPE). The pump is made from LDPE, HDPE and polypropylene. The components of the packaging material and suitability of use criteria are included in a certificate in Appendix 4. This is maintained electronically with the PIF by the Responsible Person and is available on request.

### **A.5 Normal and reasonably foreseeable use**

Instant Facial Lifting Wonder Serum and O2 Purifyer Face + Body Enhancing Serum is a product designed to help with firming and purifying and provide firming and immediate long-lasting hydration. It is a leave-on product that in normal circumstances will be used once daily on the face, neck, decollete & body.

### **A.6 Exposure to the Cosmetic Product**

Site of application	Face, neck, decollete & body
Surface area of application (cm <sup>2</sup> )	16235*
Volume of product applied (g)	8.07
Frequency of application/use per day	Once daily
Target population	Adults
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	0.25ml exposure daily Estimated exposure based on 60 kg adult = 134.5 mg/kg bw/day
Dermal absorption information	Unknown
other	N/A

\* The total surface area for application of Instant facial lifting Wonder Serum is 16235 cm<sup>2</sup> ( Skincare; Face surface area = 565 cm<sup>2</sup> and Skincare; Body Lotion surface area = 15670cm<sup>2</sup>). These figures are extracted from the SCCS guidelines for the testing of Cosmetic Ingredients and their Safety Evaluation, 9<sup>th</sup> revision, Section 4.2 , Table 1, page 76.

## A.7 Exposure to the Substances

Daily Systemic Exposure Dosage (SED) is the daily amount of a cosmetic substance applied based on the concentration of that particular substance, the percutaneous absorption and the nominal human body weight (60 kg) and this is shown in the table below.

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#1</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Almond Oil PEG-6 Esters 124046-50-0	5	134.5	1	28.25
Sodium Lactate 867-56-1	3	134.5	1	16.95
Butylene Glycol 107-88-0	2	134.5	1	11.30
Glycerin 56-81-5	2	134.5	1	11.30
Citrus Bergamia Peel Oil Expressed 93686-22-7	1	134.5	1	5.65
Carbomer 9007-20-9	0.99	134.5	1	5.59
Phenoxyethanol 122-99-6	0.92	134.5	1	5.17
Xanthan Gum 11138-66-2	0.35	134.5	1	1.98
Caesalpinia Spinosa Fruit Pod Extract 39300-88-4	0.24	134.5	1	1.34
Kappaphycus Alvarezii Extract ##	0.24	134.5	1	1.34
Sodium Hydroxide 1310-73-2	0.2	134.5	1	1.13
Hydrolyzed Candida Saitoana Extract #2	0.11	134.5	1	0.64
Caprylyl Glycol 1117-86-8	0.1	134.5	1	0.57
Butyrospermum Parkii Seedcake Extract 91080-23-8	0.092	134.5	1	0.52

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#1</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Cyclohexane 110-82-7	0.009	134.5	1	0.051
Ethylhexylglycerin 70445-33-9	0.006	134.5	1	0.034

#1 Where no dermal absorption data is available, 100% dermal absorption is used. However, where molecular weight > 500 Da and log Pow is smaller than -1 or higher than 4, the value of 10% dermal absorption is considered unless the formulation contains penetration enhancers. Dermal absorption of nanomaterials needs to be determined experimentally.

#2 No CAS number assigned.

## A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Almond Oil PEG-6 Esters 124046-50-0	A	2014 CIR Compendium. Safe for use in cosmetics when formulated to be non-irritating. Almond Oil PEG-6 esters is the product of transesterification of Prunus Amygdalus dulcis (Almond) Oil and PEG-G. The limits of the outlined reactants are stated as up to 77% and 51% respectively, where Almond oil was determined to be non-irritating and PEG-6 safe for use in cosmetics. Full amended report 09/12 available from CIR; IJT 33 (Suppl 4):13-39, 2014. It was determined that the use of Almond Oil PEG-6 Esters is safe to use in Instant Facial Wonder Serum and O <sub>2</sub> Purifying face+ Body Enhancing Serum at the level of 5%.								
Butylene Glycol 107-88-0	A	Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006								
Butyrospermum Parkii Seedcake Extract 91080-23-8	A	For use up to 5.5% in leave on cosmetic formulations. Dermal irritation studies where Butyrospermum Parkii (Shea) Seedcake Extract was used up to 0.14% was found not irritating in human studies. Further analysis determined Butyrospermum Parkii (Shea) Seedcake Extract to be non-irritating or sensitizing in HRIPTs at concentrations up to 0.42%. Final report available 09/12/2017 is available from the CIR. Butyrospermum Parkii (Shea) Seedcake Extract is present in Instant Facial Wonder Serum and O <sub>2</sub> Purifying face+ Body Enhancing Serum at 0.092% and it was determined that no adverse effects are expected when used as directed.								
Caesalpinia Spinosa Fruit Pod Extract 39300-88-4	###	A secondary assessment was performed on Caesalpinia Spinosa Fruit Pod extract, with a read across to Caesalpinia Spinosa gum. Caesalpinia Spinosa gum was approved for use as a food ingredient by the JECFA with no ADI specified. Caesalpinia Spinosa Fruit Pod extract is present in Instant Facial Lifting Wonder Serum AND O <sub>2</sub> Purifying Face + Body Enhancing Serum at 0.24%, 4 times lower than the worst case dose of 1%. With the JECFA report outlining Caesalpinia Spinosa gum as being safe for use as a food ingredient and Caesalpinia Spinosa Fruit Pod extract being 4 times lower than the worst case dose, it was determined that the addition of Caesalpinia Spinosa Fruit Pod extract is safe for use in Instant Facial Lifting Wonder Serum AND O <sub>2</sub> Purifying Face + Body Enhancing Serum.								
Caprylyl Glycol 1117-86-8	A	Safe when used up to 5%, Safety assessment of 1,2-glycols as used in cosmetics, International Journal of Toxicology 31 (S2), 1475-1685, 2012								
Carbomer	A	Safe when used up to 2%, JACT 1(2)109-41, 1982 confirmed 11/02 IJT 22(S1):1-35, 2003								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
9007-20-9										
Citrus Bergamia Peel Oil Expressed 93686-22-7	B									Supplier IFRA certificate of conformity supplied and presented in Appendix 3. Maximum allowable concentration in product is 9.96%, actual concentration 1%. Allergen components are declared in A1 Fragrance Allergen table. Safe for inclusion in this product.
Cyclohexane 110-82-7	B									Available data on Cyclohexane indicated that it has a low order of toxicity, no ADI has been established according to JECFA report 23/19*. Cyclohexane is almost completely absorbed by the oral and inhalation route with dermal absorption of pure liquid cyclohexane in contact with the skin being 5%, this percentage is significantly reduced in Instant Facial Wonder Serum and O <sub>2</sub> Purifying face+ Body Enhancing Serum due to Cyclohexane being present in the formulation at 0.009% therefore the dermal absorption would be reduced. Cyclohexane is considered to be a skin irritant with the properties being delayed and persistent while it was not considered to be sensitizer. The NOAEL ranged from 250 ppm to 2,000 ppm in a range of animal and human toxicity testing. Taking 250ppm as the worst case scenario NOAEL the MoS was calculated to be 4902. It is considered that a value above 100 is generally considered to be safe. Cyclohexane is present at a level of 0.051 mg/kg bw/day in Instant Facial Wonder Serum and O <sub>2</sub> Purifying face+ Body Enhancing Serum, considerable lower than the level outlined as a NOAEL and therefore safe for use. Cyclohexane, Summary Risk Assessment Report. (2004). European Commission Joint Research Centre, Institute for health and Consumer Protection, European Chemicals Bureau, special Publication 1.04.22, pp 1-15; Evaluation of certain food additives. Twenty-third Report of the Joint FAO/WHO Expert Committee on Food Additives. (1981). Food and Cosmetics Toxicology, 19, p381.
Ethylhexylglycerin 70445-33-9	A									2014 CIR Compendium safe with no upper limit for concentration, IJT 32 (S3): 5-21, 2013
Glycerin 56-81-5	A									GRAS#, FDA approved food additive, FDA approved over the counter (OTC) for skin
Hydrolyzed Candida Saitoana Extract #	###									A secondary assessment was performed on Hydrolyzed Candida saitoana Extract with a read across to the active ingredient of <i>glucan</i> . Hydrolyzed Candida saitoana Extract is present in Instant Facial Lifting Serum and O <sub>2</sub> Purifyer Face + Body enhancing Serum at 0.64 mg/kg bw/day, 65 times lower than the worse case scenario dose of 2500 mg/kg bw/day. It is not expected to cause any serious

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment		
			undesirable effects when used as directed.									
Kappaphycus Alvarezii Extract ##	###									A secondary assessment was preformed on Kappaphycus Alvarezii Extract. A principal component of Kappaphycus alvarezii extract is sulfonated galactans also known as Carrageenan's. Carrageenan has been generally recognized as safe (GRAS) by the FDA and has also been approved as a food additive, this has been confirmed by WHO and JECFA with no ADI established. It has been determined that Kappaphycus alvarezii extract is a safe for use in Instant facial wonder serum and O <sub>2</sub> Purifyer face +body enhancing serum.		
Phenoxyethanol 122-99-6	B									Safe for use when included up to 1%, JACT 9(2):259-77, 1990		
Sodium Hydroxide 1310-73-2	B									Safe for use up to 6.9 % in leave on formulations, where the pH is <11. Human dermal irritation studies indicated irritation caused by sodium Hydroxide at levels as low as 0.5, with dermal sensitization HRIPT challenge test sodium hydroxide was not sensitizing when induced up to 1% and when challenged at 0.125% irritation was observed. Final report 12/15/2015 available from CIR. Sodium Hydroxide is in Annex III/15 where the pH is restricted to pH <11. Sodium hydroxide is present in Instant Facial Lifting Wonder Serum at a level of 0.2%, with a pH of 4.6 there for all restrictions are satisfied and determined safe for use as directed.		
Sodium Lactate 72-17-3	B									Safe with restrictions: Glycolic and Lactic Acid, their common salts and their simple esters, are safe for use in cosmetic products at concentrations <=10%, at final formulation pH >=3.5, when formulated to avoid increasing sun sensitivity or when directions for use include the daily use of sun protection. IJT 17(S1):1-242, 1998. Sodium Lactate is included in formulation at 3%, at a pH of 4.6 and has been determined safe for use in Instant facial lifting wonder serum and O <sub>2</sub> Purifyer Face + Body Enhancing Serum.		
Xanthan Gum 11138-66-2	A									2014 CIR Compendium safe up to 6%, Safety Assessment of Microbial Polysaccharide Gums as Use in Cosmetics, Final Report, CIR, October, 2012		

<sup>a</sup> Some ingredients are excluded from a formal risk assessment where a recognized authority has published a review of the ingredient under similar conditions of use and concluded on safe use at the level of inclusion in the cosmetic product (Hazard ID=A). Hazard ID category B is for recognized authority reviews of the ingredient under similar conditions of use with restricted use or

where the ingredient is contained in the annexes to Regulation (EC) No 1223/2009 (Hazard ID=B). Where hazard ID A or B is reported, the maximum allowed usage concentration should be stated.

<sup>b</sup> all possible routes of exposure should be considered

<sup>c</sup> A MoS of greater than 100 is considered to represent safe use

# Food item, hazard and exposure data not required.

## No CAS number assigned

### Secondary assessment preformed, presented in Appendix 4

**Fragrances:**

An IFRA Certificate of Conformity which includes the allergen composition has been presented in Appendix 3. The conformity certificate certifies compliance with the standards of INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA-47<sup>th</sup> amendment, published June 2013) provided it is used at up to 9.96% for IFRA category 5 (Woman's facial creams etc.). The fragrance is included in this product at 1% and based on this low concentration, allergens Citral is present at 0.0301%, Limonene is present at 0.2735% whilst Linalool is present at 0.1005%. As these concentrations exceed >0.001% for a leave-on product (Article 19 Paragraph 1(d) & (g (ii)) of EC 1223/2009) they are declared in the list of ingredients.

**A.9 Undesirable Effects and Serious Undesirable Effects**

No undesirable effects are anticipated based on the product being used as directed on the face, neck, decollete and body once daily.

**A.10 Information on the Cosmetic Product**

Instant facial lifting wonder serum and O<sub>2</sub> Purifyer Face + Body Enhancing Serum was released in 2017. Over the period August 2017 to August 2018 2841 units of Instant Facial Lifting Wonder Serum and 438 units of O<sub>2</sub> Purifyer Face + Body Enhancing Serum have been sold and there have been no adverse reactions reported to RégimA Company.

## **B: Part Cosmetic Product Safety Assessment**

### **B.1 Assessment Conclusion**

#### Review of the ingredients

After analysis of all the available information including:

- formulation
- toxicological profile of the ingredients and their concentration in the product
- Product data sheets supplied by the ingredient manufacturer

It is not expected that Instant Facial Lifting Wonder Serum and O<sub>2</sub> Purifying Face + Body Enhancing Serum will cause damage to human health when used as directed.

It is therefore concluded that Instant Facial Lifting Wonder Serum and O<sub>2</sub> Purifying Face + Body Enhancing Serum can be placed on the market in the EU as a face and body serum.

#### Review of human data on the product

There are no human tests such as a patch test, for this product.

### **B.2 Label Warnings and Instructions for Use**

Directions for use are given on the product label and outer packaging as presented in Appendix 4.

#### **Directions:**

**Instant Facial Lifting Wonder Serum:** AM: Cleanse with RégimA, apply eye care products. Apply a few drops of Lifting Serum to face, neck and décolleté. Allow Serum to dry to a film before applying other desired RégimA serums and daily care.

**O<sub>2</sub> Purifyer Face +Body Enhancing Serum:** To be used as part of a RégimA in-salon treatment. Following a RégimA peel or facial, apply eye care then layer of O<sub>2</sub>-Purifyer Serum to all treater areas. Allow to dry to a film, one may then, if desired, also apply a thin layer of Marine Replenish Masque with fingertips to face and neck, avoiding the eye area, to finalise a purifying, hydrating, replenishing treatment.

**Warnings:**

**Instant Facial Lifting Wonder Serum:**

'Airless Container – DO NOT remove top as this would introduce air and/or bacteria'

'Product level can be viewed through the gap in label'

'Store below 77°F/25°C in a cool dry place. Protect from light'

'Must not be combined with any other product range'

**O<sub>2</sub> Purifyer Face +Body Enhancing Serum:**

' Strictly for professional use'

'Airless container DO NOT remove top as this would introduce air and/or bacteria'

'Product level can be viewed through the gap in the label'

'Store below 77°F/25°C in a cool dry place. Protect from light'

'Must not be combined with any other product range'

A Silab IBPN technology® logo is present on the label signifying RégimA having a license to use FILMEXEL® in Instant Facial Lifting Wonder Serum and O<sub>2</sub> Purifyer Face + Body Enhancing Serum. The license and technical summary is presented in Appendix 4.

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for their firming and hydrating properties and with good local tolerance. There are no reasons to anticipate tolerance problems with use when used as directed.

This product is intended for external use in adults only.

### **B.4 Assessors Credentials and Approval of Part B**

Shirley Hudson (safety assessor)

BSc, University of Aberdeen

*CBiol, MSB*

20+ years as a practicing toxicologist in the pharmaceutical and chemical industries

A handwritten signature in black ink, appearing to read "Shirley H".

After analyzing of all of the available information including the product formulation and the toxicological profile of the ingredients, I conclude that according to the current state of scientific knowledge, this product is not expected to result in any significant damage to human health and can be safely marketed for the intended and foreseeable use as a face and body serum.

### **List of References**

SCCS Notes of Guidance for the Testing of Cosmetic Substances and Their Safety Evaluation, 9<sup>th</sup> Revision, 29 September 2015 (SCCS/1564/15)  
European Commission database on cosmetic ingredients (CosIng)  
<http://ec.europa.eu/consumers/cosmetics/cosing/>  
Cosmetic ingredient review <http://www.cir-safety.org/>

## METHOD OF MANUFACTURE / GMP CERTIFICATION



## **PROOF OF EFFECT CLAIMED**

This product claims to help with firming and purifying and provide firming and immediate long-lasting hydration, confirmatory evidence has been provided by RégimA. SpaZone Instant Facial Lifting Wonder Serum and O<sub>2</sub> Purifyer Face + Body Enhancing Serum contains an active ingredient called FILMEXEL® (with active botanicals Kappaphycus Alvarezii Extract and Caesalpinia Spinosa Fruit Pod Extract), this patented dynamic ingredient is categorised as providing a non-occlusive film known as a 'Second Skin' that mimicks its properties and functions. A technical summary outlining this proof of effect along with RégimA's license to use FILMEXEL® in Instant Facial Lifting Wonder Serum and O<sub>2</sub> Purifyer Face + Body Enhancing Serum is presented in Appendix 4.

## **ANIMAL TESTING STATEMENT**

To the best of our knowledge, the manufacturer and his suppliers have not carried out or commissioned any animal testing for the purpose of developing new cosmetic products.

The statement below is a confirmation of the company policy:

## **RégimA Skin Treatments**

CK92/05371/23  
VAT No. 4590131043

**Tel: 011 615 2869 or 011 622 7827**  
**Fax: 011 616 8008**  
**Cell: 0836537020**  
**e-mail: [jax@regima.com](mailto:jax@regima.com)**

**POSTAL ADDRESS: PO BOX 9523 Edenglen 1613**

**PHYSICAL ADDRESS: 20 River Road Morninghill Bedfordview 2007 RSA**

### Animal Testing Compliance Statement

This letter is to serve as testimony as to the practice of animal testing, and confirm that RégimA Skin Treatments has not, nor will not engage in any practice that involves animal testing in any form.

RégimA Skin Treatments hereby confirms neither the manufacturer nor RégimA Skin Treatments itself have commissioned or carried out any form of animal

testing during the course of product development. This applies to any and all activities performed as part of the development process, including, but not restricted to: R&D, stability testing, safety and toxicology assessments, suitability studies or any other facet related to the product's development.

## **Appendix 1: Safety Data Sheets or Ingredient Specifications**

Safety data sheets and technical data sheets for the ingredients are maintained electronically with the PIF by the Responsible Person. They are available on request.

## **Appendix 2: Microbial Challenge Test**

A microbial challenge test is maintained electronically with the PIF by the Responsible Person. It is available on request.

## **Appendix 3: Certificates of Allergen Content**



### **Allergen Analysis**

*Compound Name : BERGAMOT OIL {BOL-BE01}*

*Code Number : RCP-76695*

flavour ingredient	CAS No.	Concentration present as a percentage (%) or 'A' for absent in flavour		
		Added as such	From natural & other sources	Total
alpha-iso-Methylionone	127-51-5	A	A	A
Amyl Cinnamal	122-40-7	A	A	A
Amylcinnamyl Alcohol	101-85-9	A	A	A
Anise Alcohol	105-13-5	A	A	A
Benzyl Alcohol	100-51-6	A	A	A
Benzyl Benzoate	120-51-4	A	A	A
Benzyl Cinnamate	103-41-3	A	A	A
Benzyl Salicylate	118-58-1	A	A	A
Butylphenyl Methylpropional (Lilial)	80-54-6	A	A	A
Cinnamal	104-55-2	A	A	A
Cinnamyl Alcohol	104-54-1	A	A	A
Citral	5392-40-5	3.00	0.01	3.01
Citronellol	106-22-9	A	A	A
Coumarin	91-64-5	A	A	A
Eugenol	97-53-0	A	A	A
Evernia Furfuraceae (Tree Moss) Extract	90028-67-4	A	A	A
Evernia Prunastri (Oak Moss) Extract	90028-68-5	A	A	A
Famesol	4602-84-0	A	A	A
Geraniol	106-24-1	A	A	A
Hexyl Cinnamal	101-86-0	A	A	A
Hydroxycitronellal	107-75-5	A	A	A
Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde (Lyral)	31906-04-4	A	A	A
Isoeugenol	97-54-1	A	A	A
Limonene	5989-27-5	A	27.35	27.35
Linalool	78-70-6	10.00	0.05	10.05
Methyl 2-Octynoate	111-12-6	A	A	A

*The information contained herein is true and accurate to the best of our knowledge. All information is valid until revisions are issued. We will not therefore accept liability for misuse of this data resulting in damage or loss.*



## IFRA Conformity Certificate

Compound Name : BERGAMOT OIL {BOL-BE01}

Code Number : RCP-76695

We certify that the above compound is in compliance with the standards of the INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA-47th amendment, published June 2013), provided it is used at a maximum concentration level of:

IFRA category (*)	Maximum level of use (%) (w/w) (**)
1A,1B (***)	1.33 (***)
2	1.66
3A	6.64
3B	6.64
3C	6.64
3D	6.64
4A	19.91
4B	19.91
4C	19.91
4D	19.91
5	9.96
6 (***)	33.19 (***)
7A	3.32
7B	3.32
8A	46.47
8B	46.47
9A	100.00
9B	100.00
9C	100.00
10A	82.97
10B	82.97
11A	100.00
11B	100.00

(\*) See annex for definition of IFRA categories

(\*\*) Usage limit N/A = Not Applicable; no IFRA restrictions

(\*\*\*) IFRA would recommend that any material used to impart perfume or flavour in products intended for human ingestion should consist of ingredients that are in compliance with appropriate regulations for foods and food flavourings

For other kinds of application or use at higher concentrations, a new safety evaluation may be needed; please contact F.D. Copeland and Sons Ltd.

The IFRA Standards regarding restrictions are based on safety assessments by the Panel of Experts of the RESEARCH INSTITUTE FOR FRAGRANCE MATERIALS (RIFM) and are enforced by the IFRA Scientific Committee.

Evaluation of individual Fragrance ingredients is made according to the safety standards contained in the relevant section of the IFRA Code of Practice.

It is the ultimate responsibility of our customer to ensure the safety of the final product (containing this fragrance) by further testing if need be.

*The information contained herein is true and accurate to the best of our knowledge. All information is valid until revisions are issued. It is your responsibility to ensure that the usage of the fragrance ingredients and the levels of such usage are permitted at all times according to the relevant laws and regulations.*

ANNEX: Definition of IFRA categories

<b>Finished Product Types</b>	<b>IFRA category</b>
Lip products of all types (solid and liquid lipsticks, balms, clear or coloured, lipwax, etc.) Toys	1A (**)
Waxes for mechanical hair removal	1B
Deodorant and Antiperspirant Products of all types (pump spray, aerosol spray, stick, roll-on, under-arm and body, etc.) Fragranced Bracelets	2
Hydroalcoholic Products applied to recently shaved skin - EdT	3A
Hydroalcoholic Products applied to recently shaved skin- Fine fragrance	3B
Eye Products of all types (eye shadow, mascara, eyeliner, eye make-up, etc.) including eye care Men's Facial Creams and Balms; Baby Creams, Lotions, Oils; Body Paint for Children	3C
Tampons	3D
EdT: Hydroalcoholic Products applied to unshaved skin, Ingredients of Perfume Kits, Scent Pads, Foil Packs, Scent Strips for Hydroalcoholic Products	4A
Hydroalcoholic Products applied to unshaved skin - Fine fragrance	4B
Hair styling aids sprays of all types (pumps, aerosol sprays etc.), Hair Deodorant Body Creams, Oils, Lotions, Fragrancing Creams of all types (except baby creams, lotions and oils) Fragrance Compounds for Cosmetic Kits, Foot Care Products, Body Paint for Adults	4C
Fragrancing cream	4D
Women's Facial Creams/Facial Make-up, Hand Cream, Facial Masks Hand Sanitisers, Wipes or Refreshing Tissues for Face, Neck, Hands, Body Baby Powder and Talc Hair Permanent and Other Hair Chemical Treatments (e.g. relaxers) but not hair dyes, Dry Shampoo or Waterless Shampoo	5
Mouthwash, including Breath Sprays, Toothpaste	6 (**)
Intimate Wipes, Baby Wipes	7A
Insect Repellent (intended to be applied to the skin)	7B
Make-up Removers of all types (not including face cleansers) Hair Styling Aids Non-Spray of all types (mousse, gels, leave-in conditioners, etc.) Nail Care, Powders and talcs (not including baby powders and talcs)	8A
Hair Dyes	8B
Shampoos of all types (including baby shampoos), Conditioner (Rinse-Off), Face Cleansers of all types (washes, gels, scrubs, etc.), Liquid Soap, Bar Soap (Toilet Soap), Depilatory(not including waxes for mechanical hair removal), Shaving Creams of all types (stick, gels, foams, etc.) Body Washes of all types (including baby washes) and Shower Gels of all types Bath Gels, Foams, Mousses, Salts, Oils and other products added to bathwater	9A
Feminine Hygiene – pads, liners, Toilet Paper Wheat bags	9B
Other' Aerosols (incl. air freshener sprays and air freshener pump sprays, but not deodorants / antiperspirants, hair styling aids spray and animal sprays) Facial Tissues, Napkins, Paper Towels	9C
Handwash Laundry Detergents of all types including concentrates Machine Wash Laundry Detergents (liquids, powders, tablets etc.) including laundry bleaches and concentrates Fabric Softeners of all types including fabric softener sheets, Hand Dishwashing Detergent including concentrates Hard Surface Cleaners of all types (bathroom and kitchen cleaners, furniture polish etc.) Other Household Cleaning Products (fabric cleaners, soft surface cleaners, carpet cleaners etc.) Dry Cleaning Kits, Shampoo for pets	10A
Diapers, Toilet Seat Wipes	10B
All non-skin contact including: Air Fresheners and Fragrancing of all types (concentrated aerosol air fresheners, plug-ins, solid substrate, membrane delivery, ambient, electrical...) excluding aerosol products, Liquid refills for air fresheners (cartridge systems), Scent delivery system using a dry air technology that releases a fragrance without sprays, aerosols or heated oils (technology of nebulization), Air delivery systems Candles, Joss Sticks, Incense, Air freshening crystals, Fragranced lamp ring, Scent pack, Machine Only Laundry Detergent (e.g. liquitabs), Toilet Blocks, Insecticides (mosquito coil, paper, electrical, for clothing etc.) excluding aerosols Fuels, Paints, Floor wax, Plastic articles (excluding toys)	11A
All incidental skin contact including: Pot pourri, powders, fragrancing sachets, Incense, Reed diffusers, Liquid refills for airfresheners (non-cartrige systems) Odoured Distilled Water (that can be added to steam irons), Machine Dishwash Detergent and Deodorizers Deodorizers/Maskers not intended for skin contact (e.g. fabric drying machine deodorizers, carpet powders) Treated Textiles (e.g. starch sprays, fabric treated with fragrances after wash, deodorizers for textiles or fabrics, tights with moisturizers) Infused socks, Scratch and sniff (sampling technology) Shoe Polishes, Cat litter, Animal Sprays (all types)	11B

(\*\*) This IFRA certificate does not include a GRAS-FEMA conformity check

## **Appendix 4: Miscellaneous**

The stability report, packaging material information and product carton insert are maintained electronically with the PIF by the Responsible Person. They are available on request.

# PRODUCT INFORMATION FILE\*

RégimA

SpaZone Marine  
Replenishing Peptide  
Masque

Prepared: August 2018  
(Label & packaging update August 2021)

\*As required under Article 11 of the European Cosmetics Regulation EC No. 1223/2009

# TABLE OF CONTENTS

## Contents

INTRODUCTION .....	3
PRODUCT DESCRIPTION .....	3
COSMETIC PRODUCT SAFETY REPORT .....	7
Part A: Cosmetic Product Safety Information.....	7
A.1 Quantitative and qualitative composition of the cosmetic product:.....	7
A.2 Physical /chemical characteristics and stability of the cosmetic product .....	10
A.3 Microbiological Quality.....	12
A.4 Impurities, traces, information about the packaging material .....	12
A.5 Normal and reasonably foreseeable use.....	12
A.6 Exposure to the Cosmetic Product .....	12
A.7 Exposure to the Substances .....	13
A.8 Toxicological Profile of the Substances .....	15
A.9 Undesirable Effects and Serious Undesirable Effects.....	20
A.10 Information on the Cosmetic Product .....	20
B: Part Cosmetic Product Safety Assessment .....	21
B.1 Assessment Conclusion .....	21
B.2 Label Warnings and Instructions for Use .....	21
B.3 Reasoning .....	23
B.4 Assessors Credentials and Approval of Part B.....	23
List of References.....	23
METHOD OF MANUFACTURE / GMP CERTIFICATION.....	25
PROOF OF EFFECT CLAIMED .....	26
ANIMAL TESTING STATEMENT.....	26
Appendix 1: Safety Data Sheets or Ingredient Specifications .....	28
Appendix 2: Microbial Challenge Test .....	29
Appendix 3: Certificates of Allergen Content .....	30
Appendix 4: Miscellaneous .....	33

## **INTRODUCTION**

### **PRODUCT DESCRIPTION**

**Product Name:** SpaZone Marine Replenishing Peptide Masque

Product type	Face Mask
Form	Gel
Colour	Hazy
Pack size	150ml
Pack type	Chubby Chunky Airless Container
Dispenser type	Polypropylene Pump
Part of a set	No
Manufacturer code	HFM 002
Normal use	<b>Directions (150mls): To be used as part of a RégimA in-salon treatment.</b> Following RégimA Peel or facial apply eye care and desired serums, particularly O <sub>2</sub> Purifyer. Then apply a thin layer of Masque with fingertips to face and neck avoiding the eye area.

**Pictures of the Item: On following page**

Container label

Marine Replenishing Peptide Masque – 150ml



## Carton label

### Marine Replenishing Peptide Masque – 150ml



**Batch code:** The batch number is printed onto the underside of the carton and the container at the point of manufacturing and filling, therefore it is not visible on the label as represented in this PIF. The batching is automated, so the batch code and date is printed onto the carton and container as they are filled and boxed.

**Product claims:**

This product claims to provide immediate and long-lasting deep hydration.

## **COSMETIC PRODUCT SAFETY REPORT**

### **Part A: Cosmetic Product Safety Information**

#### **A.1 Quantitative and qualitative composition of the cosmetic product:**

### Marine replenishing peptide masque base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Water	5.2478	10	7732-18-5	231-791-2	Humectant/ Skin Conditioning/ Viscosity Controlling/ Solvent/ Skin Protecting/ Perfuming/ Absorbent/ Emollient/ Preservative	Provital (Savannah Fine Chemicals)	Hydromani™
	Propylene Glycol	2.2		57-55-6	200-338-0			
	Glycerin	1.6		56-81-5	200-289-5			
	Hydrolysed caesalpinia Spinosa Gum	0.7		39300-88-4	254-409-6			
	Caesalpinia Spinosa Gum	0.2		39300-88-4	254-409-6			
	Phenoxyethanol	0.0375		122-99-6	204-589-7			
	Methylparaben	0.00825		99-76-3	202-785-7			
	Butylparaben	0.00315		94-26-8	202-318-7			
	Ethylparaben	0.00215		120-47-8	204-399-4			
	Propylparaben	0.00115		94-13-3	202-307-7			
2	Water	5	5	7732-18-5	231-791-2	Solvent	In-House	Aqua(Water)
3	Almond Oil PEG-6 Esters	5	5	124046-50-0	#	Emollient/ Emlusifying	Croda Chemicals	Crovola A-70
4	Water	3.832	4	7732-18-5	231-791-2	Skin Protecting/ Skin Conditioning/ Solvent/ Preservative	Silab (Meganede)	Aquaphyline™
	Hydrolysed Viola Tricolor extract	0.14		84012-42-0	281-687-4			
	Phenoxyethanol	0.02		122-99-6	204-589-7			
	Ethylhexylglycerin	0.008		70445-33-9	408-080-2			
5	Glycerin	0.16	4	56-81-5	200-289-5	Humectant/ Perfuming/ Skin Protecting/ Viscosity Controlling	Various	Glycerine CP
6	Water	2.649	3	7732-18-5	231-791-2	Skin Conditioning/ Preservative	Silab (Meganede)	Cohesium®
	Ophiopogon japonicus root extract	0.33		952500-62-8	310-127-6			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Phenoxyethanol	0.015		122-99-6	204-589-7			
	Ethylhexylglycerin	0.006		70445-33-9	408-080-2			
7	Phenoxyethanol	0.9	1	122-99-6	204-589-7	Preservative/ Emollient/ Humectant/ Skin conditioning	Dr. Straetmans (Meganede)	Verstatil PC
	Caprylyl Glycol	0.1		1117-86-8	214-254-7			
8	Sodium hydroxide	0.8	1	1310-73-2	215-185-5	Solvent/ Buffering	Various	Sodium Hydroxide 20% Solution
	Water	0.2		7732-18-5	231-791-2			
9	Cyclohexane	0.8	0.8	110-82-7	203-806-2	Solvent	Noveon (Carst & Walker)	Carbopol Ultrez 30
10	Citrus bergamia Peel Oil Expressed	0.5	0.5	89957-91-5	289-612-9	Perfuming	FD Copeland (CJP chemicals)	Bergamont Oil
11	Caesalpinia Spinosa Fruit Pod Extract	0.095	0.2	39300-88-4	254-409-6	Hair Conditioning/ Skin Conditioning	Silab (Meganede)	Filmexel
	Kappaphycus Alvarezii Extract	0.095		1220882-73- 4	310-127-6			
	Water	0.01		7732-18-5	231-791-2			
12	Water (Aqua)	65.5	65.5	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

# not assigned

Ingredient order for the label: Water (Aqua), Almond Oil PEG-6 Esters, Propylene Glycol, Glycerin, Phenoxyethanol, Cyclohexane, Sodium Hydroxide, Hydrolysed Caesalpinia Spinosa Gum, Citrus bergamia peel oil expressed, Ophiopogon Japonicus Root Extract, Caesalpinia Spinosa Gum, Hydrolysed Viola Tricolor Extract, Limonene, Caprylyl Glycol, Caesalpinia Spinosa Fruit Pod Extract, Kappaphycus Alvarezii Extract, Linalool, Citral, Ethylhexylglycerin, Methylparaben, Butylparaben, Ethylparaben, Propylparaben, Linalyl Acetate

Red font denotes ingredients present at less than 1% which may be listed in any order.

Below are the allergens and their respective concentrations in the fragrance that are required to be listed in Article 19 Paragraph 1(d) & (g (ii)) of EC 1223/2009 when present at levels >0.001% in a leave-on product.

#### Fragrance allergens

INCI (EU) Name	CAS number	EC number	Concentration % w/w
Linalyl Acetate	115-95-7	204-116-4	0.161
Alpha-pinene	80-56-8	201-291-9	0.0145
Limonene	5989-27-5	227-813-5	0.13675
Linalool	78-70-6	201-134-4	0.05025
Citral	5392-40-5	226-394-6	0.01505

#### A.2 Physical /chemical characteristics and stability of the cosmetic product

Physical and chemical characteristics of the ingredients have been listed in the safety data sheets which are maintained electronically by the Responsible Person and are available on request. A cross reference to the SDS tradename and electronic reference number has been shown in the base formula table.

## **Physical and Chemical Characterization of the product**

1 Physical state	Gel
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Emulsion
3 organoleptic properties (colour, odour, whenever relevant)	Slightly Hazy gel with a characteristic odour.
4 pH (at 25°C)	4.01
5 viscosity (at 25°C)	72000 cPs
6 thermal stability (glass bottle)	50 °C for 12 weeks
7 Specific gravity (at 25°C)	1.003g/ml

## **Stability of the product**

A shelf-life of 6 month after opening has been allocated to this product.

An on-going stability study of the product in the packaging will be available to support the shelf-life. A stability test of the product in glass jars has confirmed stability at 25°C for 12 weeks, at which point the product appeared to be very slightly yellow, the pH increased by 12% and the viscosity decreased by 17% .

It is not expected that these changes in physical parameters will affect the stability of the product as formulated. The stability report is provided in Appendix 4.

### **A.3 Microbiological Quality**

A PET test has been performed according to USP method 38 and confirms the effectiveness of the preservative for a period of 28 days. The certificate has been presented in Appendix 2.

### **A.4 Impurities, traces, information about the packaging material**

None of the ingredients of this product contained impurities at a level which would require notification.

A statement on the suitability of the product packaging is shown below.

The Chubby Chunky Airless Containers is made from Polypropylene. The pump is composed of a mixture of Polypropylene, Low density Polyethylene (LDPE) and High density Polyethylene (HDPE). The components of the packaging material and suitability of use criteria are included in a certificate in Appendix 4. This is maintained electronically with the PIF by the Responsible Person and is available on request.

### **A.5 Normal and reasonably foreseeable use**

Marine Replenishing Peptide Masque is a product designed to promote immediate and long-lasting deep hydration. It is a leave on face masque that in normal circumstances will be used once daily in the evening on the face and neck, avoiding the eye area.

### **A.6 Exposure to the Cosmetic Product**

Site of application	Face and neck
Surface area of application (cm <sup>2</sup> )	885cm <sup>2</sup> *
Volume of product applied (mg)	250
Frequency of application/use per day	1/week
Target population	Adults
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	Relative daily exposure of 0.25g was calculated to be 4.17 mg/kg bw/day based on a nominal 60kg human body weight
Dermal absorption information	None available
other	NA

\*Total Surface area for Marine Replenishing Peptide Masque =885cm<sup>2</sup>. This surface area was determined as follows; Skincare, face cream surface area 565cm<sup>2</sup> plus Skincare, neck surface area 320cm<sup>2</sup>. These figures have been extracted from SCCS Notes for Guidance for the testing of Cosmetic Ingredients and their safety Evaluation, 9<sup>th</sup> Revision, Section 4.2, Table 1, page 76.

## A.7 Exposure to the Substances

Daily Systemic Exposure Dosage (SED) is the daily amount of a cosmetic substance applied based on the concentration of that particular substance, the percutaneous absorption and the nominal human body weight (60 kg) and this is shown in the table below.

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Almond Oil PEG-6 Esters 124046-50-0	5	4.17	1	0.2085
Propylene Glycol 57-55-6	2.2	4.17	1	0.0917
Glycerin 56-81-5	1.76	4.17	1	0.0734
Phenoxyethanol 122-99-6	0.9725	4.17	1	0.0406
Cyclohexane 110-82-7	0.8	4.17	1	0.0334
Sodium hydroxide 1310-73-2	0.8	4.17	1	0.0334
Hydrolysed caesalpinia Spinosa Gum 39300-88-4	0.7	4.17	1	0.0292
Citrus bergamia peel oil expressed (also known as the perfuming name: Citrus Reticulata, X C. Sinensis Peel Extract)	0.5	4.17	1	0.02085
Ophiopogon japonicus root extract 952500-62-8	0.33	4.17	1	0.0138
Caesalpinia Spinosa Gum 39300-88-4	0.2	4.17	1	0.00834
Hydrolysed Viola Tricolor extract 84012-42-0	0.14	4.17	1	0.00584
Caprylyl Glycol 1117-86-8	0.1	4.17	1	0.00417
Caesalpinia Spinosa Fruit Pod Extract 39300-88-4	0.095	4.17	1	0.00396
Kappaphycus Alvarezii Extract 1220882-73-4	0.095	4.17	1	0.00396
Ethylhexylglycerin 70445-33-9	0.014	4.17	1	0.00058
Methylparaben 99-76-3	0.00825	4.17	1	0.00034

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Butylparaben 94-26-8	0.00315	4.17	1	0.00013
Ethylparaben 120-47-8	0.00215	4.17	1	0.000090
Propylparaben 94-13-3	0.00115	4.17	1	0.000048

# No dermal absorption is available, however 100% dermal absorption is used as Marine Replenishing Peptide Masque is a leave on product.

## A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Almond Oil PEG-6 Esters 124046-50-0	A	2014 CIR Compendium. Safe for use in cosmetics when formulated to be non-irritating. Almond Oil PEG-6 esters is the product of transesterification of Prunus Amygdalus dulcis (Almond) Oil and PEG-G. The limits of the outlined reactants are stated as up to 77% and 51% respectively, where Almond oil was determined to be non-irritating and PEG-6 safe for use in cosmetics. Full amended report 09/12 available from CIR; IJT 33 (Suppl 4):13-39, 2014. It was determined that the use of Almond Oil PEG-6 Esters is safe to use Marine Replenishing Peptide Masque at the level of 5%.								
Propylene Glycol 57-55-6	A	2014 CIR Compendium. For use up to 50%. JACT 13(6):437-91, 1994; IJT 21(2) 245-260, 2012.								
Glycerin 56-81-5	A	Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin.								
Phenoxyethanol 122-99-6	A	2014 CIR Compendium, for use up to 1%. JACT 9(2):259-77, 1990.								
Cyclohexane 110-82-7	B	Available data on Cyclohexane indicated that it has a low order of toxicity, no ADI has been established according to JECFA report 23/19. Evaluation of certain food additives. Twenty-third Report of the Joint FAO/WHO Expert Committee on Food Additives. (1981). <i>Food and Cosmetics Toxicology</i> , 19, p381.  Cyclohexane is almost completely absorbed by the oral and inhalation route with dermal absorption of pure liquid cyclohexane in contact with the skin being 5%, this percentage is significantly reduced use Marine Replenishing Peptide Masque due to Cyclohexane being present in the formulation at 0.8% therefore the dermal absorption would be reduced. Cyclohexane is considered to be a skin irritant with the properties being delayed and persistent while it was not considered to be sensitizer. The NOAEL ranged from 250 ppm to 2,000 ppm in a number of animal and human toxicity testing. Taking 250ppm as the worst case scenario NOAEL the MoS was calculated to be 7485. It is considered that a value above 100 is generally considered to be safe. Cyclohexane is present at a level of 0.0334 mg/kg bw/day in use Marine Replenishing Peptide Masque, considerable lower than the level outlined as a NOAEL and therefore safe for use. Cyclohexane, Summary Risk Assessment Report. (2004). European Commission Joint Research Centre, Institute for health								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment	
		<i>and Consumer Protection, European Chemicals Bureau, special Publication 1.04.22, pp 1-15. This report is presented in Appendix 4.</i>									
Sodium hydroxide 1310-73-2	A									For use up to 6.9% in leave on cosmetics. Restricted to use in formulations where pH must be below pH 11. The pH of Marine Replenishing Peptide Masque is indicated on the stability report as pH 4.01. Human dermal irritation studies indicated irritation caused by sodium Hydroxide at levels as low as 0.5, with dermal sensitization HRIPT challenge test sodium hydroxide was not sensitizing when induced up to 1% and when challenged at 0.125% irritation was observed. Final report 12/15, available CIR website. The pH of Marine replenishing Peptide Masque indicated a pH of 4.01 ; lower than pH 11 outlined. With the combination of sufficient pH and Sodium Hydroxide present in formulation at 0.8%, no serious undesirable effects are expected when used as directed.	
Hydrolysed caesalpinia Spinosa Gum 39300-88-4	A									For use up to 0.4% in leave on formulations, it is currently present in formulation at 0.7%. A read across to Caesalpinia Spinosa Gum toxicology was performed and the assessment found that the skin irritation potential was low and determined to be non-irritating. Hydrolysed Caesalpinia Spinosa Gum is classed as a Galactomannan, which are large molecules with a molecular weight of greater than 50,000 g/mole and often exceed 2,000,000 g/mole, therefore systemic safety is not considered as the dermal absorption potential is reduced. Caesalpinia Spinosa Gum has been approved for use as a food ingredient by the JECFA and an ADI has not been specified. IJT 34 (Suppl. 1):35-65, 2015. It was determined that the inclusion of Hydrolysed Caesalpinia Spinosa Gum in Marine Replenishing Peptide Masque will not cause any serious undesired effects when used as directed.	
Ophiopogon japonicus root extract 952500-62-8	##									A secondary assessment has been performed for <i>Ophiopogon japonicus</i> (OJ) root extract. A clinical trial (n=858) outlined a dose of 11,800 mg (196.6 mg/kg bw/day) which is 14,246 times lower than the concentration in the outlined product (0.0138 mg/kg bw/day). Mild adverse effects were noted in the high dose intravenous group (60ml/day); the effects included mild insomnia, dry mouth and stomach discomfort. No serious undesired effects are expected with the use of OJ in Marine Replenishing Peptide Masque when used as directed.	
Caesalpinia Spinosa Gum	A									Safe when used up to 0.5%, CIR compendium 2014. Final report 03/12 available from CIR. Caesalpinia Spinosa Gum is present in Marine Replenishing Peptide Masque at a level of 0.2% and it was determined	

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment								
39300-88-4			that at this level no serious undesirable effects are expected when used as desired.															
Hydrolysed Viola Tricolor extract 84012-42-0	##	A secondary assessment was performed on Hydrolysed Viola Tricolor extract. According to the EMA final assessment, the worst case dose of Hydrolysed Viola Tricolour was outlined to be 37.5 mg/kg bw/day, 6421 times greater than the stated amount in Marine Replenishing Peptide Masque. It was therefore concluded to be safe for use by adolescents and adults only. A read across was performed to a product called <i>ABS Viola Tricolor PF</i> , with INCI name of <u>Hydrolyzed Viola Tricolor</u> where <i>In vitro</i> toxicological tests concluded that Hydrolysed Tricolor was a nether a dermal nor ocular irritant. It is not expected that the presence of Hydrolysed Viola tricolor extract at a concentration of 0.14% (at 0.00584 mg/kg bw/day) would cause any serious undesired effects when used as directed.																
Caprylyl Glycol 1117-86-8	A	2014 CIR Compendium. For use up to 5%, IJT 31 (S2):147-168,2012.																
Caesalpinia Spinosa Fruit Pod Extract 39300-88-4	##	A read across was performed to Caesalpinia spinosa gum, where it was approved for use as a food ingredient by JECFA with no specific ADI assigned for man. The read across was performed to Caesalpinia Spinosa Gum due to both ingredients originating from the same plant family; Caesalpiniaceae. The fruit pod extract is similar to the gum as they are both largely contain polysaccharide's. It was determined that Caesalpinia Spinosa Fruit Pod Extract was safe for use in Marine Replenishing Peptide Masque due to its low level inclusion ( 0.095%) and a read across to Caesalpinia Spinosa Gum determining it approved as a food ingredient.																
Kappaphycus Alvarezii Extract 1220882-73-4	##	A secondary assessment was performed on Kappaphycus Alvarezii Extract where the proprietary ingredient sulphated galactan; Carrageenan was evaluated. Carrageenan is isolated from red seaweeds with molecular weights of between 200,000 and 400,000, with dermal penetration evaluated as being limited due to the large size of the molecule. Carrageenan is GRAS by the US FDA under the Code of Federal Regulations (21 CFR 182.7255) and is also approved as food additive ingredient. Carrageenan has also been considered safe for food use with no ADI and Considered acceptable for use topically It is expected that Kappaphycus Alvarezii Extract is safe for use in Marine Replenishing Masque.																
Ethylhexylglycerin 70445-33-9	A	2014 CIR Compendium. Safe for use up to 2% in leave on formulations. The skin irritation and sensitization potential of a foundation containing 0.4% ethylhexylglycerin in a RIPT with 108 males and females was evaluated where the test substance was applied for 24 hours for a total of 9 induction applications. There																

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
			was 109 participants in the challenge phase where the test sites were scored at the time of patch removal, 24 and 48 hours later. It was determined that the foundation was neither a skin irritant nor a sensitizer. IJT 32 (Suppl. 3):5-21, 2013.							
Methylparaben 99-76-3	A	2014 CIR Compendium. For use up to 0.4% if used alone; parabens mixture up to 0.8%. IJT 27(S4):1-82, 2008 JACT 3(5):147-209. 1984 (original report). Methylparaben is present in Marine Replenishing Peptide Masque in a paraben mixture and therefore is allowed a maximum value of 0.8% in formulation.								
Butylparaben 94-26-8	A	2014 CIR Compendium. For use up to 0.4% if used alone; parabens mixture up to 0.8%. IJT 27(S4):1-82, 2008 JACT 3(5):147-209. 1984 (original report). Butylparaben is present in Marine Replenishing Peptide Masque in a paraben mixture and therefore is allowed a maximum value of 0.8% in formulation.								
Ethylparaben 120-47-8	A	2014 CIR Compendium. For use up to 0.4% if used alone; parabens mixture up to 0.8%. IJT 27(S4):1-82, 2008 JACT 3(5):147-209. 1984 (original report). Ethylparaben is present in Marine Replenishing Peptide Masque in a paraben mixture and therefore is allowed a maximum value of 0.8% in formulation.								
Propylparaben 94-13-3	A	2014 CIR Compendium. For use up to 0.4% if used alone; parabens mixture up to 0.8%. IJT 27(S4):1-82, 2008 JACT 3(5):147-209. 1984 (original report). Propylparaben is present in Marine Replenishing Peptide Masque in a paraben mixture and therefore is allowed a maximum value of 0.8% in formulation.								
Citrus Bergamia Peel Oil Expressed	B	Supplier IFRA Certificate of conformity for Bergamot Oil is supplied and presented in Appendix 3. The maximum allowable concentration; Category 5 - Women's facial creams is 9.96 % w/w . The actual concentration in the formulation is 0.5%. The allergen components are declared in section A.1. Fragrance Allergen table. Citrus Bergamia Peel Oil Expressed will be indicated in the label along with its fragrance components. It has been determined that the use of Bergamot Oil is safe for use in Marine Replenishing Peptide Masque.								

<sup>a</sup> Some ingredients are excluded from a formal risk assessment where a recognized authority has published a review of the ingredient under similar conditions of use and concluded on safe use at the level of inclusion in the cosmetic product (Hazard ID=A). Hazard ID category B is for recognized authority reviews of the ingredient under similar conditions of use with restricted use or where the ingredient is contained in the annexes to Regulation (EC) No 1223/2009 (Hazard ID=B). Where hazard ID A or B is reported, the maximum allowed usage concentration should be stated.

<sup>b</sup> all possible routes of exposure should be considered

<sup>c</sup> A MoS of greater than 100 is considered to represent safe use

# Food item, hazard and exposure data not required

## A secondary assessment has been performed on this ingredient, the assessment is presented in Appendix 4

**Fragrances:**

Marine Replenishing Peptide Masque contains a fragrance called Citrus Bergamia Peel Oil Expressed (Bergamot Oil). Allergens above the limit of 0.001% for leave on cosmetics include Limonene, Linalool, Citral, Alpha-Pinene and Linalyl Acetate with their corresponding concentrations outlined in Section A.1. The IFRA certificate and conformity certificate are presented in Appendix 3.

**A.9 Undesirable Effects and Serious Undesirable Effects**

No undesirable effects are anticipated based on the product being used as directed on the face twice daily.

**A.10 Information on the Cosmetic Product**

Marine Replenishing Peptide Masque was released in 2017. Over the period August 2017 to August 2018 2045 units have been sold and there have been no adverse reactions reported to RégimA Company.

## **B: Part Cosmetic Product Safety Assessment**

### **B.1 Assessment Conclusion**

#### Review of the ingredients

After analysis of all the available information including:

- formulation
- toxicological profile of the ingredients and their concentration in the product
- Product data sheets supplied by the ingredient manufacturer

It is not expected that Marine Replenishing Peptide Masque will cause damage to human health when used as directed.

It is therefore concluded that Marine Replenishing Peptide Masque can be placed on the market in the EU as a face masque.

#### Review of human data on the product

There are no human tests such as a patch test, for this product.

### **B.2 Label Warnings and Instructions for Use**

Directions for use are given on the product label and the product outer packaging. These labels and product outer packaging is presented in Appendix 4.

**Directions (50mls) PM:** Once weekly or as desired. Following a RégimA peel or facial apply eye care and desired serums. Particularly O<sub>2</sub> Purifyer. Then apply a thin Layer of masque with fingertips to face and neck, avoiding the eye area. Leave masque on and only cleanse in the morning. To be followed by RégimA daily home care.

**Directions (150mls): To be used as part of a RégimA in-salon treatment.** Following RégimA Peel or facial apply eye care and desired serums, particularly O<sub>2</sub> Purifyer. Then apply a thin layer of Masque with fingertips to face and neck avoiding the eye area.

This is a leave-on decadent Masque designed to provide immediate and long lasting deep hydration.

**Warnings:**

**50ml Bottle:**

'Must NOT be combined with any other product range'

'Airless Container DO NOT remove top as this would introduce air and/or bacteria'

'Product level can be viewed through the gap in label'

'Store below 77°F/25°C in a cool dry place. Protect from light'

'Strictly for professional use'

**150ml Bottle:**

'Must NOT be combined with any other product range'

'Airless Container DO NOT remove top as this would introduce air and/or bacteria'

'Product level can be viewed through the gap in label'

'Store below 77°F/25°C in a cool dry place. Protect from light'

A Silab IBPN technology® logo is present on the label signifying RégimA having a license to use FILMEXEL® in Marine Replenishing Peptide Masque. The license and technical summary is presented in Appendix 4.

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for their properties and with good local tolerance when used as directed. There are no reasons to anticipate tolerance problems when used once weekly.

This product is intended for external use in adults only.

### **B.4 Assessors Credentials and Approval of Part B**

Shirley Hudson (safety assessor)

BSc, University of Aberdeen

*CBiol, MSB*

20+ years as a practicing toxicologist in the pharmaceutical and chemical industries



After analyzing of all of the available information including the product formulation and , toxicological profile of the ingredients, I conclude that according to the current state of scientific knowledge, this product is not expected to result in any significant damage to human health and can be safely marketed for the intended and foreseeable use as a face masque.

### **List of References**

SCCS Notes of Guidance for the Testing of Cosmetic Substances and Their Safety Evaluation, 9<sup>th</sup> Revision, 29 September 2015 (SCCS/1564/15)

European Commission database on cosmetic ingredients (CosIng)

<http://ec.europa.eu/consumers/cosmetics/cosing/>

Cosmetic ingredient review <http://www.cir-safety.org/>

JECFA report on the '*Evaluation of certain food additives*' referring to Cyclohexane.

[http://apps.who.int/iris/bitstream/handle/10665/41403/WHO\\_TRS\\_648.pdf?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/41403/WHO_TRS_648.pdf?sequence=1)

Cyclohexane CAS no: 110-82-7, EINECS No: 203-806-2, Summary Risk Assessment Report, European Commission, Special Publication I.04.22, Joint Research Centre,

Institute for Health and Consumer Protection, European Chemicals Bureau, Italy, 2004.  
This report is presented in Appendix 4.

## METHOD OF MANUFACTURE / GMP CERTIFICATION



## **PROOF OF EFFECT CLAIMED**

This product claims to provide immediate and long-lasting deep hydration, confirmatory evidence has been provided by RégimA. SpaZone Marine Replenishing Peptide Masque contains an active ingredient called FILMEXEL® (with active botanicals Kappaphycus Alvarezzi Extract and Caesalpinia Spinosa Fruit Pod Extract), this patented dynamic ingredient is categorised as providing a non-occlusive film known as a 'Second Skin' that mimicks its properties and functions. A technical summary outlining this proof of effect along with RégimA's license to use FILMEXEL® in Marine Replenishing Peptide Masque is presented in Appendix 4.

## **ANIMAL TESTING STATEMENT**

To the best of our knowledge, the manufacturer and his suppliers have not carried out or commissioned any animal testing for the purpose of developing new cosmetic products.

The statement below is a confirmation of the company policy:

## **RégimA Skin Treatments**

CK92/05371/23  
VAT No. 4590131043

**Tel: 011 615 2869 or 011 622 7827**  
**Fax: 011 616 8008**  
**Cell: 0836537020**  
**e-mail: [jax@regima.com](mailto:jax@regima.com)**

**POSTAL ADDRESS: PO BOX 9523 Edenglen 1613**

**PHYSICAL ADDRESS: 20 River Road Morninghill Bedfordview 2007 RSA**

### Animal Testing Compliance Statement

This letter is to serve as testimony as to the practice of animal testing, and confirm that RégimA Skin Treatments has not, nor will not engage in any practice that involves animal testing in any form.

RégimA Skin Treatments hereby confirms neither the manufacturer nor RégimA Skin Treatments itself have commissioned or carried out any form of animal testing during the course of product development. This applies to any and all activities performed as part of the development process, including, but not restricted to: R&D, stability testing, safety and toxicology assessments, suitability studies or any other facet related to the product's development.



## **Appendix 1: Safety Data Sheets or Ingredient Specifications**

Safety data sheets and technical data sheets for the ingredients are maintained electronically with the PIF by the Responsible Person. They are available on request.

## **Appendix 2: Microbial Challenge Test**

A microbial challenge test is maintained electronically with the PIF by the Responsible Person. It is available on request.

## Appendix 3: Certificates of Allergen Content

### Allergen Analysis

Compound Name : BERGAMOT OIL {BOL-BE01}

Code Number : RCP-76695

flavour ingredient	CAS No.	Concentration present as a percentage (%) or 'A' for absent in flavour		
		Added as such	From natural & other sources	Total
alpha-iso-Methylionone	127-51-5	A	A	A
Amyl Cinnamal	122-40-7	A	A	A
Amylcinnamyl Alcohol	101-85-9	A	A	A
Anise Alcohol	105-13-5	A	A	A
Benzyl Alcohol	100-51-6	A	A	A
Benzyl Benzoate	120-51-4	A	A	A
Benzyl Cinnamate	103-41-3	A	A	A
Benzyl Salicylate	118-58-1	A	A	A
Butylphenyl Methylpropional (Lilial)	80-54-6	A	A	A
Cinnamal	104-55-2	A	A	A
Cinnamyl Alcohol	104-54-1	A	A	A
Citral	5392-40-5	3.00	0.01	3.01
Citronellol	106-22-9	A	A	A
Coumarin	91-64-5	A	A	A
Eugenol	97-53-0	A	A	A
Evernia Furfuraceae (Tree Moss) Extract	90028-67-4	A	A	A
Evernia Prunastri (Oak Moss) Extract	90028-68-5	A	A	A
Famesol	4602-84-0	A	A	A
Geraniol	106-24-1	A	A	A
Hexyl Cinnamal	101-86-0	A	A	A
Hydroxycitronellal	107-75-5	A	A	A
Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde (Lyral)	31906-04-4	A	A	A
Isoeugenol	97-54-1	A	A	A
Limonene	5989-27-5	A	27.35	27.35
Linalool	78-70-6	10.00	0.05	10.05
Methyl 2-Octynoate	111-12-6	A	A	A

## IFRA Conformity Certificate

*Compound Name : BERGAMOT OIL {BOL-BE01}*  
*Code Number : RCP-76695*

We certify that the above compound is in compliance with the standards of the INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA-47th amendment, published June 2013), provided it is used at a maximum concentration level of:

<b>IFRA category (*)</b>	<b>Maximum level of use (%)(w/w) (**)</b>
1A,1B (***)	1.33 (***)
2	1.66
3A	6.64
3B	6.64
3C	6.64
3D	6.64
4A	19.91
4B	19.91
4C	19.91
4D	19.91
5	9.96
6 (***)	33.19 (***)
7A	3.32
7B	3.32
8A	46.47
8B	46.47
9A	100.00
9B	100.00
9C	100.00
10A	82.97
10B	82.97
11A	100.00
11B	100.00

(\*) See annex for definition of IFRA categories

(\*\*) Usage limit N/A = Not Applicable; no IFRA restrictions

(\*\*\*) IFRA would recommend that any material used to impart perfume or flavour in products intended for human ingestion should consist of ingredients that are in compliance with appropriate regulations for foods and food flavourings

For other kinds of application or use at higher concentrations, a new safety evaluation may be needed; please contact F.D. Copeland and Sons Ltd.

The IFRA Standards regarding restrictions are based on safety assessments by the Panel of Experts of the RESEARCH INSTITUTE FOR FRAGRANCE MATERIALS (RIFM) and are enforced by the IFRA Scientific Committee.

Evaluation of individual Fragrance ingredients is made according to the safety standards contained in the relevant section of the IFRA Code of Practice.

It is the ultimate responsibility of our customer to ensure the safety of the final product (containing this fragrance) by further testing if need be.

**ANNEX: Definition of IFRA categories**

<b>Finished Product Types</b>	<b>IFRA category</b>
Lip products of all types (solid and liquid lipsticks, balms, clear or coloured, lipwax, etc.) Toys	1A (**)
Waxes for mechanical hair removal	1B
Deodorant and Antiperspirant Products of all types (pump spray, aerosol spray, stick, roll-on, under-arm and body, etc.) Fragranced Bracelets	2
Hydroalcoholic Products applied to recently shaved skin - EdT	3A
Hydroalcoholic Products applied to recently shaved skin- Fine fragrance	3B
Eye Products of all types (eye shadow, mascara, eyeliner, eye make-up, etc.) including eye care Men's Facial Creams and Balms; Baby Creams, Lotions, Oils; Body Paint for Children	3C
Tampons	3D
EdT: Hydroalcoholic Products applied to unshaved skin, Ingredients of Perfume Kits, Scent Pads, Foil Packs, Scent Strips for Hydroalcoholic Products	4A
Hydroalcoholic Products applied to unshaved skin - Fine fragrance	4B
Hair styling aids sprays of all types (pumps, aerosol sprays etc.), Hair Deodorant Body Creams, Oils, Lotions, Fragrancing Creams of all types (except baby creams, lotions and oils) Fragrance Compounds for Cosmetic Kits, Foot Care Products, Body Paint for Adults	4C
Fragrancing cream	4D
Women's Facial Creams/Facial Make-up, Hand Cream, Facial Masks Hand Sanitisers, Wipes or Refreshing Tissues for Face, Neck, Hands, Body Baby Powder and Talc Hair Permanent and Other Hair Chemical Treatments (e.g. relaxers) but not hair dyes, Dry Shampoo or Waterless Shampoo	5
Mouthwash, including Breath Sprays, Toothpaste	6 (**)
Intimate Wipes, Baby Wipes	7A
Insect Repellent (intended to be applied to the skin)	7B
Make-up Removers of all types (not including face cleansers) Hair Styling Aids Non-Spray of all types (mousse, gels, leave-in conditioners, etc.) Nail Care, Powders and talcs (not including baby powders and talcs)	8A
Hair Dyes	8B
Shampoos of all types (including baby shampoos), Conditioner (Rinse-Off), Face Cleansers of all types (washes, gels, scrubs, etc.), Liquid Soap, Bar Soap (Toilet Soap), Depilatory(not including waxes for mechanical hair removal), Shaving Creams of all types (stick, gels, foams, etc.) Body Washes of all types (including baby washes) and Shower Gels of all types Bath Gels, Foams, Mousses, Salts, Oils and other products added to bathwater	9A
Feminine Hygiene – pads, liners, Toilet Paper Wheat bags	9B
Other' Aerosols (incl. air freshener sprays and air freshener pump sprays, but not deodorants / antiperspirants, hair styling aids spray and animal sprays) Facial Tissues, Napkins, Paper Towels	9C
Handwash Laundry Detergents of all types including concentrates Machine Wash Laundry Detergents (liquids, powders, tablets etc.) including laundry bleaches and concentrates Fabric Softeners of all types including fabric softener sheets, Hand Dishwashing Detergent including concentrates Hard Surface Cleaners of all types (bathroom and kitchen cleaners, furniture polish etc.) Other Household Cleaning Products (fabric cleaners, soft surface cleaners, carpet cleaners etc.) Dry Cleaning Kits, Shampoo for pets	10A
Diapers, Toilet Seat Wipes	10B
All non-skin contact including: Air Fresheners and Fragrancing of all types (concentrated aerosol air fresheners, plug-ins, solid substrate, membrane delivery, ambient, electrical..) excluding aerosol products, Liquid refills for air fresheners (cartridge systems), Scent delivery system using a dry air technology that releases a fragrance without sprays, aerosols or heated oils (technology of nebulization), Air delivery systems Candles, Joss Sticks, Incense, Air freshening crystals, Fragranced lamp ring, Scent pack, Machine Only Laundry Detergent (e.g. liquitabs), Toilet Blocks, Insecticides (mosquito coil, paper, electrical, for clothing etc.) excluding aerosols Fuels, Paints, Floor wax, Plastic articles (excluding toys)	11A
All incidental skin contact including: Pot pourri, powders, fragrancing sachets, incense, Reed diffusers, Liquid refills for airfresheners (non-cartridge systems) Odoured Distilled Water (that can be added to steam irons), Machine Dishwash Detergent and Deodorizers Deodorizers/Maskers not intended for skin contact (e.g. fabric drying machine deodorizers, carpet powders) Treated Textiles (e.g. starch sprays, fabric treated with fragrances after wash, deodorizers for textiles or fabrics, tights with moisturizers) Infused socks, Scratch and sniff (sampling technology) Shoe Polishes, Cat litter, Animal Sprays (all types)	11B

## **Appendix 4: Miscellaneous**

The stability report, packaging material information and product carton insert are maintained electronically with the PIF by the Responsible Person. They are available on request.

# PRODUCT INFORMATION FILE\*

RégimA Company

*Neck + Breast Refining  
Complex Masque*

Prepared: May 2018  
(Label & packaging update August 2021)

\*As required under Article 11 of the European Cosmetics Regulation EC No. 1223/2009

## TABLE OF CONTENTS

### Contents

INTRODUCTION.....	3
PRODUCT DESCRIPTION.....	3
COSMETIC PRODUCT SAFETY REPORT.....	7
Part A: Cosmetic Product Safety Information.....	7
A.1 Quantitative and qualitative composition of the cosmetic product:.....	7
A.2 Physical /chemical characteristics and stability of the cosmetic product .....	12
A.3 Microbiological Quality.....	14
A.4 Impurities, traces, information about the packaging material .....	14
A.5 Normal and reasonably foreseeable use.....	14
A.6 Exposure to the Cosmetic Product.....	14
A.7 Exposure to the Substances .....	15
A.8 Toxicological Profile of the Substances .....	17
A.9 Undesirable Effects and Serious Undesirable Effects.....	27
A.10 Information on the Cosmetic Product .....	27
B: Part Cosmetic Product Safety Assessment.....	28
B.1 Assessment Conclusion .....	28
B.2 Label Warnings and Instructions for Use .....	28
B.3 Reasoning .....	30
B.4 Assessors Credentials and Approval of Part B.....	30
List of References.....	30
METHOD OF MANUFACTURE / GMP CERTIFICATION.....	31
PROOF OF EFFECT CLAIMED .....	32
ANIMAL TESTING STATEMENT.....	33
Appendix 1: Safety Data Sheets or Ingredient Specifications .....	34
Appendix 2: Microbial Challenge Test .....	35
Appendix 3: Certificates of Allergen Content .....	36
Appendix 4: Miscellaneous .....	39

## INTRODUCTION

### PRODUCT DESCRIPTION

**Product Name:** Neck + Breast Refining Complex Masque

Product type	Neck, décolleté and breast cream
Form	Cream
Colour	Off white
Pack size	50 ml & 150ml
Pack type	Chubby Chunky Airless Containers
Dispenser type	Polypropylene pump
Part of a set	No
Manufacturer code	SBRR 002
Normal use	<p><b>Directions:</b> <b>50ml.</b> AM &amp; PM; Cleanse with RégimA, apply eye care products. Apply a thin layer of Neck + Breast Complex to neck, décolleté and breasts. To be followed daily by application of RégimA day product containing sun protection.</p> <p><b>150ml:</b> To be used as part of a RégimA in-salon treatment. This Neck + Breast Complex may be used as a Masque during a RégimA facial. Apply a think layer to neck, décolleté and breasts. This may be left on and additional hydrating or treatment products applied over if desired.</p>

**Pictures of the Item: On following page**

Container label

Commented [HM1]: Triple check labels

### Neck + Breast Refining Complex – 50ml



## Carton label

### Neck + Breast Refining Complex – 50ml



**Batch code:** The batch number is printed onto the underside of the carton and the container at the point of manufacturing and filling; therefore, it is not visible on the label as represented in this PIF. The batching is automated, so the batch code and date is printed onto the carton and container as they are filled and boxed.

**Product claims:**

This product claims the following:

*Restoration is available in the form of combined technologically advanced renewal active ingredients. Shiitake mushrooms, rich in oligosaccharides, anti-inflammatories, antioxidants, vitamins and minerals, fortify firmness and tonicity whilst lightening uneven skin colour. Increased elasticity is achieved by limiting degradation of Collagen I and III fibers, thereby reducing skin fatigability.*

*Remodeling of the contours of the neck and breasts, increasing density and firmness is ultimate anti-ageing, achieved by boosting natural actives in the form of phytonutrients, including purified black pepper berries, proven to restore elasticity, tightness, smoothing, improving colour and texture.*

*The combination of firming and contouring precious actives results in a firmer, more youthful looking skin.*

## **COSMETIC PRODUCT SAFETY REPORT**

### **Part A: Cosmetic Product Safety Information**

#### **A.1 Quantitative and qualitative composition of the cosmetic product:**

**Neck + Breast Refining Complex Masque base formula**

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Water (Aqua)	5	5	7732-18-5	231-791-2	Solvent	In House	Deionised Water
2	Cetearyl Olivate	2.5	5	85116-80-9	285-532-3	Emulsifying	Textron Tecnica (CJP Chemicals)	Olivem® 1000
	Sorbitan Olivate	2.5		223706-40-9/ 92202-01-2	296-033-5			
3	Water (Aqua)	4.85	5	7732-18-5	231-791-2	Solvent/ Emulsifying/ Skin Conditioning/ Preservative	Silab (Meganede)	Raffermine® 2
	Glycine Soja Protein	0.075		9010-10-0	232-720-8			
	Phenoxyethanol	0.075		122-99-6	204-589-7			
	Water (Aqua)	4.35		7732-18-5	231-791-2			
4	Pentylene Glycol	0.375	5	5343-92-0	226-285-3	Solvent/ Skin Conditioning	Silab (Meganede)	Fermiskin™
	Lentinus Edodes Extract	0.275		223748-90-1	310-127-6			
	Olea Europaea Fruit Oil	4		8001-25-0	232-277-0			
5	Hydrolyzed pepper fruit extract	2.916	3	7732-18-5	231-791-2	Masking/ Perfuming/ Skin Conditioning	Textron Tecnica (CJP Chemicals)	Olive Oil Extra Virgin
6	Phenoxyethanol	0.063		84929-41-9	284-524-7			
	Ethylhexylglycerin	0.015		122-99-6	204-589-7			
	Rosa Canina Fruit Oil	0.006		70445-33-9	408-80-2			
7	Ribes Nigrum Seed Oil	3	3	84696-47-9/ 84603-93-0	283-652-0	Emollient/ Skin Conditioning	Seatons (Croda)	Rose Hips Oil
8	Hydrogenated Olive Oil	3	3	68606-81-5/ 97676-19-2	271-749-0	Emollient	Textron Tecnica (CJP Chemicals)	Blackcurrant Seed Oil
9		1.95	3	226993-75-5/	269-820-6	Skin Conditioning/	Textron	Oliwax

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Olea Europaea Fruit Oil	0.825		68334-28-1		Viscosity Controlling/ Masking/ Perfuming/ Skin Conditioning	Tecnica (CJP Chemicals)	
				8001-25-0	232-277-0			
	Olea Europaea Oil Unsaponifiables	0.225		8001-25-1/ 156798-12-8	232-277-0			
10	Glycerin	3	3	56-81-5	200-289-5	Humectant/ Perfuming/ Skin Protecting/ Viscosity Controlling	Various	Refined Glycerin
11	Persea Gratissima Oil	2	2	8024-32-6	232-428-0	Skin Conditioning	Textron Tecnica (CJP Chemicals)	Avocado Oil
12	Polyacrylate Crosspolymer-6	0.95	1	#	#	Perfuming/ Solvent / Emulsion Stabilising/ Viscosity Controlling	Seppic (CJP)	Sepimax Zen
	T-Butyl Alcohol	0.05		75-65-0	200-889-7			
13	Phenoxyethanol	0.9	1	122-99-6	204-589-7	Preservative/ Emollient/ Humectant/ Skin Conditioning	Dr Straetmans (Meganede)	Verstatil PC
	Caprylyl Glycol	0.1		1117-86-8	214-254-7			
14	Caesalpinia spinosa fruit extract	0.475	1	39300-88-4	254-409-6	Skin Protecting/ Skin Conditioning/ Solvent	Silab (Meganede)	Filmexel®
	Kappaphycus alvarezii extract	0.475		1220882-73-4	310-127-6			
	Water (Aqua)	0.05		7732-18-5	231-791-2			
15	Citrus bergamia peel oil expressed (also known as the perfuming name: Citrus Reticulata, X C. Sinensis Peel Extract)	1	1	93686-22-7	297-672-2	Perfuming	FD Copeland (CJP Chemicals)	Bergamot Oil
16	Xanthan Gum	0.25	0.25	11138-66-2	234-394-2	Binding/	CP Kilco	Xanthan

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
						Emulsifying/ Emulsion Stabilising/ Gel Forming/ Skin Conditioning/ Surfactant/ Viscosity Controlling	(Tranarc)	Gum
17	Tocopherol	0.1	0.1	54-28-4 (gamma)/ 16698-35-4 (beta)/ 10191-41- 0(DL)/ 119-13-1/ 1406-18-4/ 406-66-2/ 2074-53-5 (DL)/ 59-02-9 (D)/ 616-22-0	200-201-5/ 240-747-1/ 233-466-0/ 204-299-0/ 215-798-8/ 218-197-9/ 200-412-2	Antioxidant/ Masking/ Skin Conditioning	DSM Nutritional Products (Chempure)	dl- $\alpha$ - Tocopherol
18	Water (Aqua)	54.65	54.65	7732-18-5	231-791-2	Solvent	In House	Deionised Water

# CAS/ EC not assigned

Ingredient order for the label: Water (Aqua), Olea Europaea Fruit Oil, Glycerine, Ribes Nigrum Seed Oil, Rosa Canina Fruit Oil, Cetearyl Olivate, Sorbitan Olivate, Persea Gratissima Oil, Hydrogenated Olive Oil, Citrus bergamia Peel Oil expressed, **Phenoxyethanol, Polyacrylate Crosspolymer-6, Caesalpinia Spinosa Fruit extract, Kappaphycus alvarezii extract, Pentylene Glycol, Lentinus Edodes Extract, Limonene, Xanthan Gum, Olea Europea Oil Unsaponifiables,**

Linalool, Caprylyl Glycol, Tocopherol, Glycine Soja protein, Hydrolyzed pepper fruit extract, T-butyl alcohol, Citral, Ethylhexylglycerin, Linalyl Acetate, Pinene.

Red font denotes ingredients present at less than 1% which may be listed in any order.

Below are the allergens and their respective concentrations in the fragrance that are required to be listed in Article 19 Paragraph 1(d) & (g (ii)) of EC 1223/2009 when present at levels >0.001% in a leave-on product.

#### Fragrance allergens

<b>INCI (EU) Name</b>	<b>CAS number</b>	<b>EC number</b>	<b>Concentration % w/w</b>	<b>Comment</b>
Citral	5392-40-5	226-394-6	0.0301	Annex III/70*
Limonene	5989-27-5	227-813-5	0.2735	Annex III/88*
Linalool	78-70-6	201-134-4	0.1005	Annex III/84*
Linalyl Acetate	115-95-7	204-116-4	0.25	SCCS Opinion on Fragrance allergens, Page 47 2*
Pinene	80-56-8	201-291-9	0.029	SCCS Opinion on Fragrance allergens, Page 47 2*

\*Regulation (EC) No 1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetic products, Annex III – List of substances which cosmetic products must not contain except subject to the restrictions laid down.

\*\* SCCS Opinion on Fragrance allergens in cosmetic products, 15<sup>th</sup> plenary meeting, June 2012, SCCS/1459/11, Section 7-1 – Tabular summary of evaluated individual fragrance chemicals, Table 7-1 Established Contact allergens in humans.

#### A.2 Physical /chemical characteristics and stability of the cosmetic product

Physical and chemical characteristics of the ingredients have been listed in the safety data sheets which are maintained electronically by the Responsible Person and are available on request. A cross reference to the SDS tradename and electronic reference number has been shown in the base formula table.

#### Physical and Chemical Characterization of the product

1 Physical state	Cream
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Emulsion
3 organoleptic properties (colour, odour, whenever relevant)	Off white smooth cream. Characteristic odour
4 pH (at 25°C)	4.74
5 viscosity (at 25°C)	85,000
6 thermal stability (glass bottle)	40 °C for 12 weeks
7 Specific gravity (at 25°C)	0.960 g/ml

## **Stability of the product**

A shelf-life of 6 months after opening has been allocated to this product.

An on-going stability study of the product in the packaging will be available to support the shelf-life. A stability test of the product in glass jars has confirmed stability at 25°C for 12 weeks.

Additional stability tests were performed at 5°C, 40°C and 50°C.

### **5°C Stability testing**

Testing at 5°C noted an increase in viscosity at week 4, 8 and 12 where the increase was noted as 18%, 57% and 29% respectively.

### **40°C Stability testing**

At 40°C the products appearance was noted as changed, the change was noted in week 4 onwards where the change was described as very slightly darker. The pH had reduced in week 8 and 12 by 11% and 12% respectively. Viscosity testing at 40°C indicated a significant change in week 1, 2 and week 4 where changes were noted as 16%, 23%, (-)34%

### **50°C Stability testing**

Stability at 50°C indicated that the products appearance had changed from week 4 through to week 12 where it was noted as 'v. slightly darker'. The pH had noticeable dropped in week 4, 8 and 12 where the drop was noted as 17%, 22% and 19% respectively.

Additionally, the viscosity of the product was noted to have changed in week 1 and week 2 where the change was 14% in both tests.

### **A.3 Microbiological Quality**

A PET test has been performed according to USP method 38 and confirms the effectiveness of the preservative for a period of 28 days. The certificate has been presented in Appendix 2.

### **A.4 Impurities, traces, information about the packaging material**

None of the ingredients of this product contained impurities at a level which would require notification.

A statement on the suitability of the product packaging is shown below.

The Neck + Breast Refining Complex Chubby Chunky Airless Container is made from Polypropylene and low density Polyethylene (LDPE). The pump is composed of Polypropylene, LDPE and high-density polyethylene (HDPE). The components of the packaging material and suitability of use criteria are included in a certificate in Appendix 4. This is maintained electronically with the PIF by the Responsible Person and is available on request.

### **A.5 Normal and reasonably foreseeable use**

RégimA SpaZone Neck and Breast refining complex is a product designed for application to the neck, breast and décolleté as a refining complex. It is a leave-on product that in normal circumstances will be used once daily on the neck, break and décolleté. This product is an in-salon product (150ml) with a take home product also (50ml).

### **A.6 Exposure to the Cosmetic Product**

Site of application	Neck, Breast and Décolleté
Surface area of application (cm <sup>2</sup> )	2,722.5*
Volume of product applied (mg)	3196**
Frequency of application/use per day	Twice daily <sup>#</sup>
Target population	Adults
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	3.196g applied dermal to a human with a default weight of 60kg has determined a Relative Daily exposure of 53.27mg/kg bw/day
Dermal absorption information	None

other	NA
-------	----

\* Surface area of application = 2,722.5cm<sup>2</sup> has been extracted from the Nordic Exposure Group Project 2011, Existing Default Values and Recommendations for Exposure Assessment, TemaNord 2012:505. RegimA Neck & Breast refining complex is applied to the neck, breast and décolleté area, as there is no data directly outlining the surface areas of the intended areas an extraction was made. The Nordic Exposure Group Project 2011 has outlined the total body surface area of men and women to be 19,400 and 16,900cm<sup>2</sup> respectively with an average body area of 18,150cm<sup>2</sup>. Referencing the Lund and Browder chart which outlines the % total body surface area burn, this chart is typically used in the assessment of burn victims. This chart is the most accurate method ad compensates the variation in body shape. The Lund and Browder chart indicates that the chest and neck (front and back) total 15% of the entire body, using this as the worst-case scenario the surface area of the neck and chest was calculated to be 2,722.5cm<sup>2</sup>. It was concluded that the neck, break and décolleté totaled 25% (1/4) of the trunk of an adult giving a surface are of 1427.5cm<sup>2</sup>. Hettiaratchy, S. and Papini, R. (2004). *Initial management of a major burn: II—assessment and resuscitation.* BMJ, 329(7457), pp.101-103.

\*\* Volume of product applied = 3196mg/day, this has been extracted from *Body cream/lotion* data provided by CTFA where it states 1.12mg/cm<sup>2</sup>/day is applied. The surface area of application has been outlined as 1427.5 cm<sup>2</sup> therefore the amount applied was calculated as 1598 mg/per application, where the product is applied twice a day.

# Frequency of application/use per day: worst case scenario of application twice day based on the product being used at home.

#### A.7 Exposure to the Substances

Daily Systemic Exposure Dosage (SED) is the daily amount of a cosmetic substance applied based on the concentration of that particular substance, the percutaneous absorption and the nominal human body weight (60 kg) and this is shown in the table below.

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Olea Europaea Fruit Oil 8001-25-0	4.825	53.27	1	2.570
Glycerin 56-81-5	3	53.27	1	1.598
Ribes Nigrum Seed Oil 68606-81-5	3	53.27	1	1.598
Rosa Canina Fruit Oil 84696-47-9	3	53.27	1	1.598
Cetearyl Olivate 85116-80-9	2.5	53.27	1	1.332
Sorbitan Olivate 223706-40-9	2.5	53.27	1	1.332
Persea Gratissima Oil	2	53.27	1	1.065

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
8024-32-6				
Hydrogenated Olive Oil 226993-75-5	1.95	53.27	1	1.039
Citrus bergamia peel oil expressed (also known as the perfuming name: Citrus Reticulata, X C. Sinensis Peel Extract) 93686-22-7	1	53.27	1	0.533
Phenoxyethanol 122-99-6	0.99	53.27	1	0.527
Polyacrylate Crosspolymer-6 #	0.95	53.27	1	0.506
Caesalpinia spinosa fruit extract 39300-88-4	0.475	53.27	1	0.253
Kappaphycus alvarezii extract 1220882-73-4	0.475	53.27	1	0.253
Pentylene Glycol 5343-92-0	0.375	53.27	1	0.200
Lentinus Edodes Extract 223748-90-1	0.275	53.27	1	0.146
Xanthan Gum 11138-66-2	0.25	53.27	1	0.133
Olea Europaea Oil Unsaponifiables 8001-25-1	0.225	53.27	1	0.120
Caprylyl Glycol 1117-86-8	0.1	53.27	1	0.05327
Tocopherol 54-28-4	0.1	53.27	1	0.05327
Glycine Soja Protein 9010-10-0	0.075	53.27	1	0.03995
Hydrolyzed pepper fruit extract 84929-41-9	0.063	53.27	1	0.03356
T-Butyl Alcohol 75-65-0	0.05	53.27	1	0.02663
Ethylhexylglycerin 70445-33-9	0.006	53.27	1	0.003196

# No dermal absorption data is available; 100% dermal absorption is used it is a leave on product.

#### A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	Comment
Polyacrylate Cross Polymer 6 #	C	-	Slightly irritating	Non- irritant	Non- sensitizing	Non- sensitizing and non- irritating in humans at ~5%	Not available	Not available	Not available	Not genotoxic (negative bacterial reverse mutation). Based on assumed low hazard (meets the NICNAS polymer of low concern criteria) and assessed use pattern (up to 5% in cosmetics), not considered to be an unreasonable health risk. No developmental or reproductive toxicological data is available for Polyacrylate Cross Polymer 6 therefore it is advised not to use it on pregnant or lactation females.
Olea Europaea Fruit Oil 8001-25-0	A	2014 CIR Compendium. For use up to 100%, Final report 03/11 available from CIR. the safety of Olea Europaea Fruit Oil for use in pregnant or lactating mothers has not been confirmed therefore it is advisable not to use during pregnancy and lactation.								
Glycerin 56-81-5	A	GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin. In a 2-generation reproductive study in rats, (n=10/sex), the administration of glycerin (0, 20%; ~ 2000 mg/kg/d in drinking water) for 8 weeks before								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	Comment
			mating until weaning of pups produced no adverse effects on the reproductive efficiency of the parents ( $F_0$ generation), or the growth, fertility, or reproductive performance of the untreated $F_1$ generation. No histological changes occurred in the tissues of either the $F_1$ or $F_2$ generations. The onset of estrus cycles, weight gain, and microscopic observations of the endocrine organs were comparable to those of the controls in both the $F_1$ and the $F_2$ generation. A NOAEL for maternal toxicity and teratogenicity was calculated to be 1310 mg/kg/d following the administration of glycerin to Wistar rats by oral gavage on days 6 through 15 of gestation where there was no adverse effects observed in the dams. A maternal toxicity MoS of 1640 was calculated where a MoS of greater than 100 represents safe use.  Final report 12/09/2014 available from CIR website.							
Ribes Nigrum Seed Oil 68606-81-5	A		2014 CIR Compendium. For use up to 0.3%, Final Report 03/11 available from CIR. Ribes Nigrum Seed Oil is present in Neck and Breast Refining Complex at 3%, 10 times over the limited outlined by the compendium. The FDA have stated that Blackcurrant buds and leaves; under the name <i>Ribes Nigrum L.</i> are permitted as direct addition to food for human consumption, 21CFR172.510.  To determine the safety if Ribes Nigrum Seed Oil a read across to <i>Ribes Nigrum L.</i> leaves was performed. An assessment was performed by European Medicine's Agency (EMA); A sub-acute repeated dose toxicity testing on rats was performed where daily doses of 2g/kg/day and 1.34 g/kg/day for 21 and 28 days respectively was administered.  No signs of toxicity or gastric ulceration was observed.  2g/kg/day = 2,000mg/kg/day 1.34g/kg/day = 1,340 mg/kg/day <a href="#">EMA/HMPC/745347/2016</a>							

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	Comment
										EFSA Journal 2012;10(3):2579
										<p>The EMA has stated that there is no data available on the use of <i>Ribes Nigrum L</i> leaves in fertility, pregnancy and lactation, therefore, use of <i>Ribes nigrum L.</i>, folium cannot be recommended during pregnancy and lactation.</p> <p><i>Ribes Nigrum Seed Oil</i> is present in Neck and Breast Refining Complex at 1.598 mg/kg bw/day, 101 times lower than that outlined as lowest dose of 160.8mg/kg/ bw/day.</p> <p>It was determined that <i>Ribes Nigrum L.</i> is safe for use as formulated however, the safety of <i>Ribes Nigrum Seed Oil</i> for use in pregnant or lactating mothers has not been confirmed therefore it is advisable not to use during pregnancy and lactation.</p>
Rosa Canina Fruit Oil 84696-47-9	A									2014 CIR Compendium. For use up to 19%, Final Report 03/11 available from CIR. There is no reliable information on the safety of taking Rose Hip ( <i>Rosa Canina</i> ) Fruit oil during pregnancy and breastfeeding it is therefore advisable to avoid its application to the skin.
Cetearyl Olivate 85116-80-9	A									2014 CIR Compendium. Safe for use in cosmetics when formulated to be non-irritating, Final Report 03/2013 available from CIR. There is no reliable information on the safety of taking Cetearyl Olivate during pregnancy and breastfeeding it is therefore advisable to avoid its application to the skin.
Sorbitan Olivate 223706-40-9	A									<p>2014 CIR Compendium. For use up to 7.5%, IJT 21 (S1):93-112,2002. No information was available on the reproductive and developmental effects if Sorbitan Olivate, data was available on comparable products named Sorbital and Sorbitan Stearate. The data indicated the following: <i>Fatty acids are normal components of diet for which no data was available concerning reproductive or developmental toxicity. Sorbitol (2.5% to 10%) had no adverse effects on the reproduction of CD rats during a multigenerational feeding study. Hydrogenated starch hydrolysates (~7% sorbitol) were not reproductive toxins at doses of 3000 to 7000 mg/kg/day for 2 years. Additionally, Gravid female Wistar rats, 20 per group, were dosed once daily by gavage with 0, 500 or 1000 mg/kg bw/day sorbitan stearate on days 0-20 of gestation, and the animals were killed. The NOAEL for maternal toxicity and for teratogenicity was 1000 mg/kg bw/day. No test article-related embryotoxic results were reported.</i> Final report 12/09/2014 available from CIR website.</p> <p>A maternal toxicity MoS was calculated to be 751 (Maternal NOAEL 1000mg/kg bw/day ÷ SED 1.332 mg/kg bw/day),</p>

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	Comment	
		generally a MoS of greater than 100 is representative of safe.									
Persea Gratissima Oil 8024-32-6	A	2014 CIR Compendium. For use up to 98%, Final amended Report 03/11 available from CIR; JEPT 4(4):93-103, 1980 (original) re-review IJT 22(S1):1-35, 2003. There is no reliable information on the safety of taking Persea Gratissima Oil during pregnancy and breastfeeding it is therefore advisable to avoid its application to the skin.									
Hydrogenated Olive Oil 226993-75-5	A	2014 CIR Compendium. For use up to 12%, Final Report 03/11 available from CIR. There is no reliable information on the safety of taking Hydrogenated Olive Oil during pregnancy and breastfeeding it is therefore advisable to avoid its application to the skin.									
Citrus bergamia peel oil expressed (also known as the perfuming name: Citrus Reticulata, X C. Sinensis Peel Extract) 93686-22-7	B	Supplier IFRA certificate of conformity supplied and presented in Appendix 3. Maximum allowable concentration for Category 4C (Body Creams, Oils, Lotions) is 19.91%, actual concentration in Neck and Breast Refining Complex is 1%. Allergen components are declared in A1 Fragrance Allergen table. Safe for inclusion in this product. There is no reliable information on the safety of taking Citrus bergamia peel oil expressed during pregnancy and breastfeeding it is therefore advisable to avoid its application to the skin.									
Phenoxyethanol 122-99-6	A	<p>2014 CIR Compendium. For use up to 1%, JACT 9(2):259-77, 1990. A teratogenicity/reproduction study was performed with 50 mice (of each sex) who were given 0.25, 1.25 and 2.5% Phenoxyethanol in their diet. An additional 40 mice of each sex were used in the control group. The mice were administered the test substance in the feed for 7 days prior to mating, and throughout the remainder of the study. Mice in the high-dose group produced fewer litters per pair, had smaller litters, and produced fewer live pups per litter. The decrease in weight of live pups was dose dependent.</p> <p>An additional crossover mating trial with a 7-day mating period, this was performed to determine which sex was affected by the administration of Phenoxyethanol. The study indicated that Phenoxyethanol was fetotoxic in the F<sub>0</sub> females. The only significant difference noted during the trial was in the female mice was an increased liver weight in the high-dose females.</p> <p>In another phase of the study, the final litters obtained from the continuous breeding phase of the study were one to</p>									

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	Comment	
			<p>three mice of each sex from each litter were selected for breeding within their feeding group. Dose-dependent decreases were found in body weight at birth, weaning day, and breeding day in these mice, suggesting that Phenoxyethanol was toxic throughout lactation and postweaning.</p> <p>The study concluded that 2.5% Phenoxyethanol in the diet was a reproductive toxicant in F<sub>0</sub> mice and produced a dose-dependent decrease in live pup weight during exposure of the F<sub>0</sub> mice. Phenoxyethanol was selectively fetotoxic to F<sub>0</sub> females. Continuous exposure to Phenoxyethanol reduced the body weights of the F<sub>1</sub> mice in a dose-dependent manner and produced mortalities of 39% in the mice of the 1.25% dose group and 87% in the mice of the 2.5% dose group. The weights of the F<sub>2</sub> generation were also decreased in a dose-dependent manner. Phenoxyethanol in the diet was toxic to newborn and young mice.</p> <p>A teratogenicity study using New Zealand White (NZW) rabbits was performed with undiluted phenoxyethanol of a 99% purity which was applied to the shaved backs of 25 pregnant rabbits at doses of 300, 600 or 1000 mg/kg/day from day 6 through to day 18 of gestation. It was concluded that dermal treatment of NZW rabbits with Phenoxyethanol did not result in teratogenicity, embryotoxicity, or fetotoxicity even at doses that were maternally toxic (600 mg/kg/day). A maternal MoS was calculated to be 1,139 (600mg/kg bw/day ÷ SED 0.527 mg/kg bw/day). A MoS of greater than 100 is generally considered safe. With the above studies in mind it is advisable not to use Neck + Breast Refining Complex during while pregnancy or during lactation.</p>								
Caesalpinia spinosa fruit extract 39300-88-4	2#		<p>A secondary assessment was performed on Caesalpinia Spinosa Fruit Extract. A dose range of from 1-5% was established, which was 1-10 times greater than the percentage indicated in Neck + Breast refining complex; 0.475%. A read across was also performed to Caesalpinia Spinosa Gum, this read across was justified as the gum is a plant material derived from the dried gummy exudate (plant secretion) of the Caesalpinia Spinosa. Both Caesalpinia Spinosa and Caesalpinia Spinosa fruit extract both originate from the <i>Fabaceae</i> family. Caesalpinia Spinosa Gum has been approved for use as a food ingredient by JECFA, with no ADI specified and is also present in the CIR Compendium with its use in cosmetics stated as safe for use up to 0.5%.</p>								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	Comment
			In order to determine the teratogenicity/reproductive potential of <i>Caesalpinia Spinosa</i> fruit extract a read across was performed to <i>Caesalpinia Spinosa</i> gum. This read across was justified as the gum is a plant material derived from the dried gummy exudate (plan secretion) of the <i>Caesalpinia Spinosa</i> .  A multigenerational reproduction study on <i>Caesalpinia Spinosa</i> gum was performed using groups of CD albino rats (22 days old) where the gum was administered to male and female rats at a dietary level of 5% ( 50, 000ppm) through 3 successive generations where all mating involved 10 males and 20 females per group where the fertility was described as high. The litters were maintained until the end of lactation (21 days old), it was concluded that <i>C Spinosa</i> gum had no adverse effects on reproductive performance and in utero development. Data from two progeny selected as parental animals for subsequent generations (F1 and F2 parents) indicated that these animals had normal growth patterns and reproductive performance.  The teratogenicity and embryotoxicity of <i>C spinosa</i> gum was evaluated using Wistar/HAN rats where groups of 25 rats were fed diets containing 0, 1.25%, 2.5% or 5% from days 6-16 of gestation. All females were killed on day 21 with fetuses removed by C section. Necropsy results did not reveal any abnormalities after external, visceral and skeletal examinations of fetuses, it was concluded that <i>C spinosa</i> gum did not induce maternal toxicity, embryotoxicity or teratogenicity where a NOAEL was considered to be <50,000ppm in diet. It was therefore concluded that <i>Caesalpinia spinosa</i> fruit extract was safe to use as an ingredient on pregnant consumers.							
Kappaphycus alvarezii extract 1220882-73-4	2#		A secondary assessment was performed on <i>Kappaphycus Alvarezii</i> extract. A read across was performed to carrageenan as most carrageenan's are extracted from <i>Kappaphycus Alvarezii</i> . Carrageenan is a relatively large molecule with average molecular weights of 200,000 – 400,000, thus reducing the potential of dermal penetration due to the large nature of the molecules. Carrageenan has also been categorized as GRAS by the United States FDA and has also been approved as a food additive under 21 CFR 172.620. The WHO has confirmed these findings and considers carrageenan safe for food use and that it is not necessary to specify an ADI for man. <i>Kappaphycus Alvarezii</i> extract is present in Neck + Breast Refining Complex at 0.475% and it was therefore concluded as safe for use as formulated. There is no reliable information on the safety of taking <i>Kappaphycus Alvarezii</i> extract during pregnancy and breastfeeding it is therefore advisable to avoid its application to the skin during these times.							

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	Comment
Pentylene Glycol 5343-92-0	A									2014 CIR Compendium. For use up to 5%. A read across was performed to Propylene Glycol to determine the teratogenic/developmental potential of Pentylene Glycol. This read across was justified as Propylene Glycol ( $C_3H_8O_2$ ) and Pentylene Glycol ( $C_5H_{10}O_2$ ) differ by $C_2H_2$ . The reproductive and developmental toxicity potential of Propylene Glycol (PG) was determined using multiple studies which utilized Swiss Albino mice, Dutch belted rabbits and female golden hamsters where the studies concluded that PG was not a reproductive or developmental toxicant. IJT 31 (S2):147-168, 2012.
Lentinus Edodes Extract 223748-90-1	B									A safety assessment was performed by EFSA Panel on Dietetic on Lentinex®; an aqueous mycelial extract of <i>Lentinula edodes</i> (formally <i>Lentinus Edodes</i> ). Lentinex® consists of approximately 98% water and 2% dry matter; containing $\beta$ -Glucan Lectinan, free glucose and N-containing constituents). <i>Lentinus Edodes</i> is present in RégimA Neck + Breast Refining Complex as Silab's ingredient Fermiskin®, where the composition is stated as Water (87%), Pentylene Glycol (7.5%) and Lentinus Edodes Extract (5.5%). A proposed intake of Lentinex® was estimated at 2.5mL; containing 1mg Lentinan ( $\beta$ -glucan)/ml that corresponds to 41.7 $\mu$ g/kg body weight for a standard 60kg person, therefore 2.5 mg/kg bw/day. Repeated dose toxicity studies on Beta Glucan in oral intake by humans where 6 male subjects ingested milkshakes with beta-glucan for 28 days. The test subjects ingested 6g/day for 5 days, 35g/day for 2weeks and 50g/day from day 21 to 28. Human Dermal irritation studies of Beta-glucan (the subject groups and dose/concentrations were not stated) under an occlusive patch test indicated beta-glucan to be a non-irritant. Skin sensitization was evaluated on 213 male subjects, where a modified Draize "multiple insult patch test was applied. The occlusive patches were applied every other day for 10 applications. A 48-hour challenge was performed after a 10 to 14 days of a non-treatment period. Results indicated irritation during the induction however overall it was determined not to be a sensitizer. The Panel concluded that Lentinex® is safe for use as food ingredient at the proposed levels of intake; as outlined above. IJT 35(Suppl. 1):5-49, 2016. Scientific opinion on the safety of " <i>Lentinus edodes extract</i> " (Lentinex®) as a Novel Food ingredient, EFSA Panel on Dietetic Products, Nutrition and Allergies, EFSA Journal 2010; 8(7):1685. Additional information provided by Silab regarding Fermiskin® has eluded to it being nonirritating, sensitizing and no toxicity associated with acute toxicity testing. Presented in Appendix 4. Lentinus Edodes Extract is present in Neck + Breast Refining Complex at 0.275%; 0.146 mg/kg bw/day based on an average 60kg human, 17 times less than the worst-case dose of 2.5 mg/kg bw/day. It is not expected at the level outlined to

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	Comment
		cause any adverse outcome effects when used as directed. There is no reliable information on the safety of taking lentinus edodes extract during pregnancy and breastfeeding it is therefore advisable to avoid its application to the skin during these times.								
Xanthan Gum 11138-66-2	A	2014 CIR Compendium. For use up to 6%, Final Report 09/12 available from CIR. A three generational reproductive toxicity study was performed where albino rats were fed dietary level of 0, 0.25 and 0.5 g/kg bw/day Xanthan Gum where the rats produced 2 litters per generation and the successive generations were selected from weanlings of the second litter. There were no significant differences in developmental parameters between test and control litters and no malformations were observed in any of the offspring. IJT 35(Suppl. 1):5-49, 2016								
Olea Europaea Oil Unsaponifiables 8001-25-1	A	2014 CIR Compendium. For use up to 3%, Final report 03/11 available from CIR. There is no reliable information on the safety of taking Olea Europaea Oil Unsaponifiables during pregnancy and breastfeeding it is therefore advisable to avoid its application to the skin during these times.								
Caprylyl Glycol 1117-86-8	A	2014 CIR Compendium. For use up to 5%, IJT 31 (S2):147-168, 2012. Caprylyl glycol was assigned a score of 'low' for reproductive toxicity based on negative results for surrogates in animal studies. Caprylyl glycol was assigned a score of Low for developmental toxicity based on negative findings in well-conducted animal studies for the surrogates. The report <i>Caprylyl Glycol (CAS #1117-86-6) GreenScreen® for Safer Chemicals (GreenScreen®) Assessment, Environmental Defense Fund, February 2016</i> is presented in Appendix 4.								
Tocopherol 200-201-5	A	2014 CIR Compendium. For use <=5%, IJT 21(S3):51-116, 2002; Final Report 03/2014 available from CIR. There is no reliable information on the safety of taking Tocopherol during pregnancy and breastfeeding it is therefore advisable to avoid its application to the skin during these times. An article in The Telegraph published in June 2006 outlined that experts were warning women not to take Vitamin E supplements during pregnancy as it may harm the unborn child. The article does outline that it was not recommended to take Tocopherol orally but due to limited information on its reproductive and developmental toxicity potential it is taken as a worst-case scenario. The article is presented in Appendix 4.								
Glycine Soja Protein 9010-10-0	A	For use up to 0.9% in leave on cosmetics. Glycine Soja Protein is GRAS for substances migrating to food from paper and paperboard products (CFR 182.90). Final report available from CIR Website. There is no reliable information on the safety of taking Glycine Soja Protein during pregnancy and breastfeeding it is therefore advisable to avoid its								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	Comment		
			application to the skin during these times.									
Hydrolyzed pepper fruit extract 84929-41-9	B											

Hydrolyzed Pepper fruit extract has been identified under REACH registration conditions as Pepper (Piper) P. Nigrum ext. with corresponding CAS and EC numbers. The dossier provided states Skin irritation/ corrosion was determined via calculation. It was determined as a Category 2 (irritant) based on GHS criteria; this was due to Pepper (piper)P. Nigrum extract having more than 10% of its constituents classified as Skin Irritant Category 2. The skin sensitization potential was evaluated from the ECHA Guidance on the Application of the CLP Criteria (2013); the ingredient overall has not been tested *in vitro* or *in vivo* however some of the ingredients present have been classified as skin sensitizers Category 1B and all are described as being present at above the CLP generic concentration limit of 1%. [Pepper \(Piper\), P. nigrum ext. REACH dossier](#)

Piperine is a naturally occurring alkaloid that is the major pungent compound found in spices including *Piper nigrum* L., a 90-day toxicity study in rats has established a NOAEL of 5mg/kg bw/day. A MoS of 1901 has been calculated;  $5\text{mg/kg bw/day} \div \text{SED of } 0.00263 \text{ mg/kg bw/day} = 1901$ . A MoS of greater than 100 is generally recognized as safe. Norwegian Scientific Committee for Food Safety (2016). *Risk assessment of "other substances" -Piperine*.

Hydrolyzed Pepper fruit extract is the active ingredient presented in Silab's product Retilactyl D®, the dermal irritation and sensitization capacity of Retilactyl D® was evaluated on human skin where it was determined to be a non-irritant and non-sensitizing. It was determined that Hydrolyzed Pepper Fruit extract is safe for use in Neck and Breast Refining Complex at 0.063% (0.03356 mg/kg bw/day).

Regarding reproductive and developmental toxicity of Piperine a 14-day study in Swiss albino female mice concluded that the results indicated that Piperine might interfere with several crucial reproductive events in a mammalian model showing significantly reduced implantation values. Norwegian Scientific Committee for Food Safety (2016). *Risk assessment of "other substances" -Piperine*. While the product is considered safe when used and directed and adverse effects are not expected, in consideration of the information regarding fertility, use of this product containing hydrolyzed pepper fruit extract by pregnant or lactating women is not advised and this has been stated on the label.

T-Butyl Alcohol  
75-65-0

A

2014 CIR Compendium. For use up to 0.5%, IJT 24(2):1-20, 2005 (Amended) JACT 8(4):627-41, 1989 (original report). T-butyl Alcohol did not affect the *in vitro* fertilization capacity of mouse spermatozoa. Fetotoxicity generally increased

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	Comment
										with concentration and fetal weights were slightly depressed at concentrations of 0.5 to 1%. IJT 24(2):1-20, 2005 It was therefore concluded that the use of T-Butyl Alcohol in Pregnant and lactation females is not advised.
Ethylhexylglycerin 70445-33-9	A									2014 CIR Compendium. For use up to 8%, JT 32(Suppl. 3):5-21, 2013 The effects of Ethylhexylglycerin was evaluated on pregnancy and embryo-fetal development was evaluated in a prenatal developmental toxicology study on female rats. No treatment related changes were revealed following visceral and skeletal examinations, a NOAEL was considered to be 800 mg/kg. A reproductive and developmental toxicity MoS of 250,313 was determined for Ethylhexylglycerin (NOAEL 800mg/kg ÷ SEED 0.003196 mg/kg bw/day) and was therefore considered safe for use.

<sup>a</sup> Some ingredients are excluded from a formal risk assessment where a recognized authority has published a review of the ingredient under similar conditions of use and concluded on safe use at the level of inclusion in the cosmetic product (Hazard ID=A). Hazard ID category B is for recognized authority reviews of the ingredient under similar conditions of use with restricted use or where the ingredient is contained in the annexes to Regulation (EC) No 1223/2009 (Hazard ID=B). Where hazard ID A or B is reported, the maximum allowed usage concentration should be stated.

<sup>b</sup> all possible routes of exposure should be considered

<sup>c</sup> A MoS of greater than 100 is considered to represent safe use

# Food item, hazard and exposure data not required.

2# Secondary assessment performed, presented in Appendix 4.

**Fragrances:**

Neck and Breast refining complex contains a fragrance called Bergamot Oil. The IFRA certificate and allergen content is presented in Appendix 3 with individual allergen concentrations are outlined in Section A.1.

**A.9 Undesirable Effects and Serious Undesirable Effects**

No undesirable effects are anticipated based on the product being used as directed on the Neck and Breast area once daily.

**A.10 Information on the Cosmetic Product**

Neck and Breast refining complex was released in July 2017. Over the period July 2017 to May 2019 3823 units have been sold and there have been no adverse reactions reported to RégimA Company.

## **B: Part Cosmetic Product Safety Assessment**

### **B.1 Assessment Conclusion**

#### Review of the ingredients

After analysis of all the available information including:

- formulation
- toxicological profile of the ingredients and their concentration in the product
- Product data sheets supplied by the ingredient manufacturer

It is not expected that Neck and Breast Refining Complex will cause damage to human health when used as directed.

It is therefore concluded that Neck and Breast Refining Complex can be placed on the market in the EU as a body cream for application to the neck and breast. While the product is considered safe for use when used as directed, it is not recommended for use by pregnant and breastfeeding women to avoid the possibility of adverse effects occurring to both the mother and breastfeeding child.

#### Review of human data on the product

There are no human tests such as a patch test, for this product.

### **B.2 Label Warnings and Instructions for Use**

Directions for use are given on the product label and external packaging that is presented in Appendix 4.

#### **Directions:**

##### **50ml**

AM & PM: Cleanse with RégimA, apply eye care products. Apply thin layer of Neck + Breast Complex to neck, décolleté and breasts. To be followed daily by application of a RégimA day product containing sun protection.

##### **100ml**

To be used as part of a RégimA in-salon treatment.

This Neck + Breast Complex may be used as a Masque during a RégimA facial. Apply a thin layer to neck, décolleté and breast. This may be left on and additional hydrating or treatment products applied over if desired.

An IBPN label is attached to the product label and the outer packaging, this represents RégimA's certification to use Silab's Interpenetrating BioPolymer Network technology. The certificate is presented I Appendix 4.

**Warnings:**

**50ml**

'Must not be combined with any other product range'

'Airless container DO NOT remove top as this would introduce air and/or bacteria'

'Product level can be viewed through the gap in label'

'Store below 77°F / 25°C in a cool dry place. Protect from light'

'Use sun protection'

'Do not use if Pregnant or breastfeeding'

'Discontinue use if irritation occurs.'

**100ml**

'To be used as part of a RégimA in-salon treatment'

'Strictly for professional use'

'Airless container DO NOT remove top as this would introduce air/or bacteria'

'Product level can be viewed through the gap in label'

'Store below 77°F / 25°C in a cool dry place. Protect from light'

'Use sun protection'

'Do not use if Pregnant or breastfeeding'

'Discontinue use if irritation occurs.'

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for their body moisturising properties and with good local tolerance. There are no reasons to anticipate tolerance problems with use.

This product is intended for external use in adults only.

### **B.4 Assessors Credentials and Approval of Part B**

Shirley Hudson (safety assessor)

BSc, University of Aberdeen

*CBiol, MSB*

20+ years as a practicing toxicologist in the pharmaceutical and chemical industries



After analyzing of all of the available information including the product formulation and toxicological profile of the ingredients, I conclude that according to the current state of scientific knowledge, this product is not expected to result in any significant damage to human health and can be safely marketed for the intended and foreseeable use as a Neck and breast moisturizer.

### **List of References**

SCCS Notes of Guidance for the Testing of Cosmetic Substances and Their Safety Evaluation, 9<sup>th</sup> Revision, 29 September 2015 (SCCS/1564/15)

European Commission database on cosmetic ingredients (CosIng)

<http://ec.europa.eu/consumers/cosmetics/cosing/>

Cosmetic ingredient review <http://www.cir-safety.org/>

METHOD OF MANUFACTURE / GMP CERTIFICATION



## **PROOF OF EFFECT CLAIMED**

This product claims to:

1. Fortify firmness and tonicity while lightening uneven skin colour
  - o This claim has been substantiated by additional information provided on the ingredient Retilactyl D®. Retilactyl D® is a target solution for forming up the supporting tissues in the skin. In Vitro and In vivo studies confirmed the cosmetic efficacy of Retilactyl D® when used in cosmetic products. The documentation is presented in Appendix 4.
2. Increased elasticity is achieved by limiting degradation of collagen I and II fibers, therefore reducing skin fatigability
  - o This claim has been substantiated by the ingredient Reffermine®, this ingredient by Silab claims to improve skin tone and elasticity due to it being rich in glycoproteins and polysaccharides of soyabean membranes. This effect has been confirmed by In Vitro Studies and In Vivo human studies; the document is presented in Appendix 4.
3. Remodeling of the contours of the neck and breasts, increasing density and firmness
  - o This claim has been substantiated by the additional information provided on the Ingredient Fermiskin® by Silab. Fermiskin® utilizes the firming agents, Oligosaccharides and Galacturonic acids, found in Shiitake mushrooms. In Vitro and In Vivo cosmetic efficacy is outlined in Appendix
4. Firming and contouring precious actives results in a firmer, more youthful looking skin.
  - o This claim has been substantiated by the additional information provided on the Ingredient Fermiskin® by Silab. Fermiskin® utilizes the firming agents, Oligosaccharides and Galacturonic acids, found in Shiitake mushrooms. In Vitro and In Vivo cosmetic efficacy is outlined in Appendix

#### **ANIMAL TESTING STATEMENT**

To the best of our knowledge, the manufacturer and his suppliers have not carried out or commissioned any animal testing for the purpose of developing new cosmetic products.

The statement below is a confirmation of the company policy:

### **RégimA Skin Treatments**

CK92/05371/23  
VAT No. 4590131043

Tel: 011 615 2869 or 011 622 7827  
Fax: 011 616 8008  
Cell: 0836537020  
e-mail: [jax@regima.com](mailto:jax@regima.com)

**POSTAL ADDRESS: PO BOX 9523 Edenglen 1613**

**PHYSICAL ADDRESS: 20 River Road Morninghill Bedfordview 2007 RSA**

#### Animal Testing Compliance Statement

This letter is to serve as testimony as to the practice of animal testing, and confirm that RégimA Skin Treatments has not, nor will not engage in any practice that involves animal testing in any form.

RégimA Skin Treatments hereby confirms neither the manufacturer nor RégimA Skin Treatments itself have commissioned or carried out any form of animal testing during the course of product development. This applies to any and all activities performed as part of the development process, including, but not restricted to: R&D, stability testing, safety and toxicology assessments, suitability studies or any other facet related to the product's development.

### **Appendix 1: Safety Data Sheets or Ingredient Specifications**

Safety data sheets and technical data sheets for the ingredients are maintained electronically with the PIF by the Responsible Person. They are available on request.

## **Appendix 2: Microbial Challenge Test**

A microbial challenge test is maintained electronically with the PIF by the Responsible Person. It is available on request.

## **Appendix 3: Certificates of Allergen Content**



### **IFRA Conformity Certificate**

**Compound Name :** BERGAMOT OIL {BOL-BE01}  
**Code Number :** RCP-76695

We certify that the above compound is in compliance with the standards of the INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA-47th amendment, published June 2013), provided it is used at a maximum concentration level of:

<b>IFRA category (*)</b>	<b>Maximum level of use (%)(w/w) (**)</b>
1A 1B (***)	1.33 (***)
2	1.66
3A	6.64
3B	6.64
3C	6.64
3D	6.64
4A	19.91
4B	19.91
4C	19.91
4D	19.91
5	9.96
6 (***)	33.19 (***)
7A	3.32
7B	3.32
8A	46.47
8B	46.47
9A	100.00
9B	100.00
9C	100.00
10A	82.97
10B	82.97
11A	100.00
11B	100.00

(\*) See annex for definition of IFRA categories

(\*\*) Usage limit N/A = Not Applicable; no IFRA restrictions

(\*\*\*) IFRA would recommend that any material used to impart perfume or flavour in products intended for human ingestion should consist of ingredients that are in compliance with appropriate regulations for foods and food flavourings

For other kinds of application or use at higher concentrations, a new safety evaluation may be needed; please contact F.D. Copeland and Sons Ltd.

The IFRA Standards regarding restrictions are based on safety assessments by the Panel of Experts of the RESEARCH INSTITUTE FOR FRAGRANCE MATERIALS (RIFM) and are enforced by the IFRA Scientific Committee.

Evaluation of individual Fragrance ingredients is made according to the safety standards contained in the relevant section of the IFRA Code of Practice.

It is the ultimate responsibility of our customer to ensure the safety of the final product (containing this fragrance) by further testing if need be.

The information contained herein is true and accurate to the best of our knowledge. All information is valid until revisions are issued.  
It is your responsibility to ensure that the usage of the fragrance ingredients and the levels of such usage are permitted at all times according to the relevant laws and regulations

*Page 1 of 2*

ANNEX: Definition of IFRA categories

<b>Finished Product Types</b>	<b>IFRA category</b>
Lip products of all types (solid and liquid lipsticks, balms, clear or coloured, lipwax, etc.) Toys	1A (**)
Waxes for mechanical hair removal	1B
Deodorant and Antiperspirant Products of all types (pump spray, aerosol spray, stick, roll-on, under-arm and body, etc.) Fragranced Bracelets	2
Hydroalcoholic Products applied to recently shaved skin - EdT	3A
Hydroalcoholic Products applied to recently shaved skin- Fine fragrance	3B
Eye Products of all types (eye shadow, mascara, eyeliner, eye make-up, etc.) including eye care Men's Facial Creams and Balms, Baby Creams, Lotions, Oils; Body Paint for Children	3C
Tampons	3D
EdT: Hydroalcoholic Products applied to unshaved skin, Ingredients of Perfume Kits, Scent Pads, Foil Packs, Scent Strips for Hydroalcoholic Products	4A
Hydroalcoholic products applied to unshaved skin - Fine fragrance	4B
Hair styling aids sprays of all types (pump, aerosol sprays etc.), Hair Deodorant Body Creams, Oils, Lotions, Fragranging Creams of all types (except baby creams, lotions and oils) Fragrance Compounds for Cosmetic Kits, Foot Care Products, Body Paint for Adults	4C
Fragranging cream	4D
Women's Facial Creams/Facial Make-up, Hand Cream, Facial Masks Hand Sanitisers, Wipes or Refreshing Tissues for Face, Neck, Hands, Body Baby Powder and Talc Hair Permanent and Other Hair Chemical Treatments (e.g. relaxers) but not hair dyes, Dry Shampoo or Waterless Shampoo	5
Mouthwash, including Breath Sprays, Toothpaste	6 (**)
Intimate Wipes, Baby Wipes	7A
Insect Repellent (intended to be applied to the skin)	7B
Make-up Removers of all types (not including face cleansers) Hair Styling Aids Non-Spray of all types (sprays, gels, leave-in conditioners, etc.) Nail Care, Powders and talcs (not including baby powders and talcs)	8A
Hair Dyes	8B
Shampoos of all types (including baby shampoos), Conditioner (Rinse-off), Face Cleaners of all types (washes, gel, sponges, etc.), Liquid Soap, Bar Soap (Liquid Soap), Depilatory (not including waxes for maintaining body removal), Creams, Gels, Oil Based, Gels, foams, etc.) Body Washes of all types (including baby washes) and Shower Gels of all types Bath Gels, Foams, Mousses, Salts, Oils and other products added to bathwater	9A
Feminine Hygiene - pads, liners, Toilet Paper Wet Bags	9B
Other' Aerosols (Ind. air freshener sprays and air freshener pump sprays, but not deodorants / antiperspirants, hair styling aids spray and animal sprays) Facial Tissues, Napkins, Paper Towels	9C
Handwash Laundry Detergents of all types including concentrates Fabric softeners of all types including fabric softener sheets, Hand Dishwashing Detergent (including concentrates Hard Surface Cleaners of all types (bathroom and kitchen cleaners, furniture polish etc.) Other Household Cleaning Products (fabri cleaners, soft surface cleaners, carpet cleaners etc.) Dry Cleaning Kits, Shampoo for pets	10A
Diapers, Toilet Seat Wipes	10B
Air Fresheners and Fragrancing of all types (concentrated aerosol air fresheners, plug-ins, solid substrate, membrane delivery, ambient, electrical,) excluding aerosol products, Liquid refills for air fresheners (cartridge systems), Scents delivery system using a dry air technology that releases a fragrance without sprays, aerosols or heated oils (technology of nebulization), Candles, Joss Sticks, Incense, Air Freshener Crystals, Fragranced lamp ring, Scent pack, Machine Only Laundry Detergent (e.g. liquids), Toilet Blocks, Insecticides (mosquito coil, paper, electrical, for clothing etc.) excluding aerosols Fuels, Paints, Floor wax, Plastic articles (excluding toys)	11A
All incidental skin contact including: Pot pourri, powders, fragranging sachets, incense, Reed diffusers, Liquid refills for airfresheners (non-cartridge systems) Odoured Distilled Water (that can be added to steam irons), Machine Dishwash Detergent and Deodorizers Deodorizers/Maskers not intended for skin contact (e.g. fabric drying machine deodorizers, carpet powders) Treated Textiles (e.g. starch sprays, fabric treat with fragrances and waxes, deodorizers for textiles or fabrics, tights with moisturizers) Infused soaps, Scrub and sniff (sampling technology) Shoe Polishes, Cat litter, Animal Sprays (all types)	11B

(\*\*) This IFRA certificate does not include a GRAS-FEMA conformity check



## Allergen Analysis

Compound Name : BERGAMOT OIL {BOL-BE01}

Code Number : RCP-76695

flavour ingredient	CAS No.	Concentration present as a percentage (%) or 'A' for absent in flavour		
		Added as such	From natural & other sources	Total
alpha-Iso-Methylionane	127-51-5	A	A	A
AmylCinnamal	122-40-7	A	A	A
Amylcinnamyl Alcohol	101-85-9	A	A	A
Anise Alcohol	105-13-5	A	A	A
Benzyl Alcohol	100-51-6	A	A	A
Benzyl Benzoate	120-51-4	A	A	A
Benzyl Cinnamate	101-41-1	A	A	A
Benzyl Salicylate	118-58-1	A	A	A
ButylPhenylMethylpiapinal (Linal)	80-54-6	A	A	A
Cinnamal	104-55-2	A	A	A
CinnamylAlcohol	104-54-1	A	A	A
Citral	5392-40-5	3.00	0.01	3.01
Citronellol	106-22-9	A	A	A
Coumarin	91-64-5	A	A	A
Eugenol	97-53-0	A	A	A
Evernia Furfurosa (Tree Moss) Extract	90028-67-4	A	A	A
Evernia Prunastri (Oak Moss) Extract	90028-68-5	A	A	A
Farnesol	4602-84-0	A	A	A
Geraniol	106-24-1	A	A	A
Hexyl Cinnamal	101-86-0	A	A	A
Hydroxycitronellol	107-75-5	A	A	A
Hydroxyhexyl 3-Cyclanexene Carboxaldehyde (Lyral)	21906-04-4	A	A	A
Isoeugenol	97-54-1	A	A	A
Limonene	5989-27-5	A	27.35	27.35
Linalool	78-70-6	10.00	0.05	10.05
Methyl 2-Octynoate	111-12-6	A	A	A

The information contained herein is true and accurate to the best of our knowledge. All information is valid until revisions are issued.  
We will not therefore accept liability for misuse of this data resulting in damage or loss.

#### **Appendix 4: Miscellaneous**

The stability report, packaging material information and product carton insert are maintained electronically with the PIF by the Responsible Person. They are available on request.

# PRODUCT INFORMATION FILE\*

RegimA

Instant Facial Lifting Wonder  
Serum and O2 Purifyer Face  
+ Body Enhancing Serum

Prepared: August 2018  
(Label & packaging update August 2021)

\*As required under Article 11 of the European Cosmetics Regulation EC No. 1223/2009

# TABLE OF CONTENTS

## Contents

INTRODUCTION .....	3
PRODUCT DESCRIPTION .....	3
COSMETIC PRODUCT SAFETY REPORT .....	7
Part A: Cosmetic Product Safety Information.....	7
A.1 Quantitative and qualitative composition of the cosmetic product:.....	7
A.2 Physical /chemical characteristics and stability of the cosmetic product .....	11
A.3 Microbiological Quality.....	13
A.4 Impurities, traces, information about the packaging material .....	13
A.5 Normal and reasonably foreseeable use.....	13
A.6 Exposure to the Cosmetic Product .....	13
A.7 Exposure to the Substances .....	14
A.8 Toxicological Profile of the Substances .....	16
A.9 Undesirable Effects and Serious Undesirable Effects.....	20
A.10 Information on the Cosmetic Product .....	20
B: Part Cosmetic Product Safety Assessment .....	21
B.1 Assessment Conclusion .....	21
B.2 Label Warnings and Instructions for Use .....	21
B.3 Reasoning .....	23
B.4 Assessors Credentials and Approval of Part B.....	23
List of References.....	23
METHOD OF MANUFACTURE / GMP CERTIFICATION.....	24
PROOF OF EFFECT CLAIMED .....	25
ANIMAL TESTING STATEMENT.....	25
Appendix 1: Safety Data Sheets or Ingredient Specifications .....	27
Appendix 2: Microbial Challenge Test .....	28
Appendix 3: Certificates of Allergen Content .....	29
Appendix 4: Miscellaneous .....	32

## **INTRODUCTION**

### **PRODUCT DESCRIPTION**

**Product Names:** Instant Facial Lifting Wonder Serum and O2 Purifyer Face + Body Enhancing Serum\*

Product type	Serum to help with firming and purifying
Form	Gel
Colour	Slightly hazy brown
Pack size	50 ml (Instant Facial Lifting Wonder Serum), 200ml (O2 Purifyer Face + Body Enhancing Serum)
Pack type	Airless container
Dispenser type	Pump
Part of a set	No
Manufacturer code	PBP 003
Normal use	<p><u>Instant Facial Lifting Wonder Serum</u></p> <p>AM: Cleanse with RegimA. Apply eye care products. Apply a few drops of Lifting Serum to face, neck and decollete. Allow Serum to dry to a film before applying other desired RegimA serums and daily care.</p> <p><u>O2 Purifyer Face + Body Enhancing Serum</u></p> <p>To be used as part of a RegimA Peel or facial, apply eye care then a layer of O2 Purifyer Face + Body Enhancing Serum to all treated areas. Allow to dry to a film, one may then, if desired, also apply a thin layer of Marine Replenish Masque with fingertips to face and neck, avoiding the eye area, to finalise a purifying, hydrating, replenishing treatment</p>

\*This PIF contains two products with differing names, with the exact same formulation. The Instant Facial Wonder Serum is a take home product, while the O2 Purifyer Face + Body Enhancing Serum is a salon use product.

**Pictures of the Item: On following page**

## Container label

### Instant Facial Lifting Wonder Serum



### O2 Purifyer Face + Body Enhancing Serum



## Carton label

## Instant Facial Lifting Wonder Serum



## O2 Purifyer Face + Body Enhancing Serum



**Batch code:** The batch number is printed onto the underside of the carton and the container at the point of manufacturing and filling, therefore it is not visible on the label as represented in this PIF. The batching is automated, so the batch code and date is printed onto the carton and container as they are filled and boxed.

**Product claims:**

This product claims to help with firming and purifying and provide firming and immediate long-lasting hydration.

## **COSMETIC PRODUCT SAFETY REPORT**

### **Part A: Cosmetic Product Safety Information**

#### **A.1 Quantitative and qualitative composition of the cosmetic product:**

**Instant Facial Lifting Wonder Serum and O2 Purifyer Face + Body Enhancing Serum Base formula**

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Aqua	5	5	7732-18-5	231-791-2	Solvent	In-House Croda Chemicals	Water Crovola A-70
2	Almond Oil PEG-6 Esters	5		124046-50-0	#			
3	Sodium Lactate	3	5	72-17-3 / 867-56-1	200-772-0 / 212-762-3	Emollient/ Emulsifying Buffering/ Humectat/ Keratolyic/ Solvent	Purac (Chempure)	Purasal S
	Aqua	2		7732-18-5	231-791-2			
4	Butylene Glycol	2	4	107-88-0	203-529-7	Humectant/ Skin Conditioning/ Solvent/ Viscosity Controlling/ Skin Protecting	Silab (Meganede)	Detoxyl
	Aqua	1.91		7732-18-5	231-791-2			
	Butyrospermum Parkii Seedcake Extract	0.092		91080-23-8	293-515-7			
5	Aqua	2.87	3	7732-18-5	231-791-2	Solvent/ Skin Conditioning/ Skin Protecting/ Preservative	Silab (Meganede)	Celldetox
	Hydrolyzed Candida Saitoana Extract	0.11		#	#			
	Phenoxyethanol	0.015		122-99-6	204-589-7			
	Ethylhexylglycerin	0.006		70445-33-9	408-080-2			
6	Glycerin	2	2	122-99-6	204-589-7	Humectant/ Perfuming/ Skin protecting/ Viscosity Controlling	Various	Glycerine CP
7	Phenoxyethanol	0.9	1	1117-86-8	214-254-7	Preservative/ Emollient/	Vestatil PC	Dr. Straetmans (Meganede)
	Caprylyl Glycol	0.1		7732-18-5	231-791-2			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
						Humectant/ Skin Conditioning		
8	Aqua	0.8	1	1310-73-2	215-185-5	Solvent/ Buffering/ Denaturant	Various	Sodium Hydroxide 20% Solution
	Sodium Hydroxide	0.2		93686-22-7	297-672-2			
9	Citrus bergamia peel oil expressed (also known as the perfuming name: Citrus Reticulata, X C. Sinensis Peel Extract)	1	1	93686-22-7	203-806-2	Perfuming	FD Copeland (CJP Chemicals)	Bergamot Oil
10	Cyclohexane	0.009	1	9007-20-9 / 9003-01-4 / 76050-42-5 / 9062-04-8 / 9007-16-3 / 9007-17-4	#	Solvent/ Emulsion Stabilizing/ Gel Forming/ Viscosity Controlling	Noveon (Carst & Walker)	Carbopol Ultrez 30 Polymer
	Carbomer	0.99		#	#			
11	Kappaphycus Alvarezii Extract	0.2375	0.5	39300-88-4	254-409-6	Hair Conditioning/ Solvent/ Skin Conditioning/	Silab (Meganede)	Filmexel
	Caesalpinia Spinosa Fruit Pod Extract	0.2375		7732-18-5	231-791-2			
	Aqua	0.025		11138-66-2	234-394-2			
12	Xanthan Gum	0.35	71.5	7732-18-5	231-791-2	Binding/ Emulsifying/ Emulsion Stabilizing/ Gel Forming/ Skin Conditioning/	CP Kelco (Tranarc)	Keltol T Plus

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
						Surfactant/ Viscosity Controlling		
13	Aqua	71.15	71.5	7732-18-5	231-791-2	Solvent	In-House	Water

# not assigned

Ingredient order for the label: Aqua (Water), Almond Oil PEG-6 Esters, Sodium Lactate, Butylene Glycol, Glycerin, Citrus Bergamia Peel Oil Expressed, Carbomer, Phenoxyethanol, Xanthan Gum, Limonene, Caesalpinia Spinosa Fruit Pod Extract, Kappaphycus Alvarezii Extract, Sodium Hydroxide, Hydrolyzed Candida Saitoana Extract, Linalool, Caprylyl Glycol, Butyrospermum Parkii Seedcake Extract, Citral, Cyclohexane, Ethylhexylglycerin.

Red font denotes ingredients present at less than 1% which may be listed in any order.

Below are the allergens and their respective concentrations in the fragrance that are required to be listed in Article 19 Paragraph 1(d) & (g (ii)) of EC 1223/2009 when present at levels >0.001% in a leave-on product.

**Fragrance allergens\***

<b>INCI (EU) Name</b>	<b>CAS number</b>	<b>EC number</b>	<b>Concentration % w/w</b>	<b>IFRA Standard</b>	<b>Comment</b>
Citral	5392-40-5	226-394-6	0.0301		Above 0.001% limit for leave on product
Limonene	5989-27-5	227-813-5	0.2735	d-, l- and dl-limonene and natural products containing substantial amounts of it, 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 liter, determined according to the FMA method.	Entire product has less than 20 mmoles/L. The product also contains antioxidants tocopherol and tocopheryl acetate and the preservative phenoxyethanol.  Above 0.001% limit for leave on product
Linalool	78-70-6	201-134-4	0.1005		Above 0.001% limit for leave on product

#### **A.2 Physical /chemical characteristics and stability of the cosmetic product**

Physical and chemical characteristics of the ingredients have been listed in the safety data sheets which are maintained electronically by the Responsible Person and are available on request. A cross reference to the SDS tradename and electronic reference number has been shown in the base formula table.

#### **Physical and Chemical Characterization of the product**

1 Physical state	Gel
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	o/w
3 organoleptic properties (colour, odour, whenever relevant)	Slight hazy gel, characteristic odour
4 pH (at 25°C)	4.6
5 viscosity (at 25°C)	360000 cPs
6 thermal stability (glass bottle)	2 weeks @ 40°C
7 Specific gravity	1 g/ml

### Stability of the product

A shelf-life of 6 months after opening has been allocated to this product.

An on-going stability study of the product in the packaging will be available to support the shelf-life. A stability test of the product in glass jars has confirmed stability at 40°C and 50°C for 2 weeks, at which point the appearance was slightly darker in both samples and the viscosity decreased by 14% and 12%, respectively.

A 12 week stability test of the product in glass jars at room temperature has confirmed the stability of the product as formulated, at which point the products appearance was slightly darker on top. No other significant changes were noted during the 12 week period.

An accelerated aging rate of 475 days was calculated which confirmed the 6 month shelf life for the product after opening. Presented below is how the accelerated aging rate was calculated. An industry standard of 2 was used for Q10 with 84 real time testing days.

$Q10^{((\text{Accelerated Aging temperature} - \text{Ambient Temperature})/10)} \times \text{real time testing days}$

$$2^{((50-25)/10)} = 5.66$$

$$5.66 \times 84 \text{ real time testing days} = 475 \text{ days}$$

### **A.3 Microbiological Quality**

A PET test has been performed according to USP method 38 and confirms the effectiveness of the preservative for a period of 28 days. The certificate has been presented in Appendix 2.

### **A.4 Impurities, traces, information about the packaging material**

None of the ingredients of this product contained impurities at a level which would require notification.

A statement on the suitability of the product packaging is shown below.

The Chubby Chunky Airless container is made from Polypropylene, light density polyethylene (LDPE) and high density polyethylene (HDPE). The pump is made from LDPE, HDPE and polypropylene. The components of the packaging material and suitability of use criteria are included in a certificate in Appendix 4. This is maintained electronically with the PIF by the Responsible Person and is available on request.

### **A.5 Normal and reasonably foreseeable use**

Instant Facial Lifting Wonder Serum and O2 Purifyer Face + Body Enhancing Serum is a product designed to help with firming and purifying and provide firming and immediate long-lasting hydration. It is a leave-on product that in normal circumstances will be used once daily on the face, neck, decollete & body.

### **A.6 Exposure to the Cosmetic Product**

Site of application	Face, neck, decollete & body
Surface area of application (cm <sup>2</sup> )	16235*
Volume of product applied (g)	8.07
Frequency of application/use per day	Once daily
Target population	Adults
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	0.25ml exposure daily Estimated exposure based on 60 kg adult = 134.5 mg/kg bw/day
Dermal absorption information	Unknown
other	N/A

\* The total surface area for application of Instant facial lifting Wonder Serum is 16235 cm<sup>2</sup> ( Skincare; Face surface area = 565 cm<sup>2</sup> and Skincare; Body Lotion surface area = 15670cm<sup>2</sup>). These figures are extracted from the SCCS guidelines for the testing of Cosmetic Ingredients and their Safety Evaluation, 9<sup>th</sup> revision, Section 4.2 , Table 1, page 76.

## A.7 Exposure to the Substances

Daily Systemic Exposure Dosage (SED) is the daily amount of a cosmetic substance applied based on the concentration of that particular substance, the percutaneous absorption and the nominal human body weight (60 kg) and this is shown in the table below.

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#1</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Almond Oil PEG-6 Esters 124046-50-0	5	134.5	1	28.25
Sodium Lactate 867-56-1	3	134.5	1	16.95
Butylene Glycol 107-88-0	2	134.5	1	11.30
Glycerin 56-81-5	2	134.5	1	11.30
Citrus Bergamia Peel Oil Expressed 93686-22-7	1	134.5	1	5.65
Carbomer 9007-20-9	0.99	134.5	1	5.59
Phenoxyethanol 122-99-6	0.92	134.5	1	5.17
Xanthan Gum 11138-66-2	0.35	134.5	1	1.98
Caesalpinia Spinosa Fruit Pod Extract 39300-88-4	0.24	134.5	1	1.34
Kappaphycus Alvarezii Extract ##	0.24	134.5	1	1.34
Sodium Hydroxide 1310-73-2	0.2	134.5	1	1.13
Hydrolyzed Candida Saitoana Extract #2	0.11	134.5	1	0.64
Caprylyl Glycol 1117-86-8	0.1	134.5	1	0.57
Butyrospermum Parkii Seedcake Extract 91080-23-8	0.092	134.5	1	0.52

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#1</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Cyclohexane 110-82-7	0.009	134.5	1	0.051
Ethylhexylglycerin 70445-33-9	0.006	134.5	1	0.034

#1 Where no dermal absorption data is available, 100% dermal absorption is used. However, where molecular weight > 500 Da and log Pow is smaller than -1 or higher than 4, the value of 10% dermal absorption is considered unless the formulation contains penetration enhancers. Dermal absorption of nanomaterials needs to be determined experimentally.

#2 No CAS number assigned.

## A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Almond Oil PEG-6 Esters 124046-50-0	A	2014 CIR Compendium. Safe for use in cosmetics when formulated to be non-irritating. Almond Oil PEG-6 esters is the product of transesterification of Prunus Amygdalus dulcis (Almond) Oil and PEG-G. The limits of the outlined reactants are stated as up to 77% and 51% respectively, where Almond oil was determined to be non-irritating and PEG-6 safe for use in cosmetics. Full amended report 09/12 available from CIR; IJT 33 (Suppl 4):13-39, 2014. It was determined that the use of Almond Oil PEG-6 Esters is safe to use in Instant Facial Wonder Serum and O <sub>2</sub> Purifying face+ Body Enhancing Serum at the level of 5%.								
Butylene Glycol 107-88-0	A	Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006								
Butyrospermum Parkii Seedcake Extract 91080-23-8	A	For use up to 5.5% in leave on cosmetic formulations. Dermal irritation studies where Butyrospermum Parkii (Shea) Seedcake Extract was used up to 0.14% was found not irritating in human studies. Further analysis determined Butyrospermum Parkii (Shea) Seedcake Extract to be non-irritating or sensitizing in HRIPTs at concentrations up to 0.42%. Final report available 09/12/2017 is available from the CIR. Butyrospermum Parkii (Shea) Seedcake Extract is present in Instant Facial Wonder Serum and O <sub>2</sub> Purifying face+ Body Enhancing Serum at 0.092% and it was determined that no adverse effects are expected when used as directed.								
Caesalpinia Spinosa Fruit Pod Extract 39300-88-4	###	A secondary assessment was performed on Caesalpinia Spinosa Fruit Pod extract, with a read across to Caesalpinia Spinosa gum. Caesalpinia Spinosa gum was approved for use as a food ingredient by the JECFA with no ADI specified. Caesalpinia Spinosa Fruit Pod extract is present in Instant Facial Lifting Wonder Serum AND O <sub>2</sub> Purifying Face + Body Enhancing Serum at 0.24%, 4 times lower than the worst case dose of 1%. With the JECFA report outlining Caesalpinia Spinosa gum as being safe for use as a food ingredient and Caesalpinia Spinosa Fruit Pod extract being 4 times lower than the worst case dose, it was determined that the addition of Caesalpinia Spinosa Fruit Pod extract is safe for use in Instant Facial Lifting Wonder Serum AND O <sub>2</sub> Purifying Face + Body Enhancing Serum.								
Caprylyl Glycol 1117-86-8	A	Safe when used up to 5%, Safety assessment of 1,2-glycols as used in cosmetics, International Journal of Toxicology 31 (S2), 1475-1685, 2012								
Carbomer	A	Safe when used up to 2%, JACT 1(2)109-41, 1982 confirmed 11/02 IJT 22(S1):1-35, 2003								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
9007-20-9										
Citrus Bergamia Peel Oil Expressed 93686-22-7	B									Supplier IFRA certificate of conformity supplied and presented in Appendix 3. Maximum allowable concentration in product is 9.96%, actual concentration 1%. Allergen components are declared in A1 Fragrance Allergen table. Safe for inclusion in this product.
Cyclohexane 110-82-7	B									Available data on Cyclohexane indicated that it has a low order of toxicity, no ADI has been established according to JECFA report 23/19*. Cyclohexane is almost completely absorbed by the oral and inhalation route with dermal absorption of pure liquid cyclohexane in contact with the skin being 5%, this percentage is significantly reduced in Instant Facial Wonder Serum and O <sub>2</sub> Purifying face+ Body Enhancing Serum due to Cyclohexane being present in the formulation at 0.009% therefore the dermal absorption would be reduced. Cyclohexane is considered to be a skin irritant with the properties being delayed and persistent while it was not considered to be sensitizer. The NOAEL ranged from 250 ppm to 2,000 ppm in a range of animal and human toxicity testing. Taking 250ppm as the worst case scenario NOAEL the MoS was calculated to be 4902. It is considered that a value above 100 is generally considered to be safe. Cyclohexane is present at a level of 0.051 mg/kg bw/day in Instant Facial Wonder Serum and O <sub>2</sub> Purifying face+ Body Enhancing Serum, considerable lower than the level outlined as a NOAEL and therefore safe for use. Cyclohexane, Summary Risk Assessment Report. (2004). European Commission Joint Research Centre, Institute for health and Consumer Protection, European Chemicals Bureau, special Publication 1.04.22, pp 1-15; Evaluation of certain food additives. Twenty-third Report of the Joint FAO/WHO Expert Committee on Food Additives. (1981). Food and Cosmetics Toxicology, 19, p381.
Ethylhexylglycerin 70445-33-9	A									2014 CIR Compendium safe with no upper limit for concentration, IJT 32 (S3): 5-21, 2013
Glycerin 56-81-5	A									GRAS#, FDA approved food additive, FDA approved over the counter (OTC) for skin
Hydrolyzed Candida Saitoana Extract #	###									A secondary assessment was performed on Hydrolyzed Candida saitoana Extract with a read across to the active ingredient of <i>glucan</i> . Hydrolyzed Candida saitoana Extract is present in Instant Facial Lifting Serum and O <sub>2</sub> Purifyer Face + Body enhancing Serum at 0.64 mg/kg bw/day, 65 times lower than the worse case scenario dose of 2500 mg/kg bw/day. It is not expected to cause any serious

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment		
			undesirable effects when used as directed.									
Kappaphycus Alvarezii Extract ##	###									A secondary assessment was preformed on Kappaphycus Alvarezii Extract. A principal component of Kappaphycus alvarezii extract is sulfonated galactans also known as Carrageenan's. Carrageenan has been generally recognized as safe (GRAS) by the FDA and has also been approved as a food additive, this has been confirmed by WHO and JECFA with no ADI established. It has been determined that Kappaphycus alvarezii extract is a safe for use in Instant facial wonder serum and O <sub>2</sub> Purifyer face +body enhancing serum.		
Phenoxyethanol 122-99-6	B									Safe for use when included up to 1%, JACT 9(2):259-77, 1990		
Sodium Hydroxide 1310-73-2	B									Safe for use up to 6.9 % in leave on formulations, where the pH is <11. Human dermal irritation studies indicated irritation caused by sodium Hydroxide at levels as low as 0.5, with dermal sensitization HRIPT challenge test sodium hydroxide was not sensitizing when induced up to 1% and when challenged at 0.125% irritation was observed. Final report 12/15/2015 available from CIR. Sodium Hydroxide is in Annex III/15 where the pH is restricted to pH <11. Sodium hydroxide is present in Instant Facial Lifting Wonder Serum at a level of 0.2%, with a pH of 4.6 there for all restrictions are satisfied and determined safe for use as directed.		
Sodium Lactate 72-17-3	B									Safe with restrictions: Glycolic and Lactic Acid, their common salts and their simple esters, are safe for use in cosmetic products at concentrations <=10%, at final formulation pH >=3.5, when formulated to avoid increasing sun sensitivity or when directions for use include the daily use of sun protection. IJT 17(S1):1-242, 1998. Sodium Lactate is included in formulation at 3%, at a pH of 4.6 and has been determined safe for use in Instant facial lifting wonder serum and O <sub>2</sub> Purifyer Face + Body Enhancing Serum.		
Xanthan Gum 11138-66-2	A									2014 CIR Compendium safe up to 6%, Safety Assessment of Microbial Polysaccharide Gums as Use in Cosmetics, Final Report, CIR, October, 2012		

<sup>a</sup> Some ingredients are excluded from a formal risk assessment where a recognized authority has published a review of the ingredient under similar conditions of use and concluded on safe use at the level of inclusion in the cosmetic product (Hazard ID=A). Hazard ID category B is for recognized authority reviews of the ingredient under similar conditions of use with restricted use or

where the ingredient is contained in the annexes to Regulation (EC) No 1223/2009 (Hazard ID=B). Where hazard ID A or B is reported, the maximum allowed usage concentration should be stated.

<sup>b</sup> all possible routes of exposure should be considered

<sup>c</sup> A MoS of greater than 100 is considered to represent safe use

# Food item, hazard and exposure data not required.

## No CAS number assigned

### Secondary assessment preformed, presented in Appendix 4

**Fragrances:**

An IFRA Certificate of Conformity which includes the allergen composition has been presented in Appendix 3. The conformity certificate certifies compliance with the standards of INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA-47<sup>th</sup> amendment, published June 2013) provided it is used at up to 9.96% for IFRA category 5 (Woman's facial creams etc.). The fragrance is included in this product at 1% and based on this low concentration, allergens Citral is present at 0.0301%, Limonene is present at 0.2735% whilst Linalool is present at 0.1005%. As these concentrations exceed >0.001% for a leave-on product (Article 19 Paragraph 1(d) & (g (ii)) of EC 1223/2009) they are declared in the list of ingredients.

**A.9 Undesirable Effects and Serious Undesirable Effects**

No undesirable effects are anticipated based on the product being used as directed on the face, neck, decollete and body once daily.

**A.10 Information on the Cosmetic Product**

Instant facial lifting wonder serum and O<sub>2</sub> Purifyer Face + Body Enhancing Serum was released in 2017. Over the period August 2017 to August 2018 2841 units of Instant Facial Lifting Wonder Serum and 438 units of O<sub>2</sub> Purifyer Face + Body Enhancing Serum have been sold and there have been no adverse reactions reported to RégimA Company.

## **B: Part Cosmetic Product Safety Assessment**

### **B.1 Assessment Conclusion**

#### Review of the ingredients

After analysis of all the available information including:

- formulation
- toxicological profile of the ingredients and their concentration in the product
- Product data sheets supplied by the ingredient manufacturer

It is not expected that Instant Facial Lifting Wonder Serum and O<sub>2</sub> Purifying Face + Body Enhancing Serum will cause damage to human health when used as directed.

It is therefore concluded that Instant Facial Lifting Wonder Serum and O<sub>2</sub> Purifying Face + Body Enhancing Serum can be placed on the market in the EU as a face and body serum.

#### Review of human data on the product

There are no human tests such as a patch test, for this product.

### **B.2 Label Warnings and Instructions for Use**

Directions for use are given on the product label and outer packaging as presented in Appendix 4.

#### **Directions:**

**Instant Facial Lifting Wonder Serum:** AM: Cleanse with RégimA, apply eye care products. Apply a few drops of Lifting Serum to face, neck and décolleté. Allow Serum to dry to a film before applying other desired RégimA serums and daily care.

**O<sub>2</sub> Purifyer Face +Body Enhancing Serum:** To be used as part of a RégimA in-salon treatment. Following a RégimA peel or facial, apply eye care then layer of O<sub>2</sub>-Purifyer Serum to all treater areas. Allow to dry to a film, one may then, if desired, also apply a thin layer of Marine Replenish Masque with fingertips to face and neck, avoiding the eye area, to finalise a purifying, hydrating, replenishing treatment.

**Warnings:**

**Instant Facial Lifting Wonder Serum:**

'Airless Container – DO NOT remove top as this would introduce air and/or bacteria'

'Product level can be viewed through the gap in label'

'Store below 77°F/25°C in a cool dry place. Protect from light'

'Must not be combined with any other product range'

**O<sub>2</sub> Purifyer Face +Body Enhancing Serum:**

' Strictly for professional use'

'Airless container DO NOT remove top as this would introduce air and/or bacteria'

'Product level can be viewed through the gap in the label'

'Store below 77°F/25°C in a cool dry place. Protect from light'

'Must not be combined with any other product range'

A Silab IBPN technology® logo is present on the label signifying RégimA having a license to use FILMEXEL® in Instant Facial Lifting Wonder Serum and O<sub>2</sub> Purifyer Face + Body Enhancing Serum. The license and technical summary is presented in Appendix 4.

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for their firming and hydrating properties and with good local tolerance. There are no reasons to anticipate tolerance problems with use when used as directed.

This product is intended for external use in adults only.

### **B.4 Assessors Credentials and Approval of Part B**

Shirley Hudson (safety assessor)

BSc, University of Aberdeen

*CBiol, MSB*

20+ years as a practicing toxicologist in the pharmaceutical and chemical industries

A handwritten signature in black ink, appearing to read "Shirley H".

After analyzing of all of the available information including the product formulation and the toxicological profile of the ingredients, I conclude that according to the current state of scientific knowledge, this product is not expected to result in any significant damage to human health and can be safely marketed for the intended and foreseeable use as a face and body serum.

### **List of References**

SCCS Notes of Guidance for the Testing of Cosmetic Substances and Their Safety Evaluation, 9<sup>th</sup> Revision, 29 September 2015 (SCCS/1564/15)  
European Commission database on cosmetic ingredients (CosIng)  
<http://ec.europa.eu/consumers/cosmetics/cosing/>  
Cosmetic ingredient review <http://www.cir-safety.org/>

## METHOD OF MANUFACTURE / GMP CERTIFICATION



## **PROOF OF EFFECT CLAIMED**

This product claims to help with firming and purifying and provide firming and immediate long-lasting hydration, confirmatory evidence has been provided by RégimA. SpaZone Instant Facial Lifting Wonder Serum and O<sub>2</sub> Purifyer Face + Body Enhancing Serum contains an active ingredient called FILMEXEL® (with active botanicals Kappaphycus Alvarezii Extract and Caesalpinia Spinosa Fruit Pod Extract), this patented dynamic ingredient is categorised as providing a non-occlusive film known as a 'Second Skin' that mimicks its properties and functions. A technical summary outlining this proof of effect along with RégimA's license to use FILMEXEL® in Instant Facial Lifting Wonder Serum and O<sub>2</sub> Purifyer Face + Body Enhancing Serum is presented in Appendix 4.

## **ANIMAL TESTING STATEMENT**

To the best of our knowledge, the manufacturer and his suppliers have not carried out or commissioned any animal testing for the purpose of developing new cosmetic products.

The statement below is a confirmation of the company policy:

## **RégimA Skin Treatments**

CK92/05371/23  
VAT No. 4590131043

**Tel: 011 615 2869 or 011 622 7827**  
**Fax: 011 616 8008**  
**Cell: 0836537020**  
**e-mail: [jax@regima.com](mailto:jax@regima.com)**

**POSTAL ADDRESS: PO BOX 9523 Edenglen 1613**

**PHYSICAL ADDRESS: 20 River Road Morninghill Bedfordview 2007 RSA**

### Animal Testing Compliance Statement

This letter is to serve as testimony as to the practice of animal testing, and confirm that RégimA Skin Treatments has not, nor will not engage in any practice that involves animal testing in any form.

RégimA Skin Treatments hereby confirms neither the manufacturer nor RégimA Skin Treatments itself have commissioned or carried out any form of animal

testing during the course of product development. This applies to any and all activities performed as part of the development process, including, but not restricted to: R&D, stability testing, safety and toxicology assessments, suitability studies or any other facet related to the product's development.

## **Appendix 1: Safety Data Sheets or Ingredient Specifications**

Safety data sheets and technical data sheets for the ingredients are maintained electronically with the PIF by the Responsible Person. They are available on request.

## **Appendix 2: Microbial Challenge Test**

A microbial challenge test is maintained electronically with the PIF by the Responsible Person. It is available on request.

## **Appendix 3: Certificates of Allergen Content**



### **Allergen Analysis**

*Compound Name : BERGAMOT OIL {BOL-BE01}*

*Code Number : RCP-76695*

flavour ingredient	CAS No.	Concentration present as a percentage (%) or 'A' for absent in flavour		
		Added as such	From natural & other sources	Total
alpha-iso-Methylionone	127-51-5	A	A	A
Amyl Cinnamal	122-40-7	A	A	A
Amylcinnamyl Alcohol	101-85-9	A	A	A
Anise Alcohol	105-13-5	A	A	A
Benzyl Alcohol	100-51-6	A	A	A
Benzyl Benzoate	120-51-4	A	A	A
Benzyl Cinnamate	103-41-3	A	A	A
Benzyl Salicylate	118-58-1	A	A	A
Butylphenyl Methylpropional (Lilial)	80-54-6	A	A	A
Cinnamal	104-55-2	A	A	A
Cinnamyl Alcohol	104-54-1	A	A	A
Citral	5392-40-5	3.00	0.01	3.01
Citronellol	106-22-9	A	A	A
Coumarin	91-64-5	A	A	A
Eugenol	97-53-0	A	A	A
Evernia Furfuraceae (Tree Moss) Extract	90028-67-4	A	A	A
Evernia Prunastri (Oak Moss) Extract	90028-68-5	A	A	A
Famesol	4602-84-0	A	A	A
Geraniol	106-24-1	A	A	A
Hexyl Cinnamal	101-86-0	A	A	A
Hydroxycitronellal	107-75-5	A	A	A
Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde (Lyral)	31906-04-4	A	A	A
Isoeugenol	97-54-1	A	A	A
Limonene	5989-27-5	A	27.35	27.35
Linalool	78-70-6	10.00	0.05	10.05
Methyl 2-Octynoate	111-12-6	A	A	A

*The information contained herein is true and accurate to the best of our knowledge. All information is valid until revisions are issued.  
We will not therefore accept liability for misuse of this data resulting in damage or loss.*



## IFRA Conformity Certificate

Compound Name : BERGAMOT OIL {BOL-BE01}

Code Number : RCP-76695

We certify that the above compound is in compliance with the standards of the INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA-47th amendment, published June 2013), provided it is used at a maximum concentration level of:

IFRA category (*)	Maximum level of use (%) (w/w) (**)
1A,1B (***)	1.33 (***)
2	1.66
3A	6.64
3B	6.64
3C	6.64
3D	6.64
4A	19.91
4B	19.91
4C	19.91
4D	19.91
5	9.96
6 (***)	33.19 (***)
7A	3.32
7B	3.32
8A	46.47
8B	46.47
9A	100.00
9B	100.00
9C	100.00
10A	82.97
10B	82.97
11A	100.00
11B	100.00

(\*) See annex for definition of IFRA categories

(\*\*) Usage limit N/A = Not Applicable; no IFRA restrictions

(\*\*\*) IFRA would recommend that any material used to impart perfume or flavour in products intended for human ingestion should consist of ingredients that are in compliance with appropriate regulations for foods and food flavourings

For other kinds of application or use at higher concentrations, a new safety evaluation may be needed; please contact F.D. Copeland and Sons Ltd.

The IFRA Standards regarding restrictions are based on safety assessments by the Panel of Experts of the RESEARCH INSTITUTE FOR FRAGRANCE MATERIALS (RIFM) and are enforced by the IFRA Scientific Committee.

Evaluation of individual Fragrance ingredients is made according to the safety standards contained in the relevant section of the IFRA Code of Practice.

It is the ultimate responsibility of our customer to ensure the safety of the final product (containing this fragrance) by further testing if need be.

*The information contained herein is true and accurate to the best of our knowledge. All information is valid until revisions are issued. It is your responsibility to ensure that the usage of the fragrance ingredients and the levels of such usage are permitted at all times according to the relevant laws and regulations.*

**ANNEX: Definition of IFRA categories**

<b>Finished Product Types</b>	<b>IFRA category</b>
Lip products of all types (solid and liquid lipsticks, balms, clear or coloured, lipwax, etc.) Toys	1A (**)
Waxes for mechanical hair removal	1B
Deodorant and Antiperspirant Products of all types (pump spray, aerosol spray, stick, roll-on, under-arm and body, etc.) Fragranced Bracelets	2
Hydroalcoholic Products applied to recently shaved skin - EdT	3A
Hydroalcoholic Products applied to recently shaved skin- Fine fragrance	3B
Eye Products of all types (eye shadow, mascara, eyeliner, eye make-up, etc.) including eye care Men's Facial Creams and Balms; Baby Creams, Lotions, Oils; Body Paint for Children	3C
Tampons	3D
EdT: Hydroalcoholic Products applied to unshaved skin, Ingredients of Perfume Kits, Scent Pads, Foil Packs, Scent Strips for Hydroalcoholic Products	4A
Hydroalcoholic Products applied to unshaved skin - Fine fragrance	4B
Hair styling aids sprays of all types (pumps, aerosol sprays etc.), Hair Deodorant Body Creams, Oils, Lotions, Fragrancing Creams of all types (except baby creams, lotions and oils) Fragrance Compounds for Cosmetic Kits, Foot Care Products, Body Paint for Adults	4C
Fragrancing cream	4D
Women's Facial Creams/Facial Make-up, Hand Cream, Facial Masks Hand Sanitisers, Wipes or Refreshing Tissues for Face, Neck, Hands, Body Baby Powder and Talc Hair Permanent and Other Hair Chemical Treatments (e.g. relaxers) but not hair dyes, Dry Shampoo or Waterless Shampoo	5
Mouthwash, including Breath Sprays, Toothpaste	6 (**)
Intimate Wipes, Baby Wipes	7A
Insect Repellent (intended to be applied to the skin)	7B
Make-up Removers of all types (not including face cleansers) Hair Styling Aids Non-Spray of all types (mousse, gels, leave-in conditioners, etc.) Nail Care, Powders and talcs (not including baby powders and talcs)	8A
Hair Dyes	8B
Shampoos of all types (including baby shampoos), Conditioner (Rinse-Off), Face Cleansers of all types (washes, gels, scrubs, etc.), Liquid Soap, Bar Soap (Toilet Soap), Depilatory(not including waxes for mechanical hair removal), Shaving Creams of all types (stick, gels, foams, etc.) Body Washes of all types (including baby washes) and Shower Gels of all types Bath Gels, Foams, Mousses, Salts, Oils and other products added to bathwater	9A
Feminine Hygiene – pads, liners, Toilet Paper Wheat bags	9B
Other' Aerosols (incl. air freshener sprays and air freshener pump sprays, but not deodorants / antiperspirants, hair styling aids spray and animal sprays) Facial Tissues, Napkins, Paper Towels	9C
Handwash Laundry Detergents of all types including concentrates Machine Wash Laundry Detergents (liquids, powders, tablets etc.) including laundry bleaches and concentrates Fabric Softeners of all types including fabric softener sheets, Hand Dishwashing Detergent including concentrates Hard Surface Cleaners of all types (bathroom and kitchen cleaners, furniture polish etc.) Other Household Cleaning Products (fabric cleaners, soft surface cleaners, carpet cleaners etc.) Dry Cleaning Kits, Shampoo for pets	10A
Diapers, Toilet Seat Wipes	10B
All non-skin contact including: Air Fresheners and Fragrancing of all types (concentrated aerosol air fresheners, plug-ins, solid substrate, membrane delivery, ambient, electrical...) excluding aerosol products, Liquid refills for air fresheners (cartridge systems), Scent delivery system using a dry air technology that releases a fragrance without sprays, aerosols or heated oils (technology of nebulization), Air delivery systems Candles, Joss Sticks, Incense, Air freshening crystals, Fragranced lamp ring, Scent pack, Machine Only Laundry Detergent (e.g. liquitabs), Toilet Blocks, Insecticides (mosquito coil, paper, electrical, for clothing etc.) excluding aerosols Fuels, Paints, Floor wax, Plastic articles (excluding toys)	11A
All incidental skin contact including: Pot pourri, powders, fragrancing sachets, Incense, Reed diffusers, Liquid refills for airfresheners (non-cartrige systems) Odoured Distilled Water (that can be added to steam irons), Machine Dishwash Detergent and Deodorizers Deodorizers/Maskers not intended for skin contact (e.g. fabric drying machine deodorizers, carpet powders) Treated Textiles (e.g. starch sprays, fabric treated with fragrances after wash, deodorizers for textiles or fabrics, tights with moisturizers) Infused socks, Scratch and sniff (sampling technology) Shoe Polishes, Cat litter, Animal Sprays (all types)	11B

(\*\*) This IFRA certificate does not include a GRAS-FEMA conformity check

## **Appendix 4: Miscellaneous**

The stability report, packaging material information and product carton insert are maintained electronically with the PIF by the Responsible Person. They are available on request.

# PRODUCT INFORMATION FILE\*

RégimA

O<sub>2</sub> Radiance Luminosity  
Masque

Prepared: August 2018  
(Label & packaging update August 2021)

\*As required under Article 11 of the European Cosmetics Regulation EC No. 1223/2009

# TABLE OF CONTENTS

## Contents

INTRODUCTION .....	3
PRODUCT DESCRIPTION .....	3
COSMETIC PRODUCT SAFETY REPORT .....	7
Part A: Cosmetic Product Safety Information.....	7
A.1 Quantitative and qualitative composition of the cosmetic product:.....	7
A.2 Physical /chemical characteristics and stability of the cosmetic product .....	12
A.3 Microbiological Quality.....	14
A.4 Impurities, traces, information about the packaging material .....	14
A.5 Normal and reasonably foreseeable use.....	14
A.6 Exposure to the Cosmetic Product .....	14
A.7 Exposure to the Substances .....	15
A.8 Toxicological Profile of the Substances .....	17
A.9 Undesirable Effects and Serious Undesirable Effects.....	22
A.10 Information on the Cosmetic Product .....	22
B: Part Cosmetic Product Safety Assessment .....	23
B.1 Assessment Conclusion .....	23
B.2 Label Warnings and Instructions for Use .....	23
B.3 Reasoning .....	25
B.4 Assessors Credentials and Approval of Part B.....	25
List of References.....	25
METHOD OF MANUFACTURE / GMP CERTIFICATION.....	26
PROOF OF EFFECT CLAIMED .....	27
ANIMAL TESTING STATEMENT.....	27
Appendix 1: Safety Data Sheets or Ingredient Specifications .....	28
Appendix 2: Microbial Challenge Test .....	29
Appendix 3: Certificates of Allergen Content .....	30
Appendix 4: Miscellaneous .....	33

## **INTRODUCTION**

### **PRODUCT DESCRIPTION**

**Product Name:** O<sub>2</sub> Radiance Luminosity Masque

Product type	Facial masque
Form	Cream
Colour	Off white
Pack size	150ml
Pack type	Chubby Chunky Airless container
Dispenser type	Polyethylene Pump
Part of a set	No
Manufacturer code	IRFM 002
Normal use	<b>Directions:</b> Cleanse with RégimA. Apply a thin layer of Masque with finger tips to face and neck, avoiding the eye area. Allow 15-20 minutes for penetration and action. Remove thoroughly with RégimA Cleanser. Follow with appropriate RégimA after treatment products.

**Pictures of the Item: On following page**

Container label



## Carton label



**Batch code:** The batch number is printed onto the underside of the carton and the container at the point of manufacturing and filling, therefore it is not visible on the label as represented in this PIF. The batching is automated, so the batch code and date is printed onto the carton and container as they are filled and boxed.

**Product claims:**

This product makes no claims.

## **COSMETIC PRODUCT SAFETY REPORT**

### **Part A: Cosmetic Product Safety Information**

#### **A.1 Quantitative and qualitative composition of the cosmetic product:**

### O<sub>2</sub> Radiance Luminosity Masque base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Water (Aqua)	5	5	7732-18-5	231-791-2	Solvent	In-House	Deionised Water
2	Propylene Glycol	2.4525	5	57-55-6	200-338-0	Humectant/ Skin Conditioning/ Solvent/ Viscosity Controlling	Greentech (Natchem)	Pineapple Phytelene EG 401
	Water (Aqua)	2.4525		7732-18-5	231-791-2			
	Ananas Sativus fruit extract	0.095		68917-26-0	272-839-2			
3	Water (Aqua)	2.4775	5	7732-18-5	231-791-2	Solvent/ Humectant/ Skin Conditioning/ Viscosity Controlling	Greentech (Natchem)	Papaya Phytelene EG 402
	Propylene Glycol	2.475		57-55-6	200-338-0			
	Carica Papaya Fruit Extract	0.05		84012-30-6	281-675-0			
4	Glycine Soja Oil	4	4	8001-22-7	232-274-4	Emollient/ Perfuming/ Skin Conditioning	Textron Tecnica (CJP Chemicals)	Soyabean Oil refined No-GMO
5	Cetearyl Olivate	2	4	85116-80-9	285-532-3	Emulsifying	Textron Tecnica (CJP Chemicals)	Olivem® 1000
	Sorbitan Olivate	2		223706-40-9/ 92202-01-2	296-033-5			
6	Olea Europaea Fruit Oil	4	4	8001-25-0	232-277-0	Masking/ Perfuming/ Skin Conditioning	Textron Tecnica (CJP Chemicals)	Olive Oil Extra Virgin
7	Water (Aqua)	3.1	4	7732-18-5	231-791-2	Solvent/ Skin Protecting/ Preservative	Silab (meganede)	Eclaline® 2
	Hydrolyzed Lupine Protein Octenylsuccinate	0.84		84082-55-3	282-001-8			
	Phenoxyethanol	0.06		122-99-6	204-589-7			
8	Hydrogenated Olive Oil	1.80	3	68334-28-1/ 226993-75-5	269-820-6	Emollient/ Skin Conditioning/ Masking/	Textron Tecnica (CJP Chemicals)	Oliwax
	Olea Europaea Fruit Oil	0.9		8001-25-0	232-277-0			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename		
9	Olea Europaea Oil Unsaponifiables	0.3	3	8001-25-0/ 156798-12-8	232-277-0	Perfuming	Silab (meganede)	Oxygenskin®		
	Water (Aqua)	2.8935		7732-18-5	231-791-2	Solvent/ Skin Conditioning/ Preservative				
	Tropaeolum Majus Flower/leaf/Stem Extract	0.0855		84625-49-0	283-419-3					
	Phenoxyethanol	0.015		122-99-6	204-59-7					
	Ethylhexylglycerin	0.006		70445-33-9	408-080-2					
10	Saccharomyces/Xylinum/Black Tea Ferment	2.58294	3	100085-62-9	309-204-7	Preservative/ Buffering/ Chelating/ Masking/ Skin Conditioning/ Humectant/ Perfuming/ Skin Protecting/ Viscosity Controlling/ Emulsion Stabilizing/ Film forming/ Stabilizing	Sederma (Croda Chemicals)	Kombuchka™ PH		
	Glycerin	0.3		56-81-5	200-289-5					
	Hydroxyethylcellulose	0.045		9004-62-0	#					
	Phenoxyethanol	0.03		122-99-6	204-589-7					
	Potassium Sorbate	0.003		24634-61-5/ 590-001	246-376-1					
	Citric Acid	0.012		5949-29-1/ 77-92-9	201-069-1					
	Sodium Citrate	0.027		68-04-2/ 6132-04-3	200-675-3					
	Biotin	0.00006		58-85-5	200-399-3					
11	Glycerin	2	2	56-81-5	200-289-5	Humectant/ Perfuming/ Skin Protecting/ Viscosity Controlling	Various	Refined Glycerine		
12	Persea Gratissima Oil	2	2	8024-32-6	232-428-0	Skin Conditioning	Textron Tecnica (CJP Chemicals)	Avocado Oil		
13	Phenoxyethanol	0.9	1	122-99-6	204-589-7	Preservative/ Emollient/	Dr. Straetmans (Meganede)	Verstatil® PC		
	Caprylyl Glycol	0.1		1117-86-8	214-254-7					

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
						Humectant/ Skin Conditioning		
14	Citrus bergamia peel oil expressed (also known as the perfuming name: Citrus Reticulata, X C. Sinensis Peel Extract)	0.5	0.5	93686-22-7	297-672-2	Perfuming	FD Copeland (CJP Chemicals)	Bergamot Oil
15	Xanthan Gum	0.35	0.35	11138-66-2	234-394-2	Binding/ Emulsifying/ Emulsion Stabilising/ Gel forming/ Skin Conditioning/ Surfactant/ Viscosity Controlling	CP Kelco (Tranarc)	Keltrol T- Plus
16	Water (Aqua)	0.01	0.2	7732-18-5	231-791-2	Solvent/ Skin Conditioning	Silab (meganede)	Filmexel®
	Kappaphycus Alvarezii Extract	0.095		1220882-73- 4	310-127-6			
	Caesalpinia Spinosa Fruit Pod extract	0.095		39300-88-4	254-409-6			
17	Tocopherol	0.1	0.1	54-28- 4(gamma)/ 16698-35- 4(beta)/ 10191-41-0 (DL)/ 119-13-1/ 1406-18-4/ 1406-66-2/	200-201-5/ 240-747-1/ 2333-466-0/ 204-299-0/ 215-798-8/ 218-197-9/ 200-412-2	Antioxidant/ Masking/ Skin Conditioning	DSM Nutritional Products (Chempure)	dl- $\alpha$ - Tocopherol

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
				2074-53-5 (DL)/ 59-02-9 (D)/ 7616-22-0				
18	Water (Aqua)	53.85	53.85	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

# not assigned

Ingredient order for the label: Water (Aqua), Propylene Glycol, Olea Europaea Fruit Oil, Glycine Soja Oil, Saccharomyces/Xylinum/Black Tea Ferment, Glycerin, Cetearyl Olivate, Persea Gratissima Oil, Sorbitan Olivate, Hydrogenated Olive Oil, Phenoxyethanol, **Hydrolyzed Lupine Protein Octenylsuccinate**, Citrus Bergamia Peel Oil Expressed\*, Xanthum Gum, Olea Europaea Oil Unsaponifiables, D-Limonene, Ananas Sativus fruit extract, Caprylyl Glycol, Tocopherol, Caesalpinia Spinosa Fruit Pod extract, Kappaphycus Alvarezii Extract, Tropaeolum Majus Flower/leaf/stem Extract, Linalool, Carica Papaya Fruit extract, Hydroxyethylcellulose, Sodium Citrate, Citral, Citric Acid, Ethylhexylglycerin, Potassium Sorbate, Biotin, Linalyl Acetate, Alpha-Pinene.

Red font denotes ingredients present at less than 1% which may be listed in any order.

\* Bergamot oil is not a mixture, but it does contain sensitizers. Sensitizers (allergens) which are above the 0.001% level in a leave-on product are placed on the ingredients label list as outlined in Article 19 Paragraph 1(d) & (g (ii)) of EC 1223/2009.

Below are the allergens and their respective concentrations in the fragrance that are required to be listed in Article 19 Paragraph 1(d) & (g (ii)) of EC 1223/2009 when present at levels >0.01% in a leave-on product.

#### **Fragrance allergens**

<i>INCI (EU) Name</i>	<i>CAS number</i>	<i>EC number</i>	<i>Concentration % w/w</i>
Citral	5392-40-5	226-394-6	0.01505
D-Limonene	5989-27-5	227-813-5	0.13675
Linalool	78-70-6	201-134-4	0.05025
Linalyl Acetate	115-95-7	204-116-4	0.26895
Alpha-pinene	80-56-8	201-291-9	0.0145

#### **A.2 Physical /chemical characteristics and stability of the cosmetic product**

Physical and chemical characteristics of the ingredients have been listed in the safety data sheets which are maintained electronically by the Responsible Person and are available on request. A cross reference to the SDS tradename and electronic reference number has been shown in the base formula table.

#### **Physical and Chemical Characterization of the product**

1 Physical state	Cream
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	w/o mixture
3 organoleptic properties (colour, odour, whenever relevant)	Off white smooth light cream with a characteristic Bergamot odour
4 pH (at 25°C)	5.96
5 viscosity (at 25°C)	16,000 cPs
6 thermal stability (glass bottle)	25°C for 12 weeks
7 Specific gravity (at 25°C)	0.991 g/ml

#### **Stability of the product**

A shelf-life of 6 months after opening has been allocated to this product.

An on-going stability study of the product in the packaging will be available to support the shelf-life. A stability test of the product in was performed in glass jars has confirmed stability at 25°C for 12 weeks, at which point the viscosity increased by 22.5%. The

colour, odour pH and specific gravity all showed unremarkable change over this time period.

### **A.3 Microbiological Quality**

A PET test has been performed according to USP method 38 and confirms the effectiveness of the preservative for a period of 28 days. The certificate has been presented in Appendix 2.

### **A.4 Impurities, traces, information about the packaging material**

None of the ingredients of this product contained impurities at a level which would require notification.

A statement on the suitability of the product packaging is shown below.

The chubby Chunky airless container is made from Polypropylene. The pump is made from polypropylene, Low density Polyethylene (LDPE) and High Density Polyethylene (HDPE). The components of the packaging material and suitability of use criteria are included in a certificate in Appendix 4. This is maintained electronically with the PIF by the Responsible Person and is available on request.

### **A.5 Normal and reasonably foreseeable use**

O<sub>2</sub> Radiance Luminosity Masque is a product designed as a face and neck masque. It is a wash off product that in normal circumstances will be used strictly in salons where it would be used once daily.

### **A.6 Exposure to the Cosmetic Product**

Site of application	Face and neck
Surface area of application (cm <sup>2</sup> )	885*
Volume of product applied (mL)	250
Frequency of application/use per day	1**
Target population	Adults
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	Relative daily exposure of 0.25mL was calculated to be 4.17mg/kg bw/day based on a nominal 60kg human body weight
Dermal absorption information	No
other	NA

\*The total surface area for Urban Stress Protect + Detox Clarifying Masque is applied too= 885cm<sup>2</sup> (Skincare: 565cm<sup>2</sup>- Face surface area + 320cm<sup>2</sup> -Neck surface area). The figures used are adapted from SCCS Notes of the Guidance for the testing of Cosmetic Ingredients and their Safety Evaluation, 9<sup>th</sup> Revision, Section 4.2, Table 1, page 76

\*\* The frequency of application O<sub>2</sub> Radiance Luminosity Masque was determined as 1 applications per day, this was extracted from this RégimA product being for strictly in salon use where maximum use would be once daily.

## A.7 Exposure to the Substances

Daily Systemic Exposure Dosage (SED) is the daily amount of a cosmetic substance applied based on the concentration of that particular substance, the percutaneous absorption and the nominal human body weight (60 kg) and this is shown in the table below.

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Propylene Glycol 57-55-6	4.925	4.17	0.01	0.00206
Olea Europaea Fruit Oil 8001-25-0	4.9	4.17	0.01	0.00204
Glycine Soja Oil 8001-22-7	4	4.17	0.01	0.00167
Saccharomyces/Xylinum/Black Tea Ferment 100085-62-9	2.58	4.17	0.01	0.00108
Glycerin 56-81-5	2.3	4.17	0.01	0.00096
Cetearyl Olivate 85116-80-9	2	4.17	0.01	0.00084
Persea Gratissima Oil 8024-32-6	2	4.17	0.01	0.00083
Sorbitan Olivate 223706-40-9	2	4.17	0.01	0.00083
Hydrogenated Olive Oil 68334-28-1	1.803	4.17	0.01	0.00075
Phenoxyethanol 122-99-6	1.005	4.17	0.01	0.00042
Hydrolyzed Lupine Protein Octenylsuccinate 84082-55-3	0.84	4.17	0.01	0.00035
Citrus bergamia peel oil expressed (also known as the perfuming name: Citrus Reticulata, X C. Sinensis Peel Extract)	0.5	4.17	0.01	0.00021
Xanthan Gum 11138-66-2	0.35	4.17	0.01	0.00015

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Olea Europaea Oil Unsaponifiables 8001-25-0	0.3	4.17	0.01	0.00012
Caprylyl Glycol 1117-86-8	0.1	4.17	0.01	0.00004
Tocopherol 54-28-4	0.1	4.17	0.01	0.00004
Ananas Sativus fruit extract 68917-26-0	0.095	4.17	0.01	0.0000396
Caesalpinia Spinosa Fruit Pod extract 39300-88-4	0.095	4.17	0.01	0.0000396
Kappaphycus Alvarezii Extract 1220882-73-4	0.095	4.17	0.01	0.0000396
Tropaeolum Majus Flower/leaf/Stem Extract 84625-49-0	0.0855	4.17	0.01	0.0000357
Carica Papaya Fruit Extract 84012-30-6	0.05	4.17	0.01	0.0000188
Hydroxyethylcellulose 9004-62-0	0.045	4.17	0.01	0.0000188
Sodium Citrate 68-04-2	0.027	4.17	0.01	0.0000113
Citric Acid 5949-29-1	0.012	4.17	0.01	0.0000050
Ethylhexylglycerin 70445-33-9	0.006	4.17	0.01	0.0000025
Potassium Sorbate 24634-61-5	0.003	4.17	0.01	0.0000013
Biotin 58-85-5	0.00006	4.17	0.01	0.000000025

# 1% dermal absorption is used in the assessment of O<sub>2</sub> Radiance Luminosity Masque. The dermal penetration factor was obtained from *Face washes, gels and scrubs*, Table 3, Dermal sensitization quantitative risk Assessment (QRA) for fragrance ingredients, *Regulatory Toxicology and Pharmacology* 52, 3-23, Api et al, 2007.

#### A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Hydroxyethylcellulose 9004-62-0	A	2014 CIR Compendium, for use up to 6%. Amended safety assessment 03/09 – Available from CIR JACT 5(3):1-59, 1986 (original report)								
Saccharomyces/Xylinum/Black Tea Ferment 100085-62-9	#	Traditional food item, GRAS. Saccharomyces/Xylinum/Black Tea Ferment is present in O <sub>2</sub> Radiance Luminosity Masque at a level of 0.00108 mg/kg bw/day (2.6%) and considered safe for use.								
Propylene Glycol 57-55-6	A	2014 CIR Compendium. For use up to 50%, JACT 13(6):437-91, 1994; IJT 31(2) 245-260, 2012								
Olea Europaea Fruit Oil 8001-25-0	A	2014 CIR Compendium. For use up to 100%, Final report 03/11 available from CIR								
Glycine Soja Oil 8001-22-7	A	2014 CIR Compendium. For use up to 95%, Final report 03/11 available from CIR								
Cetearyl Olivate 85116-80-9	A	2014 CIR Compendium. For use up to 3% in dermal contact products. Safe for use in cosmetics when formulated to be non-irritating. IJT 34(Suppl.2):5-69, 2015; Final report 03/2013 available from CIR. Cetearyl Olivate is present in O <sub>2</sub> Radiance Luminosity Masque at a level of 2%; below the maximum use level and therefore considered safe for use as formulated.								
Glycerin 56-81-5	#	GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin								
Persea Gratissima Oil 8024-32-6	A	2014 CIR Compendium. For use up to 98%, Final amended report 03/11 available from CIR; JEPT 4(4):93-103, 1980 (original) re-review IJT 22(S1):1-35, 2003								
Sorbitan Olivate 223706-40-9	A	2014 CIR Compendium. For use up to 7.5%, IJT 21 (S1):93-112, 2002								
Hydrogenated Olive Oil 68334-28-1	A	2014 CIR Compendium. For use up to 12%, final report 03/11 available from CIR								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Phenoxyethanol 122-99-6	A									2014 CIR Compendium. For use up to 1%, JACT 9(2):259-77, 1990
Hydrolyzed Lupine Protein Octenylsuccinate 84082-55-3	A									Read across to <i>Hydrolyzed Lupine Protein</i> . For use up to 0.99% in leave on products and 0.6% in wash off products. It is comprised of >90% peptides (w/w) and <4% carbohydrates (w/w). Genotoxicity testing determined Hydrolysed Lupine Protein as being not mutagenic in an Ames test, additional <i>In Vitro</i> testing of <i>Hydrolyzed Lupine Protein</i> in 3D human skin model (MTT+ IL 1 $\alpha$ ) resulted in 100% concentration being non-irritating. The indication of <i>Hydrolyzed Lupine Protein</i> being non-irritating was confirmed in human patch tests where concentrations ranging from 1.92% to 6% were well tolerated and confirmed as non-irritating. Human sensitization test with concentrations ranging from 0.005% to 6% in HRIPT resulted in no indication of dermal sensitization. Final report <i>Safety Assessment of plant-derived Proteins and Peptides as Used in Cosmetics</i> 09/12/2017 available from CIR.  Hydrolyzed Lupine Protein is present in O <sub>2</sub> Radiance Luminosity Masque at a level of 0.84% (0.00035 mg/kg bw/day), it is not expected to cause any adverse effects when used as directed.
Xanthan Gum 11138-66-2	A									2014 CIR Compendium. For use up to 6%, Final report 09/12 available from CIR
Olea Europaea Oil Unsaponifiables 8001-25-0	A									2014 CIR Compendium. For use up to 3%, Final report 03/11 available from CIR
Caprylyl Glycol 1117-86-8	A									2014 CIR Compendium. For use up to 5%, IJT 31(S2):147-168, 2012
Tocopherol 54-28-4	A									2014 CIR Compendium. For use <= 5%, IJT 21(S3):15-116, 2002; Final report 03/2014 available from CIR
Ananas Sativus fruit extract 68917-26-0	#									Food item, GRAS category as food for human consumption, non-irritant.

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Caesalpinia Spinosa Fruit Pod extract 39300-88-4	##	A Secondary assessment was performed on Caesalpinia Spinosa Fruit Extract with a read across to Caesalpinia Spinosa Gum. Caesalpinia Spinosa Gum is safe for use up to 0.5% with JECFA approving its use as a food ingredient with no ADI specified. A maximum stated dose for use is indicated as 5%, 53 times greater than that amount present; 0.095%, in O <sub>2</sub> Radiance Luminosity Masque. It was determined that Caesalpinia Spinosa Fruit Extract is safe for use when used as directed.								
Kappaphycus Alvarezii Extract 1220882-73-4	##	Read across to Carrageenan, sulfated galactans extracted from red algae, Kappaphycus Alvarezii are kappa carrageenan's extracted from the red algae. GRAS approved by the FDA, with use up to 15.7% in cosmetic formulations. Dermal irritation and sensitization studies of food grade iota carrageenan on guinea pigs indicated it was not a skin sensitizer. Final report <i>Safety Assessment of Polysaccharide Gums as used in cosmetics</i> , 09/22/2015 available from the CIR. <i>Kappaphycus Alvarezii Extract</i> is present at 0.095% (0.0000395 mg/kg bw/day) and it is not expected at this level to induce any adverse outcome effects when used as directed.								
Tropaeolum Majus Flower/leaf/Stem Extract 84625-49-0	##	A secondary assessment was performed on Tropaeolum Majus Flower/leaf/stem Extract. A worst case dose of 4-6 g/day was identified as dried watercress(a common name for genus Tropaeolum ), this is a relative daily exposure of between 66.6 and 100 mg/kg bw/day. Tropaeolum Majus Flower/leaf/stem Extract is present in O <sub>2</sub> Radiance Luminosity Masque at a level of 0.0000357 mg/kg bw/day, 1,865,546 to 2,801,120 times lower than the worst case dose. It was determined that Tropaeolum Majus Flower/leaf/Stem Extract is safe for use in O <sub>2</sub> Radiance Luminosity Masque when used as directed.								
Carica Papaya Fruit Extract 84012-30-6	A	2014 CIR Compendium safe up to 0.1%, Final report 03/2011 (CIR) Read across to Carica Papaya Seed Oil, non-irritant.								
Ethylhexylglycerin 70445-33-9	A	2014 CIR Compendium. Safe for use up to 2% in leave on formulations. The skin irritation and sensitization potential of a foundation containing 0.4% ethylhexylglycerin in a RIPT with 108 males and females where the test substance was applied for 24 hours for a total of 9 induction								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment	
			applications. There was 109 participants in the challenge phase where the test sites were scored at the time of patch removal, 24 and 48 hours later. It was determined that the foundation was neither a skin irritant nor a sensitizer. IJT 32 (Suppl. 3):5-21, 2013.								
Citrus Bergamia Peel Oil Expressed	B		Supplier IFRA Certificate of conformity for Bergamot Oil is supplied and presented in Appendix 3. The maximum allowable concentration; Category 5 - Women's facial creams is 9.96 % w/w. The actual concentration in the formulation is 0.5%. The allergen components are declared in section A.1. Fragrance Allergen table. Citrus Bergamia Peel Oil Expressed will be indicated in the label along with its fragrance components. It has been determined that the use of Bergamot Oil is safe for use in O <sub>2</sub> Radiance Luminosity Masque.								
Sodium Citrate 68-04-2	A		2014 CIR Compendium, for use up to 10%. IJT 33 (S2):29-127, 2006								
Citric Acid 5949-29-1	A		2014 CIR Compendium, for use up to 39%. IJT 33 (S2): 16-46, 2014								
Potassium Sorbate 24634-61-5	A		2014 CIR Compendium, for use up to 1%. JACT 7(6):87-80,1988 confirmed 04/06								
Biotin 58-85-5	A		2014 CIR Compendium, for use up to 1%. IJT 20(S4): 1-12, 2001								

<sup>a</sup> Some ingredients are excluded from a formal risk assessment where a recognized authority has published a review of the ingredient under similar conditions of use and concluded on safe use at the level of inclusion in the cosmetic product (Hazard ID=A). Hazard ID category B is for recognized authority reviews of the ingredient under similar conditions of use with restricted use or where the ingredient is contained in the annexes to Regulation (EC) No 1223/2009 (Hazard ID=B). Where hazard ID A or B is reported, the maximum allowed usage concentration should be stated.

<sup>b</sup> all possible routes of exposure should be considered

<sup>c</sup> A MoS of greater than 100 is considered to represent safe use

# Food item, hazard and exposure data not required.

## A secondary assessment was performed to evaluate the substances toxicological potential. The assessment can be found in Appendix 4.

**Fragrances:**

O<sub>2</sub> Radiance Luminosity Masque contains a fragrance called Bergamot Oil and the IFRA certificate is presented in Appendix 3. Fragrance allergens present in Bergamot Oil are outlined in Section A.1.

**A.9 Undesirable Effects and Serious Undesirable Effects**

No undesirable effects are anticipated based on the product being used as directed on the face once daily.

**A.10 Information on the Cosmetic Product**

O<sub>2</sub> Radiance Luminosity Masque was released in 2017. Over the period August 2017 to August 2018, 900 units have been sold and there have been no adverse reactions reported to RégimA Company.

## B: Part Cosmetic Product Safety Assessment

### B.1 Assessment Conclusion

#### Review of the ingredients

After analysis of all the available information including:

- formulation
- toxicological profile of the ingredients and their concentration in the product
- Product data sheets supplied by the ingredient manufacturer

It is not expected that O<sub>2</sub> Radiance Luminosity Masque will cause damage to human health when used as directed.

It is therefore concluded that O<sub>2</sub> Radiance Luminosity Masque can be placed on the market in the EU as a facial masque.

#### Review of human data on the product

There are no human tests such as a patch test, for this product.

### B.2 Label Warnings and Instructions for Use

Directions for use are given on the product label that is presented in Appendix 4.

**Directions:** To be used as part of a RégimA in-salon treatment. Cleanse with RégimA. Apply a thin layer of Masque with fingertips to face and neck, avoiding the eye area. Allow 15-20 minutes for penetration and action.

Remove thoroughly with RégimA cleanser. Follow with appropriate RégimA after treatment products.

#### **Warnings:**

'Strictly for professional use'

'Airless container DO NOT remove top as this would introduce air and/or bacteria'

'Product level can be viewed through the gap in label'

'Store below 77°F/25°C in a cool dry place. Protect from light'

'Must not be combined with any other product range'

'Avoid eye area'

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for their face masque properties and with e.g. good local tolerance. There are no reasons to anticipate tolerance problems with use.

This product is intended for external use in adults only.

### **B.4 Assessors Credentials and Approval of Part B**

Shirley Hudson (safety assessor)

BSc, University of Aberdeen

*CBiol, MSB*

20+ years as a practicing toxicologist in the pharmaceutical and chemical industries

A handwritten signature in black ink, appearing to read "Shirley H".

After analyzing of all of the available information including the product formulation and toxicological profile of the ingredients, I conclude that according to the current state of scientific knowledge, this product is not expected to result in any significant damage to human health and can be safely marketed for the intended and foreseeable use as a face masque.

### **List of References**

SCCS Notes of Guidance for the Testing of Cosmetic Substances and Their Safety Evaluation, 9<sup>th</sup> Revision, 29 September 2015 (SCCS/1564/15)  
European Commission database on cosmetic ingredients (CosIng)  
<http://ec.europa.eu/consumers/cosmetics/cosing/>  
Cosmetic ingredient review <http://www.cir-safety.org/>

## METHOD OF MANUFACTURE / GMP CERTIFICATION



## **PROOF OF EFFECT CLAIMED**

This product makes no direct or implied claims and consequently no proof is required.

## **ANIMAL TESTING STATEMENT**

To the best of our knowledge, the manufacturer and his suppliers have not carried out or commissioned any animal testing for the purpose of developing new cosmetic products.

The statement below is a confirmation of the company policy:

# **RégimA Skin Treatments**

CK92/05371/23  
VAT No. 4590131043

**Tel: 011 615 2869 or 011 622 7827**  
**Fax: 011 616 8008**  
**Cell: 0836537020**  
**e-mail: [jax@regima.com](mailto:jax@regima.com)**

**POSTAL ADDRESS: PO BOX 9523 Edenglen 1613**

**PHYSICAL ADDRESS: 20 River Road Morninghill Bedfordview 2007 RSA**

### Animal Testing Compliance Statement

This letter is to serve as testimony as to the practice of animal testing, and confirm that RégimA Skin Treatments has not, nor will not engage in any practice that involves animal testing in any form.

RégimA Skin Treatments hereby confirms neither the manufacturer nor RégimA Skin Treatments itself have commissioned or carried out any form of animal testing during the course of product development. This applies to any and all activities performed as part of the development process, including, but not restricted to: R&D, stability testing, safety and toxicology assessments, suitability studies or any other facet related to the product's development.

## **Appendix 1: Safety Data Sheets or Ingredient Specifications**

Safety data sheets and technical data sheets for the ingredients are maintained electronically with the PIF by the Responsible Person. They are available on request.

## **Appendix 2: Microbial Challenge Test**

A microbial challenge test is maintained electronically with the PIF by the Responsible Person. It is available on request.

## Appendix 3: Certificates of Allergen Content

### Allergen Analysis

*Compound Name : BERGAMOT OIL {BOL-BE01}*

*Code Number : RCP-76695*

flavour ingredient	CAS No.	Concentration present as a percentage (%) or 'A' for absent in flavour		
		Added as such	From natural & other sources	Total
alpha-iso-Methylionone	127-51-5	A	A	A
Amyl Cinnamal	122-40-7	A	A	A
Amylcinnamyl Alcohol	101-85-9	A	A	A
Anise Alcohol	105-13-5	A	A	A
Benzyl Alcohol	100-51-6	A	A	A
Benzyl Benzoate	120-51-4	A	A	A
Benzyl Cinnamate	103-41-3	A	A	A
Benzyl Salicylate	118-58-1	A	A	A
Butylphenyl Methylpropional (Lilial)	80-54-6	A	A	A
Cinnamal	104-55-2	A	A	A
Cinnamyl Alcohol	104-54-1	A	A	A
Citral	5392-40-5	3.00	0.01	3.01
Citronellol	106-22-9	A	A	A
Coumarin	91-64-5	A	A	A
Eugenol	97-53-0	A	A	A
Evernia Furfuraceae (Tree Moss) Extract	90028-67-4	A	A	A
Evernia Prunastri (Oak Moss) Extract	90028-68-5	A	A	A
Famesol	4602-84-0	A	A	A
Geraniol	106-24-1	A	A	A
Hexyl Cinnamal	101-86-0	A	A	A
Hydoxycitronellal	107-75-5	A	A	A
Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde (Lyral)	31906-04-4	A	A	A
Isoeugenol	97-54-1	A	A	A
Limonene	5989-27-5	A	27.35	27.35
Linalool	78-70-6	10.00	0.05	10.05
Methyl 2-Octynoate	111-12-6	A	A	A

## IFRA Conformity Certificate

*Compound Name : BERGAMOT OIL {BOL-BE01}*  
*Code Number : RCP-76695*

We certify that the above compound is in compliance with the standards of the INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA-47th amendment, published June 2013), provided it is used at a maximum concentration level of:

<b>IFRA category (*)</b>	<b>Maximum level of use (%) (w/w) (**)</b>
1A,1B (***)	1.33 (***)
2	1.66
3A	6.64
3B	6.64
3C	6.64
3D	6.64
4A	19.91
4B	19.91
4C	19.91
4D	19.91
5	9.96
6 (***)	33.19 (***)
7A	3.32
7B	3.32
8A	46.47
8B	46.47
9A	100.00
9B	100.00
9C	100.00
10A	82.97
10B	82.97
11A	100.00
11B	100.00

(\*) See annex for definition of IFRA categories

(\*\*) Usage limit N/A = Not Applicable; no IFRA restrictions

(\*\*\*) IFRA would recommend that any material used to impart perfume or flavour in products intended for human ingestion should consist of ingredients that are in compliance with appropriate regulations for foods and food flavourings

For other kinds of application or use at higher concentrations, a new safety evaluation may be needed; please contact F.D. Copeland and Sons Ltd.

The IFRA Standards regarding restrictions are based on safety assessments by the Panel of Experts of the RESEARCH INSTITUTE FOR FRAGRANCE MATERIALS (RIFM) and are enforced by the IFRA Scientific Committee.

Evaluation of individual Fragrance ingredients is made according to the safety standards contained in the relevant section of the IFRA Code of Practice.

It is the ultimate responsibility of our customer to ensure the safety of the final product (containing this fragrance) by further testing if need be.

## ANNEX: Definition of IFRA categories

<b>Finished Product Types</b>	<b>IFRA category</b>
Lip products of all types (solid and liquid lipsticks, balms, clear or coloured, lipwax, etc.) Toys	1A (**)
Waxes for mechanical hair removal	1B
Deodorant and Antiperspirant Products of all types (pump spray, aerosol spray, stick, roll-on, under-arm and body, etc.) Fragranced Bracelets	2
Hydroalcoholic Products applied to recently shaved skin - EdT	3A
Hydroalcoholic Products applied to recently shaved skin- Fine fragrance	3B
Eye Products of all types (eye shadow, mascara, eyeliner, eye make-up, etc.) including eye care Men's Facial Creams and Balms; Baby Creams, Lotions, Oils; Body Paint for Children	3C
Tampons	3D
EdT: Hydroalcoholic Products applied to unshaved skin, Ingredients of Perfume Kits, Scent Pads, Foil Packs, Scent Strips for Hydroalcoholic Products	4A
Hydroalcoholic Products applied to unshaved skin - Fine fragrance	4B
Hair styling aids sprays of all types (pumps, aerosol sprays etc.), Hair Deodorant Body Creams, Oils, Lotions, Fragrancing Creams of all types (except baby creams, lotions and oils) Fragrance Compounds for Cosmetic Kits, Foot Care Products, Body Paint for Adults	4C
Fragrancing cream	4D
Women's Facial Creams/Facial Make-up, Hand Cream, Facial Masks Hand Sanitisers, Wipes or Refreshing Tissues for Face, Neck, Hands, Body Baby Powder and Talc Hair Permanent and Other Hair Chemical Treatments (e.g. relaxers) but not hair dyes, Dry Shampoo or Waterless Shampoo	5
Mouthwash, including Breath Sprays, Toothpaste	6 (**)
Intimate Wipes, Baby Wipes	7A
Insect Repellent (intended to be applied to the skin)	7B
Make-up Removers of all types (not including face cleansers) Hair Styling Aids Non-Spray of all types (mousse, gels, leave-in conditioners, etc.) Nail Care, Powders and talcs (not including baby powders and talcs)	8A
Hair Dyes	8B
Shampoos of all types (including baby shampoos), Conditioner (Rinse-Off), Face Cleaners of all types (washes, gels, scrubs, etc.), Liquid Soap, Bar Soap (Toilet Soap), Depilatory (not including waxes for mechanical hair removal), Shaving Creams of all types (stick, gels, foams, etc.) Body Washes of all types (including baby washes) and Shower Gels of all types Bath Gels, Foams, Mousses, Salts, Oils and other products added to bathwater	9A
Feminine Hygiene - pads, liners, Toilet Paper Wheat bags	9B
Other' Aerosols (incl. air freshener sprays and air freshener pump sprays, but not deodorants / antiperspirants, hair styling aids spray and animal sprays) Facial Tissues, Napkins, Paper Towels	9C
Handwash Laundry Detergents of all types including concentrates Machine Wash Laundry Detergents (liquids, powders, tablets etc.) including laundry bleaches and concentrates Fabric Softeners of all types including fabric softener sheets, Hand Dishwashing Detergent including concentrates Hard Surface Cleaners of all types (bathroom and kitchen cleaners, furniture polish etc.) Other Household Cleaning Products (fabric cleaners, soft surface cleaners, carpet cleaners etc.) Dry Cleaning Kits, Shampoo for pets	10A
Diapers, Toilet Seat Wipes	10B
All non-skin contact including: Air Fresheners and Fragrancing of all types (concentrated aerosol air fresheners, plug-ins, solid substrate, membrane delivery, ambient, electrical...) excluding aerosol products, Liquid refills for air fresheners (cartridge systems), Scent delivery system using a dry air technology that releases a fragrance without sprays, aerosols or heated oils (technology of nebulization), Air delivery system Candles, Joss Sticks, Incense, Air freshening crystals, Fragranced lamp ring, Scent pack, Machine Only Laundry Detergent (e.g. liquitabs), Toilet Blocks, Insecticides (mosquito coil, paper, electrical, for clothing etc.) excluding aerosols Fuels, Paints, Floor wax, Plastic articles (excluding toys)	11A
All incidental skin contact including: Pot pourri, powders, fragrancing sachets, incense, Reed diffusers, Liquid refills for airfresheners (non-cartridge systems) Odoured Distilled Water (that can be added to steam irons), Machine Dishwash Detergent and Deodorizers Deodorizers/Maskers not intended for skin contact (e.g. fabric drying machine deodorizers, carpet powders) Treated Textiles (e.g. starch sprays, fabric treated with fragrances after wash, deodorizers for textiles or fabrics, tights with moisturizers) Infused socks, Scratch and sniff (sampling technology) Shoe Polishes, Cat litter, Animal Sprays (all types)	11B

(\*\*) This IFRA certificate does not include a GRAS-FEMA conformity check

## **Appendix 4: Miscellaneous**

The stability report, packaging material information and product carton insert are maintained electronically with the PIF by the Responsible Person. They are available on request.

# PRODUCT INFORMATION FILE\*

RégimA Company

**Slimming Sculpting Solution  
Lift-Firm-Tone-Sculpt**

Prepared: March 2019  
(Label & packaging update August 2021)

\*As required under Article 11 of the European Cosmetics Regulation EC No. 1223/2009

# TABLE OF CONTENTS

## Contents

INTRODUCTION .....	3
PRODUCT DESCRIPTION .....	3
COSMETIC PRODUCT SAFETY REPORT .....	7
Part A: Cosmetic Product Safety Information.....	7
A.1 Quantitative and qualitative composition of the cosmetic product:.....	7
A.2 Physical /chemical characteristics and stability of the cosmetic product .....	11
A.3 Microbiological Quality.....	13
A.4 Impurities, traces, information about the packaging material .....	13
A.5 Normal and reasonably foreseeable use.....	13
A.6 Exposure to the Cosmetic Product .....	13
A.7 Exposure to the Substances .....	14
A.8 Toxicological Profile of the Substances .....	16
A.9 Undesirable Effects and Serious Undesirable Effects.....	21
A.10 Information on the Cosmetic Product .....	21
B: Part Cosmetic Product Safety Assessment .....	22
B.1 Assessment Conclusion .....	22
B.2 Label Warnings and Instructions for Use .....	22
B.3 Reasoning .....	24
B.4 Assessors Credentials and Approval of Part B .....	24
List of References.....	24
METHOD OF MANUFACTURE / GMP CERTIFICATION.....	25
PROOF OF EFFECT CLAIMED .....	26
ANIMAL TESTING STATEMENT.....	26
Appendix 1: Safety Data Sheets or Ingredient Specifications .....	28
Appendix 2: Microbial Challenge Test .....	29
Appendix 3: Certificates of Allergen Content .....	30
Appendix 4: Miscellaneous .....	33

## **INTRODUCTION**

### **PRODUCT DESCRIPTION**

**Product Name:** Slimming Sculpting Solution Lift-Firm-Tone-Sculpt

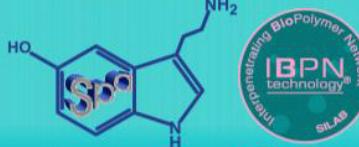
Product type	Body Cream
Form	Cream
Colour	Off White
Pack size	100ml and 200ml
Pack type	Chubby Chunky Airless Container
Dispenser type	Polypropylene pump
Part of a set	No
Manufacturer code	BSS 002
Normal use	<p><b>Directions for use:</b></p> <p><b>200ml Box</b></p> <p>To be used as part of a RégimA in-salon treatment.</p> <p>Cleanse the body of cream and oil, except SpaZone O<sub>2</sub>-Purifyer Serum and/or Target Cellulite, which may be used in combination.</p> <p>Apply one pump depression per target area such as thighs, inner knees, abdomen, upper arms. Gently massage a thin layer of cream solution to target areas. A cooling sensation may be felt. Therapist may then apply plastic wrap firmly over treated areas and leave for one hour. Plastic wrap is then removed.</p> <p>These SpaZone products are leave on treatments that work synergistically so are not cleansed off until the next morning if possible.</p>

**Pictures of the Item: On following page**

## Container label

**Ingredients**

Aqua (Water), Cetearyl Olivate (and) Sorbitan Olivate, Shea Butter Glycerides, Olea Europaea (Olive) Fruit Oil, Tropaeolum Majus Flower/Leaf/Stem Extract, Hydrolyzed Celosia Cristata Flower/Seed Extract, Hydrolyzed Prunella Vulgaris Extract, Rosa Canina Fruit Oil, Ribes Nugrum (Black Currant) Seed Oil, Hydrogenated Olive Oil, Olea Europaea (Olive) Fruit Oil, Olea Europaea (Olive) Oil Unsaponifiables, Glycerin, Persea Gratissima (Avocado) Oil, Kappaphycus Alarezii Extract, Caesalpinia Spinosa Fruit Extract, Tocopherol, Xanthan Gum, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Phenoxyethanol (and) Caprylyl Glycol


**Régim<sup>a</sup>**  
International Skin Treatments  
50 Van Buren Road, Bedfordview, 2008  
Gauteng, South Africa  
[www.regima.zone](http://www.regima.zone)  
Manufactured in South Africa

EU - RP CSI-Europe: The Greenway, Ardilaun Court, St. Stephen's Green, Dublin 2, Ireland  
UK - RP CSI-UK: Pentlands Science Park, Penicuik, Nr Edinburgh, EH26 0PZ, UK  
US - FDA - 1007858


RÉGIMA IS AGAINST ANIMAL TESTING

**Régim<sup>a</sup> SpaZONE**

# SLIMMING SCULPTING SOLUTION

## LIFT – FIRM – TONE SLIM – SCULPT

**ALL SKIN TYPES**

**Directions for use:**

To be used as part of a Régim<sup>a</sup> in-salon treatment.

Cleanse the body of cream and oil, except SpaZone O2-Purifyer Serum and/or Target Cellulite, which may be used in combination.

Apply one pump depression per target area, such as thighs, inner knees, abdomen, upper arms. Gently massage a thin layer of Cream Solution to target areas. A cooling sensation may be felt. Therapist may then apply plastic wrap firmly over treated areas and leave for one hour. Plastic wrap is then removed.

These SpaZone products are leave-on treatments that work synergistically, so are not cleansed off, until the next morning if possible.

**MUST NOT be combined with any other product range**

**STRICTLY FOR PROFESSIONAL USE**

**AIRLESS CONTAINER DO NOT REMOVE TOP**  
AS THIS WOULD INTRODUCE AIR AND/OR BACTERIA

**PRODUCT LEVEL CAN BE VIEWED THROUGH THE GAP IN LABEL**

**STORE BELOW 77°F / 25°C IN A COOL DRY PLACE. PROTECT FROM LIGHT**

200 ml. Net 6.7 fl. oz.

## Carton label



**Batch code:** The batch number is printed onto the underside of the carton and the container at the point of manufacturing and filling, therefore it is not visible on the label as represented in this PIF. The batching is automated, so the batch code and date is printed onto the carton and container as they are filled and boxed.

**Product claims:**

This product claims to limit the development of fat masses, particularly in the abdomen and thighs and to firm the upper arms. It helps to facilitate the elimination of fat, stimulating lipolytic activity (breaking down of fat) of adipocytes (fat cells).

Provides a dual action mechanism by tightening the dermal fiber network, allowing the skin to regain elasticity and tone, restoring curve contour.

It has been described that with continued treatments the consumer can experience a decrease in oedema (fluid retention), thigh and abdominal circumference, dermal tightening, helping regain elasticity and tone.

## **COSMETIC PRODUCT SAFETY REPORT**

### **Part A: Cosmetic Product Safety Information**

#### **A.1 Quantitative and qualitative composition of the cosmetic product:**

**Slimming Sculpting Solution Lift Firm Tone Sculpt base formula**

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Cetearyl Olivate	2.5	5	85116-80-9	285-532-3	Emulsifying	Textron Tecnica (CJP Chemicals)	Olivem® 1000
	Sorbitan Olivate	2.5		223706-40-9/ 92202-01-2	296-0335-5			
2	Shea butter Glycerides	5	5	194043-92-0/ 68424-61-3	270-312-0			
3	Olea Europaea Fruit Oil	5	5	8001-25-0	232-277-0	Masking/ Perfuming/ Skin Conditioning	Textron Tecnica (CJP Chemicals)	Olive Oil Extra Virgin
4	Water (Aqua)	3.38	4	7732-18-5	231-791-2	Solvent/ Skin Conditioning/ Abbrasive/ Bulking	Silab (Meganede)	Coheliss™
	Pentylene Glycol	0.4		5343-92-0	226-285-3			
	Secale Cereale Seed Extract	0.22		90106-48-2	290-271-3			
5	Water (Aqua)	3.464	4	7732-18-5	231-791-2	Solvent/ Skin Conditioning/ Skin Protecting	Silab (Meganede)	BioSculptine® s GR
	Pentylene Glycol	0.4		5343-92-0	226-285-3			
	Hydrolyzed Celosia Cristata Flower/Seed Extract	0.1088		669066-11-9	613-997-8			
	Hydrolyzed Prunella Vulgaris Extract	0.0272		90105-92-3	290-211-6			
6	Rosa Canina Fruit Oil	3	3	84603-93-0/ 84696-47-9	238-652-0	Emollient/ Skin Conditioning	Seatons (Croda)	Seatons Rosehip Oil Ref-LQ-(JL)
7	Ribes Nigrum Seed Oil	3	3	68606-81-5/ 97676-19-2	271-749-0	Emollient	Textron Tecnica (CJP Chemicals)	Blackcurrent Seed Oil
8	Hydrogenated Olive Oil	1.95	3	226993-75-5/ 68334-28-1	269-820-6/	Skin Conditioning/ Viscosity Controlling/	Textron Tecnica (CJP	Oliwax®

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Olea Europaea Fruit Oil	0.825		8001-25-0	232-277-0	Masking/ Perfuming	Chemicals)	
	Olea Europaea Oil Unsaponifiables	0.225		8001-25-0/ 798-12-8	232-277-0			
9	Glycerin	3	3	56-81-5	200-289-5	Humectant/ Perfuming/ Skin Protecting/ Viscosity Controlling	Various	Refined Glycerine
10	Persea Gratissima Oil	2	2	8024-32-6	232-428-0	Skin Conditioning	Textron Tecnica (CJP Chemicals)	Cold Pressed refined Avocado Oil
11	Phenoxyethanol	0.9	1	122-99-6	204-589-7	Preservative/ Emollient/ Humectant/ Skin Conditioning	Dr. Strartmans (Meganede)	Verstatil® PC
	Caprylyl Glycol	0.1		117-86-8	214-254-7			
12	Water (Aqua)	0.05	1	7732-18-5	231-791-2	Solvent/ Skin Conditioning	Silab (Meganede)	Filmexel®
	Kappaphycus Alvarezii extract	0.475		1220882-73-4	310-127-6			
	Caesalpinia Spinosa Fruit pod extract	0.475		39300-88-4	254-409-6			
13	D-Limonene	0.2735	1	5989-27-5	227-813-5	Perfuming/ Masking/ Antifoaming	FD Copeland (CJP Chemicals)	Bergamot Oil
	Linalyl Acetate	0.5379		115-95-7	204-116-4			
	Linalool	0.1005		78-70-6	201-134-4			
	Citral	0.0301		5392-40-5	226-394-6			
	Gamma-Terpinene	0.029		99-85-4	202-794-6			
	Pinene	0.029		80-56-8	201-291-9			
14	Xanthan Gum	0.25	0.25	11138-66-2	234-394-2	Binding/ Emulsifying/ Smulsion Stabilising/	CP Kelco (Tranarc)	Keltrol T-Plus

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
						Gel Forming/ Skin Conditioning/ Surfactant/ Viscosity Controlling		
15	Tocopherol	0.1	0.1	54-28-4 (gamma)/ 166698-35-4 (beta)/ 10191-41- 0(DL)/ 119-13-1/ 1406-18-4/ 14066-66-2/ 2074-53- 5(DL)/ 59-02-9(D)/ 7616-22-0	200-201-5/ 240-747-1/ 233-466-0/ 204-299-0/ 215-798-8/ 218-197-9/ 200-412-2	Antioxidant/ Masking/ Skin Conditioning	DL- $\alpha$ - Tocopherol	DSM nutritional products (Chempure)
16	Water (Aqua)	59.65	59.65	7732-185	231-791-2	Solvent	In House	Deionised water

# not assigned

Ingredient order for the label: Water (Aqua), Olea Europaea Fruit Oil, Shea Butter Glycerides, Glycerin, Ribes Nigrum Seed Oil, Rosa Canina Fruit Oil, Cetearyl Olivate, Sorbitan Olivate, Persea Gratissima Oil, Hydrogenated Olive Oil, Citrus bergamia peel Oil expressed, Phenoxyethanol, Pentyleneglycol, Caesalpinia Spinosa Fruit Pod extract, Kappaphycus Alvarezii Extract, Limonene, Xanthan Gum, Olea Europaea Oil Unsaponifiables, Secale Cereale Seed Extract, Hydrolyzed Celosia Cristata Flower/Seed Extract, Linalool, Caprylyl Glycol, Tocopherol, Citral, Hydrolyzed Prunella Vulgaris Extract, Alpha-Pinene, Linalyl Acetate.  
 Red font denotes ingredients present at less than 1% which may be listed in any order.

Below are the allergens and their respective concentrations in the fragrance that are required to be listed in Article 19 Paragraph 1(d) & (g (ii)) of EC 1223/2009 when present at levels >0.001% in a leave-on product.

### Fragrance allergens

<i>INCI (EU) Name</i>	<i>CAS number</i>	<i>EC number</i>	<i>Concentration % w/w</i>	<i>Reference</i>
Alpha -pinene	80-56-8	201-291-9	0.029	SCCS opinion on Fragrance allergens in cosmetic products, medium risk allergen *
Linalyl Acetate	115-95-7	204-116-4	0.5379	SCCS opinion on Fragrance allergens in cosmetic products, low risk allergen *
Citral	5392-40-5	226-394-6	0.0301	Annex III/70 2*
Limonene	5989-27-5	227-813-5	0.2795	Annex III/88 2*
Linalool	78-70-6	201-134-4	0.1005	Annex III/84 2*

The restrictions of the fragrance allergens relate to the following sources:

\* SCCS Opinion on Fragrance allergens in cosmetic products, SCCS/1459/11.

2\* Regulation (EC) No. 1223/2009 of the European parliament and of the council of 30 November 2009 on cosmetic products, Annex III List of substances which cosmetic products must no contain except to the restrictions laid down, L342/128.

### A.2 Physical /chemical characteristics and stability of the cosmetic product

Physical and chemical characteristics of the ingredients have been listed in the safety data sheets which are maintained electronically by the Responsible Person and are available on request. A cross reference to the SDS tradename and electronic reference number has been shown in the base formula table.

### Physical and Chemical Characterization of the product

1 Physical state	Cream
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	w/o
3 organoleptic properties (colour, odour, whenever relevant)	Off white cream, characteristic Bergamot odour
4 pH (at 25°C)	4.43
5 viscosity (at 25°C)	19,000 cPs
6 thermal stability (glass bottle)	40°C for 12 weeks
7 Specific gravity (at 25°C)	0.961/ml

### Stability of the product

A shelf-life of 6 months after opening has been allocated to this product.

An on-going stability study of the product in the packaging will be available to support the shelf-life. A stability test of the product in glass jars has confirmed stability at 25°C for 12 weeks. During the test period the viscosity had significantly increased by 21%.

Additional testing was performed at 5°C, 40°C and 50°C over a 12 week period.

#### **5°C Stability testing**

During stability testing at 5°C at the week 12 time point the appearance of the product was described as having oily globules. An 44% increase in viscosity was also noted.

#### **40°C Stability testing**

Accelerated stability testing at 40°C showed changes in the product appearance at week 12 where it was noted as having 'oily globules'. Additionally, in week 12, the odour was noted to have changed where it was described as 'slightly stronger base odour' and the pH had dropped by 21%.

#### **50°C Stability testing**

A slight yellowish appearance change was noted from week 2 to 8 when the product was tested at 50°C, with the appearance noted as separating on week 12.

The pH had notably changed in week 2 where there was a 14% drop, this decrease continued through to week 12 where there was a 29% decrease. Additionally during viscosity testing there was a change noted from week 1 there was a 43% increase additional changes were noted in week 4, 8 and 12 where the changes were 49%, 20% and 40% respectively

.  
A label warning is in place to store Slimming Sculpting Solution-Lift-Firm-Tone-Sculpt at a temperature of 25°C, with this it is not expected to affect the stability of the product as formulated.

### **A.3 Microbiological Quality**

A PET test has been performed according to USP method 38 and confirms the effectiveness of the preservative for a period of 28 days. The certificate has been presented in Appendix 2.

### **A.4 Impurities, traces, information about the packaging material**

None of the ingredients of this product contained impurities at a level which would require notification.

A statement on the suitability of the product packaging is shown below.

The Airless Chubby Chunky Containers used in the 100ml slimming sculpting solution are made from Polypropylene and Low-density Polyethylene (LDPE), the pump is LDPE. The Airless Chubby Chunky Containers used in the 200ml slimming sculpting solution are made from Polypropylene with the pump being made from LDPE and High-density Polyethylene (HDPE). The components of the packaging material and suitability of use criteria are included in Appendix 4. This is maintained electronically with the PIF by the Responsible Person and is available on request.

### **A.5 Normal and reasonably foreseeable use**

Slimming Sculpting Solution Lift-Firm-Tone-Sculpt is a product designed to limit the development of fat masses, helping facilitate the elimination of fat, stimulating lipolytic activity (breaking down of fat) of adipocytes (fat cells). It is a leave-on product that in normal circumstances will be used once daily on the thighs, inner knees, abdomen and upper arms.

### **A.6 Exposure to the Cosmetic Product**

Site of application	Total body area (Area body -Area head female)
Surface area of application (cm <sup>2</sup> )	15670*
Volume of product applied (mg)	7820**
Frequency of application/use per day	Once daily
Target population	Adults
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance	7.82g used once daily on a 60kg person, Relative Daily Exposure has been

tables (mg/kg bw/day)	calculated as 130.33 mg/kg bw/day
Dermal absorption information	None
other	NA

\* Surface area of application has been established as 15670cm<sup>2</sup>, taking worst case scenario of RégimA Slimming Sculpting Solution Lift-Firm-Tone-Sculpt being applied to the entire body during one treatment session. Area body – Area head female = 15670cm<sup>2</sup>. Table 1; Mean exposed skin surface area per product type and frequency of application per product type, Section 4-2, page 76, SCCS Notes of guidance for the testing of cosmetic ingredients and their Safety Evaluation, 9<sup>th</sup> revision.

\*\* Volume of product applied = 7820mg; taken as worst case scenario of application of product to the entire body. Volume of product applied has been extracted from Skin Care, *Body lotion*, Table 2: Estimated daily exposure levels for different cosmetic product types according to Cosmetics Europe Data, SCCS Notes of Guidance for the testing of Cosmetic Ingredients and their Safety evaluation, 9<sup>th</sup> revision.

## A.7 Exposure to the Substances

Daily Systemic Exposure Dosage (SED) is the daily amount of a cosmetic substance applied based on the concentration of that particular substance, the percutaneous absorption and the nominal human body weight (60 kg) and this is shown in the table below.

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Olea Europaea Fruit Oil 8001-25-0	5.825	130.33	1	7.5917
Shea butter Glycerides 194043-92-0	5	130.33	1	6.5165
Glycerin 56-81-5	3	130.33	1	3.9099
Ribes Nigrum Seed Oil 68606-81-5	3	130.33	1	3.9099
Rosa Canina Fruit Oil 84603-93-0	3	130.33	1	3.9099
Cetearyl Olivate 85116-80-9	2.5	130.33	1	3.2583
Sorbitan Olivate 223706-40-9	2.5	130.33	1	3.2583
Persea Gratissima Oil 8024-32-6	2	130.33	1	2.6066
Hydrogenated Olive Oil 226993-75-5	1.95	130.33	1	2.5414
Citrus bergamia peel oil expressed	1	130.33	1	1.3033

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
93686-22-7				
Phenoxyethanol 122-99-6	0.9	130.33	1	1.1730
Pentylene Glycol 5343-92-0	0.8	130.33	1	1.0426
Caesalpinia Spinosa Fruit pod extract 39300-88-4	0.475	130.33	1	0.6191
Kappaphycus Alvarezii extract 1220882-73-4	0.475	130.33	1	0.6191
Xanthan Gum 11138-66-2	0.25	130.33	1	0.3258
Olea Europaea Oil Unsaponifiables 8001-25-0	0.225	130.33	1	0.2932
Secale Cereale Seed Extract 90106-48-2	0.22	130.33	1	0.2867
Hydrolyzed Celosia Cristata Flower/Seed Extract 669066-11-9	0.1088	130.33	1	0.142
Caprylyl Glycol 117-86-8	0.1	130.33	1	0.130
Tocopherol 54-28-4	0.1	130.33	1	0.130
Hydrolyzed Prunella Vulgaris Extract 90105-92-3	0.0272	130.33	1	0.0354

# No dermal absorption data is available, 100% dermal absorption assumed as it is a leave on product.

#### A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Olea Europaea Fruit Oil 8001-25-0	A	2014 CIR Compendium. For use up to 100%, Final report 03/11 available from CIR. Present in the current formulation at 5.825% and is therefore considered safe for use.								
Shea butter Glycerides 194043-92-0	A	For use up to 6.5%, Final report 09/12/2017 available from CIR. Present in the current formulation at 5% and is therefore considered safe for use.								
Glycerin 56-81-5	A	Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin.								
Ribes Nigrum Seed Oil 68606-81-5	A	2014 CIR Compendium. For use up to 0.3%, Final report 03/11 available from CIR. Ribes Nigrum Seed Oil is present in Slimming Sculpting Solution-Lift-Firm-Tone-Sculpt at 3%. A dermal irritation and sensitization study was performed using a skin cream containing 0.2% Ribes Nigrum (Blackcurrant) oil was evaluated with 106 participants in a HRIPT with an occlusive patch. The test indicated that it was not a dermal irritant or a sensitizer. Ribes Nigrum at 0.25% was formulated in a cream (type not specified) which was evaluated on 119 participants to determine Primary cutaneous irritation the results showed no primary irritation . <i>Ribes Nigrum</i> (Blackcurrant) seed oil is also a food item; GRAS, it is therefore considered safe for use in Slimming Sculpting Solution-Lift-Firm-Tone-Sculpt.								
Rosa Canina Fruit Oil 84603-93-0	A	2014 CIR Compendium. For use up to 19%, final report 03/11 available from CIR. Present in the current formulation at 3% and is therefore considered safe for use.								
Cetearyl Olivate 85116-80-9	A	2014 CIR Compendium. For use up to 3% and when formulated to be non-irritating, Final report 03/2013 available from CIR. Present in the current formulation at 2.5% and is therefore considered safe for use.								
Sorbitan Olivate 223706-40-9	A	2014 CIR Compendium. For use up to 7.5%, IJT 21(S1):93-112, 2002. Present in the current formulation at 2.5% and is therefore considered safe for use.								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Persea Gratissima Oil 8024-32-6	A	2014 CIR Compendium. For use up to 89%, Final amended report 03/11 available from CIR; JEPT 4(4):93-103, 1980 (original) re-review IJT 22(S1) :1-35, 2003. Present in the current formulation at 2% and is therefore considered safe for use.								
Hydrogenated Olive Oil 226993-75-5	A	2014 CIR Compendium. For use up to 12%, Final report 03/11 available from CIR. Present in the current formulation at 1.95% and is therefore considered safe for use.								
Phenoxyethanol 122-99-6	A	2014 CIR Compendium. For use up to 1%, JACT 9(2):259-77,1990. Present in the current formulation at 0.9% and is therefore considered safe for use.								
Pentylene Glycol 5343-92-0	A	2014 CIR Compendium. For use up to 5%, IJT 31 (S2):147-168, 2012. Present in the current formulation at 0.8% and is therefore considered safe for use.								
Caesalpinia Spinosa Fruit pod extract 39300-88-4	##	A secondary assessment was performed on <i>Caesalpinia Spinosa</i> Fruit Pod extract. A recommended dose was established as 1-5%; where 5% was used as the worst case scenario dose. <i>Caesalpinia Spinosa</i> Fruit Pod extract is present in Slimming Sculpting Solution lift-Firm-Tone-Sculpt at 0.475%, 10.5 times lower than that of the worst case dose outlined. A read across to <i>Caesalpinia Spinosa</i> gum was performed due to the gum being derived from the dried, gummy exudate of <i>Caesalpinia Spinosa leuminosae</i> . <i>Caesalpinia Spinosa</i> gum has been approved for use as a food ingredient with no specific ADI for man established. 2014 CIR Compendium has outlined a use concentration of 0.5% for <i>Caesalpinia Spinosa</i> gum (Final report 03/12 available from CIR). It's present in the current formulation at 0.475% and is therefore considered safe for use.. <i>Caesalpinia Spinosa</i> Fruit pod extract is not expected to cause any adverse outcome effects in Slimming Sculpting Solution lift-Firm-Tone-Sculpt as formulated when used as directed.								
Kappaphycus Alvarezii extract 1220882-73-4	##	A secondary assessment was performed on <i>Kappaphycus Alvarezii</i> extract. A read across was performed to Carrageenan as the primary component of <i>Kappaphycus Alvarezii</i> is sulfonated galactans knowns as Carrageenan. Carrageenan is GRAS the US FDA and is an approved food additive. The WHO JECFA report established confirmed that carrageenan is safe for food use and concluded that it is not necessary to specify an ADI. The carrageenan molecule is a large molecule								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
			with average molecular weights of 200,000-400,000 leading to a low dermal absorption potential and therefore reducing the risk of a systemic effect. It was therefore concluded that the presence of Kappaphycus Alvarezii extract in Slimming Sculpting Solution Lift-Firm-Tone-Sculpt at 0.475% is not expected to cause an adverse outcome effect when used as directed.							
Xanthan Gum 11138-66-2	A	2014 CIR Compendium. For use up to 6%, Final report 09/12 available from CIR. Present in the current formulation at 0.25% and is therefore considered safe for use.								
Olea Europaea Oil Unsaponifiables 8001-25-0	A	2014 CIR Compendium. For use up to 3%, Final report 03/11 available from CIR. Present in the current formulation at 0.225% and is therefore considered safe for use.								
Secale Cereale Seed Extract 90106-48-2	A	The common name for <i>Secale Cereale Seed Extract</i> is Rye Seed Extract. Rye seeds are a common food ingredient with no safety concerns associated with it. It was determined that <i>Secale Cereale Seed Extract</i> is not expected to cause any adverse outcomes when used as directed, at 0.22% (0.0092 mg/kg bw/day).								
Hydrolyzed Celosia Cristata Flower/Seed Extract 669066-11-9	##	A secondary assessment of Hydrolyzed Celosia Cristata Flower/Seed Extract has been performed. It has been used in traditional medical for the purposes of headaches, ulcers and eye inflammation. Limited toxicological data is available however an oral administration study where a methanol extract of <i>Celosia Cristata</i> was administered in feed at doses of between 1000-4000 mg/kg which equated to 150-600 mg/kg bw/day with a conversion factor was applied. Hydrolyzed Celosia Cristata Flower/Seed Extract is present in Slimming Sculpting Lift-Firm-Tone-Slim-Sculpt at 0.142 mg/kg bw/day; 1056 –4225 times lower than the doses previously outlined. Hydrolyzed Celosia Cristata Flower/Seed Extract is a component of Silab® product marketed as Biosculptine, the combined safety has been examined and was confirmed as both non-irritating in cutaneous irritation tests <i>in vivo</i> on human volunteers and non-sensitizing following evaluation in human volunteers using the Marzulli-Maibach method, these studies are outlined in the Biosculptine leaflet in Appendix 4. It is therefore concluded that Hydrolyzed Celosia Cristata Flower/Seed Extract is not expected to cause any adverse outcomes when used as directed, in Slimming Sculpting Lift-								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment	
		Firm-Tone-Slim-Sculpt as formulated.									
Caprylyl Glycol 117-86-8	A	2014 CIR Compendium. For use up to 5%, IJT 31 (S2):147-168, 2012. Present in the current formulation at 0.1% and is therefore considered safe for use.									
Tocopherol 54-28-4	A	2014 CIR Compendium. For use <=5%, IJT 21(S3):51-116, 2002; Final report 03/2014 available from CIR. Present in the current formulation at 0.1% and is therefore considered safe for use.									
Hydrolyzed Prunella Vulgaris Extract 90105-92-3	##	<p>A secondary assessment has been performed on Hydrolysed Prunella Vulgaris extract. Limited toxicological data was available with a dose range of 0.75g to 30g established via oral administration and topical application. Hydrolysed Prunella Vulgaris extract is present in Slimming Sculpting Solution Lift-Firm-Tone-Sculpt at 0.0354 mg/kg bw/day. The systemic exposure was calculated to be 12.5 mg/kg bw/day and 500mg/kg bw/day based on a 60kg human which equated to 353 and 14124 times greater than that outlined in formulation for 0.75g (750mg) and 30g (30,000mg) respectively. Prunella Vulgaris is a common Chinese herbal medicine that is used to treat a range of illnesses that include high blood pressure. Prunella Vulgaris has been listed on the FDA Poisonous Plant Database, it was also found that small doses of Prunella Vulgaris is considered safe. <i>Hydrolyzed Prunella Vulgaris Extract</i> is a component of Silab® product marketed as Biosculptine, the combined safety has been stated as non-irritating in cutaneous irritation tests when used between 2 and 4% in human volunteers. Along with the irritation potential being evaluated the sensitizing potential was evaluated and resulted in a non-sensitizing affirmation following its evaluation <i>in vivo</i> on human volunteers using the Marzulli-Maibach method, this is presented in the Biosculptine leaflet presented in Appendix 4. As hydrolyzed Purnella Vulgaris is present in Slimming Sculpting Solution Lift-Firm-Tone-Sculpt at a low level (0.0272%) and considering the available safety information, it is not expected that there would be adverse effects and it is expected to be safe for use when used as directed.</p>									

<sup>a</sup> Some ingredients are excluded from a formal risk assessment where a recognized authority has published a review of the ingredient under similar conditions of use and concluded on safe use at the level of inclusion in the cosmetic product (Hazard ID=A).

Hazard ID category B is for recognized authority reviews of the ingredient under similar conditions of use with restricted use or where the ingredient is contained in the annexes to Regulation (EC) No 1223/2009 (Hazard ID=B). Where hazard ID A or B is reported, the maximum allowed usage concentration should be stated.

<sup>b</sup> all possible routes of exposure should be considered

<sup>c</sup> A MoS of greater than 100 is considered to represent safe use

# Food item, hazard and exposure data not required.

## Secondary assessment performed and report presented in Appendix 4.

**Fragrances:**

Slimming Sculpting Solution Lift-Firm-Tone-Sculpt contains the fragrance Citrus Bergima Peel Oil expressed, known as Bergamot Oil. The IFRA certificate is presented in Appendix 3 and fragrance allergen composition is outlined in Section A.1.

**A.9 Undesirable Effects and Serious Undesirable Effects**

No undesirable effects are anticipated based on the product being used as directed on the total body area, once daily.

**A.10 Information on the Cosmetic Product**

Slimming Sculpting Solution Lift-Firm-Tone-Sculpt was released in July 2017. Over the period July 2017 to October 2018 , 346 units have been sold and there have been no adverse reactions reported to RégimA Company.

## **B: Part Cosmetic Product Safety Assessment**

### **B.1 Assessment Conclusion**

#### Review of the ingredients

After analysis of all the available information including:

- formulation
- toxicological profile of the ingredients and their concentration in the product
- Product data sheets supplied by the ingredient manufacturer

It is not expected that Slimming Sculpting Solution Lift-Firm-Tone-Sculpt will cause damage to human health when used as directed.

It is therefore concluded that Slimming Sculpting Solution Lift-Firm-Tone-Sculpt can be placed on the market in the EU as a body cream.

#### Review of human data on the product

There are no human tests such as a patch test, for this product.

### **B.2 Label Warnings and Instructions for Use**

Directions for use are given on the product label and (Appendix 4).

#### **Directions:**

##### **100ml Box**

Cleanse the body of cream and oil, except SpaZone Target Cellulite, which may be used in combination.

Apply one pump depression per target area, such as thighs, inner knees, abdomen, upper arms. Gently massage a thin layer of cream solution to target areas. A cooling sensation may be felt.

These SpaZone products are leave-on treatments that work synergistically, so do not cleanse off until the next morning if possible.

##### **200ml Box**

To be used as part of a RégimA in-salon treatment.

Cleanse the body of cream and oil, except SpaZone O<sub>2</sub>-Purifyer Serum and/or Target Cellulite, which may be used in combination.

Apply one pump depression per target area such as thighs, inner knees, abdomen, upper arms. Gently massage a thin layer of cream solution to target areas. A cooling sensation may be felt. Therapist may then apply plastic wrap firmly over treated areas and leave for one hour. Plastic wrap is then removed.

These SpaZone products are leave on treatments that work synergistically so are not cleansed off until the next morning if possible.

A IBPN technology® label is attached to packaging indicating that RégimA hold the license to utilize Silab's Interpenetrating biopolymer Network in their cosmetics. The certificate stating this is presented in Appendix 4.

**Warnings:**

**100ml**

'Must not be combined with any other product range'

'A cooling sensation may be felt'

'Airless Container DO NOT remove top as this would introduce air and/or bacteria'

'Product level can be viewed through the gap in the label'

'Store below 77°F/25°C in a cool dry place. Protect from light'

'If irritation occurs, discontinue use'

**200ml**

'To be used as part of RégimA in-salon treatment'

'Must not be combined with any other product range'

'A cooling sensation may be felt'

'Strictly for professional use'

'Airless Container DO NOT remove top as this would introduce air and/or bacteria'

'Product level can be viewed through the gap in the label'

'Store below 77°F/25°C in a cool dry place. Protect from light'

'If irritation occurs, discontinue use'

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for their body lotion properties and with good local tolerance. There are no reasons to anticipate tolerance problems with use.

This product is intended for external use in adults only.

### **B.4 Assessors Credentials and Approval of Part B**

Shirley Hudson (safety assessor)

BSc, University of Aberdeen

*CBiol, MSB*

20+ years as a practicing toxicologist in the pharmaceutical and chemical industries

A handwritten signature in black ink, appearing to read "Shirley H".

After analyzing of all of the available information including the product formulation and toxicological profile of the ingredients, I conclude that according to the current state of scientific knowledge, this product is not expected to result in any significant damage to human health and can be safely marketed for the intended and foreseeable use as a body lotion.

### **List of References**

SCCS Notes of Guidance for the Testing of Cosmetic Substances and Their Safety Evaluation, 9<sup>th</sup> Revision, 29 September 2015 (SCCS/1564/15)  
European Commission database on cosmetic ingredients (CosIng)  
<http://ec.europa.eu/consumers/cosmetics/cosing/>  
Cosmetic ingredient review <http://www.cir-safety.org/>

## METHOD OF MANUFACTURE / GMP CERTIFICATION

**CERTIFICATE  
OF REGISTRATION**



This is to certify that the management system of:

**Prime Product  
Manufacturing (Pty) Ltd**

Main Site: Necsa Site, Building V85, Elias Motsoaledi Street Ext (Church Street West), R104 Pelindaba, Madibeng Municipality, North West

has been registered by Intertek as conforming to the requirements of:

**ISO 22716:2007**

The management system is applicable to:

The production and packing of personal care products as hair care, skin care, sun care, toiletries and fragrances, including aerosols

**Certificate Number:**  
0072927-00

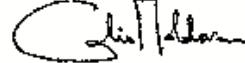
**Initial Certification Date:**  
07 March 2018

**Date of Certification Decision:**  
07 March 2018

**Issuing Date:**  
07 March 2018

**Valid Until:**  
06 March 2021

**Certificate  
Mark**  
coming soon



Calin Moldovean  
President, Business Assurance



In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at [certificate.validation@intertek.com](mailto:certificate.validation@intertek.com) or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.



## **PROOF OF EFFECT CLAIMED**

This product claims to limit the development of fat masses, particularly in the abdomen and thighs, firm upper arms, helping facilitate elimination of fat, stimulating lipolytic activity (breaking down of fat) of adipocytes (fat cells).

A new slenderizing strategy, short and long term, is obtained from the synergy of specific plant polyphenols, providing a dual action mechanical stress and by tightening the dermal fiber network. Skin regains elasticity and tone, restoring curve contour.

With continued treatments one can experience a decrease in oedema (fluid retention), thigh and abdominal circumference, dermal tightening, helping regain elasticity ad tone.

The claims relating to Slimming Sculpting Solution -Lift-Firm-Tone-Sculpt are substantiated by supplemented data supplied by Silab. RégimA is a licensed user of Silab products which include Biosculptine®, Coheliss and Filmexel where through *In Vitro* and human *In Vivo* testing have shown to substantiate the results claimed.

The additional information on Silab® ingredients are located in Appendix 4.

## **ANIMAL TESTING STATEMENT**

To the best of our knowledge, the manufacturer and his suppliers have not carried out or commissioned any animal testing for the purpose of developing new cosmetic products.

The statement below is a confirmation of the company policy:

## **RégimA Skin Treatments**

CK92/05371/23

VAT No. 4590131043

Tel: 011 615 2869 or 011 622 7827

Fax: 011 616 8008

Cell: 0836537020

e-mail: [jax@regima.com](mailto:jax@regima.com)

**POSTAL ADDRESS: PO BOX 9523 Edenglen 1613**

**PHYSICAL ADDRESS: 20 River Road Morninghill Bedfordview 2007 RSA**

Animal Testing Compliance Statement

This letter is to serve as testimony as to the practice of animal testing, and confirm that RégimA Skin Treatments has not, nor will not engage in any practice that involves animal testing in any form.

RégimA Skin Treatments hereby confirms neither the manufacturer nor RégimA Skin Treatments itself have commissioned or carried out any form of animal testing during the course of product development. This applies to any and all activities performed as part of the development process, including, but not restricted to: R&D, stability testing, safety and toxicology assessments, suitability studies or any other facet related to the product's development.

## **Appendix 1: Safety Data Sheets or Ingredient Specifications**

Safety data sheets and technical data sheets for the ingredients are maintained electronically with the PIF by the Responsible Person. They are available on request.

## **Appendix 2: Microbial Challenge Test**

A microbial challenge test is maintained electronically with the PIF by the Responsible Person. It is available on request.

## Appendix 3: Certificates of Allergen Content



### **IFRA Conformity Certificate**

**Compound Name : BERGAMOT OIL {BOL-BE01}**  
**Code Number : RCP-76695**

We certify that the above compound is in compliance with the standards of the INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA-47th amendment, published June 2013), provided it is used at a maximum concentration level of:

<b>IFRA category (*)</b>	<b>Maximum level of use (%)(w/w) (**)</b>
1A 1B (***)	1.33 (***)
2	1.66
3A	6.64
3B	6.64
3C	6.64
3D	6.64
4A	19.91
4B	19.91
4C	19.91
4D	19.91
5	9.96
6 (***)	33.19 (***)
7A	3.32
7B	3.32
8A	46.47
8B	46.47
9A	100.00
9B	100.00
9C	100.00
10A	82.97
10B	82.97
11A	100.00
11B	100.00

(\*) See annex for definition of IFRA categories

(\*\*) Usage limit N/A = Not Applicable; no IFRA restrictions

(\*\*\*) IFRA would recommend that any material used to impart perfume or flavour in products intended for human ingestion should consist of ingredients that are in compliance with appropriate regulations for foods and food flavourings

For other kinds of application or use at higher concentrations, a new safety evaluation may be needed; please contact F.D. Copeland and Sons Ltd.

The IFRA Standards regarding restrictions are based on safety assessments by the Panel of Experts of the RESEARCH INSTITUTE FOR FRAGRANCE MATERIALS (RIFM) and are enforced by the IFRA Scientific Committee.

Evaluation of individual Fragrance ingredients is made according to the safety standards contained in the relevant section of the IFRA Code of Practice.

It is the ultimate responsibility of our customer to ensure the safety of the final product (containing this fragrance) by further testing if need be.

The information contained herein is true and accurate to the best of our knowledge. All information is valid until revisions are issued. It is your responsibility to ensure that the usage of the fragrance ingredients and the levels of such usage are permitted at all times according to the relevant laws and regulations.

ANNEX: Definition of IFRA categories

<b>Finished Product Types</b>	<b>IFRA category</b>
Lip products of all types (solid and liquid lipsticks, balms, clear or coloured, lipwax, etc.) Toys	1A (**)
Waxes for mechanical hair removal	1B
Deodorant and Antiperspirant Products of all types (pump spray, aerosol spray, stick, roll-on, under-arm and body, etc.) Fragranced Bracelets	2
Hydroalcoholic Products applied to recently shaved skin - EdT	3A
Hydroalcoholic Products applied to recently shaved skin- Fine fragrance	3B
Eye Products of all types (eye shadow, mascara, eyeliner, eye make-up, etc.) including eye care Men's Facial Creams and Balms; Baby Creams, Lotions, Oils; Body Paint for Children	3C
Tampons	3D
EdT: Hydroalcoholic Products applied to unshaved skin, Ingredients of Perfume Kits, Scent Pads, Foil Packs, Scent Strips for Hydroalcoholic Products	4A
Hydroalcoholic Products applied to unshaved skin - Fine fragrance	4B
Hair styling aids sprays of all types (pumps, aerosol sprays etc.), Hair Deodorant Body Creams, Oils, Lotions, Fragrancing Creams of all types (except baby creams, lotions and oils) Fragrance Compounds for Cosmetic Kits, Foot Care Products, Body Paint for Adults	4C
Fragrancing cream	4D
Women's Facial Creams/Facial Make-up, Hand Cream, Facial Masks Hand Sanitizers, Wipes or Refreshing Tissues for Face, Neck, Hands, Body Baby Powder and Talc Hair Permanent and Other Hair Chemical Treatments (e.g. relaxers) but not hair dyes, Dry Shampoo or Waterless Shampoo	5
Mouthwash, including Breath Sprays, Toothpaste	6 (**)
Intimate Wipes, Baby Wipes	7A
Insect Repellent (intended to be applied to the skin)	7B
Make-up Removers of all types (not including face cleansers) Hair Styling Aids Non-Spray of all types (mousse, gels, leave-in conditioners, etc.) Nail Care, Powders and talcs (not including baby powders and talcs)	8A
Hair Dyes	8B
Shampoos of all types (including baby shampoos), Conditioner (Rinse-Off), Face Cleaners of all types (washes, gels, scrubs, etc.), Liquid Soap, Bar Soap (Toilet Soap), Depilatory (not including waxes for mechanical hair removal), Shaving Creams of all types (stick, gels, foams, etc.) Body Washes of all types (including baby washes) and Shower Gels of all types Bath Gels, Foams, Mousses, Salts, Oils and other products added to bathwater	9A
Feminine Hygiene - pads, liners, Toilet Paper Wheat bags	9B
Other* Aerosols (incl. air freshener sprays and air freshener pump sprays, but not deodorants / antiperspirants, hair styling aids spray and animal sprays) Facial Tissues, Napkins, Paper Towels	9C
Handwash Laundry Detergents of all types including concentrates Machine Wash Laundry Detergents (liquids, powders, tablets etc.) including laundry bleaches and concentrates Fabric Softeners of all types including fabric softener sheets, Hand Dishwashing Detergent including concentrates Hard Surface Cleaners of all types (bathroom and kitchen cleaners, furniture polish etc.) Other Household Cleaning Products (fabric cleaners, soft surface cleaners, carpet cleaners etc.) Dry Cleaning Kits, Shampoo for pets	10A
Diapers, Toilet Seat Wipes	10B
All non-skin contact including: Air Fresheners and Fragrancing of all types (concentrated aerosol air fresheners, plug-ins, solid substrate, membrane delivery, ambient, electrical...) excluding aerosol products, Liquid refills for air fresheners (cartridge systems), Scent delivery system using a dry air technology that releases a fragrance without sprays, aerosols or heated oils (technology of nebulization), Air delivery systems Candles, Joss Sticks, Incense, Air freshening crystals, Fragranced lamp ring, Scent pack, Machine Only Laundry Detergent (e.g. liquid tabs), Toilet Blocks, Insecticides (mosquito coil, paper, electrical, for clothing etc.) excluding aerosols Fuels, Paints, Floor wax, Plastic artides (excluding toys)	11A
All incidental skin contact including: Pot pourri, powders, fragrancing sachets, incense, Reed diffusers, Liquid refills for airfresheners (non-cartridge systems) Odoured Distilled Water (that can be added to steam irons), Machine Dishwash Detergent and Deodorizers Deodorizers/Maskers not intended for skin contact (e.g. fabric drying machine deodorizers, carpet powders) Treated Textiles (e.g. starch sprays, fabric treated with fragrances after wash, deodorizers for textiles or fabrics, tights with moisturizers) Infused socks, Scratch and sniff (sampling technology) Shoe Polishes, Cat litter, Animal Sprays (all types)	11B

(\*\*) This IFRA certificate does not include a GRAS-FEMA conformity check



## Allergen Analysis

Compound Name : BERGAMOT OIL {BOL-BE01}

Code Number : RCP-76695

flavour ingredient	CAS No.	Concentration present as a percentage (%) or 'A' for absent in flavour		
		Added as such	From natural & other sources	Total
alpha-Iso-Methylionane	127-51-5	A	A	A
Amyl Cinnamal	122-40-7	A	A	A
Amylcinnamyl Alcohol	101-85-9	A	A	A
Anise Alcohol	105-13-5	A	A	A
Benzyl Alkanal	100-51-6	A	A	A
Benzyl Benzoate	120-51-4	A	A	A
Benzyl Cinnamate	103-41-3	A	A	A
Benzyl Salicylate	118-58-1	A	A	A
Butylphenyl Methylpiapinal (Lilial)	80-54-6	A	A	A
Cinnamal	104-55-2	A	A	A
Cinnamyl Alcohol	104-54-1	A	A	A
Citral	5392-40-5	1.00	0.01	1.01
Citronellal	106-22-9	A	A	A
Coumarin	91-64-5	A	A	A
Eugenol	97-51-0	A	A	A
Evernia Furfuracea (Tee Moss) Extract	90028-67-4	A	A	A
Evernia Prunastri (Oak Moss) Extract	90028-68-5	A	A	A
Famesol	4602-84-0	A	A	A
Genial	106-24-1	A	A	A
Hexyl Cinnamal	101-86-0	A	A	A
Hydroxycitronellal	107-75-5	A	A	A
Hydroxyisobutyl 3-Cyclotexene Carboxaldehyde (Lyral)	31906-04-4	A	A	A
Isoeugenol	97-54-1	A	A	A
Limonene	5989-27-5	A	27.35	27.35
Linalool	78-70-6	10.00	0.05	10.05
Methyl 2-Octynoate	111-12-6	A	A	A

The information contained herein is true and accurate to the best of our knowledge. All information is valid until revisions are issued.  
We will not therefore accept liability for misuse of this data resulting in damage or loss.

## **Appendix 4: Miscellaneous**

The stability report, packaging material information and product carton insert are maintained electronically with the PIF by the Responsible Person. They are available on request.

# PRODUCT INFORMATION FILE\*

RégimA

Target Cellulite Contouring  
Complex

Prepared: April 2019  
(Label and packaging update August 2021)

\*As required under Article 11 of the European Cosmetics Regulation EC No. 1223/2009

# TABLE OF CONTENTS

## Contents

INTRODUCTION .....	3
PRODUCT DESCRIPTION .....	3
COSMETIC PRODUCT SAFETY REPORT .....	7
Part A: Cosmetic Product Safety Information.....	7
A.1 Quantitative and qualitative composition of the cosmetic product:.....	7
A.2 Physical /chemical characteristics and stability of the cosmetic product .....	12
A.3 Microbiological Quality.....	15
A.4 Impurities, traces, information about the packaging material .....	15
A.5 Normal and reasonably foreseeable use.....	15
A.6 Exposure to the Cosmetic Product .....	15
A.7 Exposure to the Substances .....	16
A.8 Toxicological Profile of the Substances .....	18
A.9 Undesirable Effects and Serious Undesirable Effects.....	23
A.10 Information on the Cosmetic Product .....	23
B: Part Cosmetic Product Safety Assessment .....	24
B.1 Assessment Conclusion .....	24
B.2 Label Warnings and Instructions for Use .....	24
B.3 Reasoning .....	26
B.4 Assessors Credentials and Approval of Part B .....	26
List of References.....	26
METHOD OF MANUFACTURE / GMP CERTIFICATION.....	27
PROOF OF EFFECT CLAIMED .....	28
ANIMAL TESTING STATEMENT.....	29
Appendix 1: Safety Data Sheets or Ingredient Specifications .....	30
Appendix 2: Microbial Challenge Test .....	31
Appendix 3: Certificates of Allergen Content .....	32
Appendix 4: Miscellaneous .....	Error! Bookmark not defined.

## **INTRODUCTION**

### **PRODUCT DESCRIPTION**

**Product Name:** Target Cellulite Silhouette Contouring Complex

Product type	Cream
Form	Emulsion
Colour	Off white
Pack size	200ml and 100ml
Pack type	Chubby chunky airless tube
Dispenser type	NA
Part of a set	No
Manufacturer code	CCC 003
Normal use	<p><b>Directions:</b> AM or PM: cleanse the body of any cream and oil, except SpaZone O<sub>2</sub>- Purifying Serum if undertaking a combined treatment. If the body is warm following a bath or shower this aids penetration.</p> <p>Massage briskly a layer of Complex to all areas prone to cellulite, thighs, buttocks, abdomen and inner knees. Then very gently ensure areas of lymph drainage (where toxins are eliminated) are covered, targeting mainly behind the knees, groin, armpits, up to the neck. Leave treatment on. One may apply Slimming Sculpting Solution to target areas over the top.</p>

**Pictures of the Item: On following page**

## Container label

### Target Cellulite Silhouette Contouring Complex – 200ml



## Carton label

### Target Cellulite Silhouette Contouring Complex – 200ml



**Batch code:** The batch number is printed onto the underside of the carton and the container at the point of manufacturing and filling; therefore, it is not visible on the label as represented in this PIF. The batching is automated, so the batch code and date is printed onto the carton and container as they are filled and boxed.

**Product claims:**

This product claims the following:

- That it targets cellulite, facilitates progressive elimination of oedema (fluid retention), stimulates microcirculation by vaso-dilatation and decongestion. Sacred Locus breaks down fat storage, limits formation of new fat cells. Natural biopolymer has a tensor, lifting, anti-winkle effect, smoothing and visibly elasticizing, improving contour, plus the look and feel of lack lustre skin.

## **COSMETIC PRODUCT SAFETY REPORT**

### **Part A: Cosmetic Product Safety Information**

#### **A.1 Quantitative and qualitative composition of the cosmetic product:**

**Target Cellulite Silhouette Contouring Complex base formula**

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Prunus Amygdalus Dulcis Oil	11.40612	12	8007-69-0/ 90320-37-9	291-063-5	Skin Conditioning/ Emollient	Textron Tecnica (CJP Chemicals)	Sweet Almond Oil
	Tocopherol	0.00588		54-28-4 (gamma)/ 16698-35-4 (beta)/ 10191-41-0 (DL)/ 119-13-1/ 1406-18-4/ 1406-66-2/ 2074-53-5 (DL)/ 59-02-9 (D)/ 7616-22-0	200-201-5/ 240-747-1/ 233-466-0/ 204-299-0/ 215-798-8 218-197-9/ 200-412-2			
	Olus Oil	0.588		68956-68-3	273-313-5			
2	Water (Aqua)	5	5	7732-18-5	231-791-2	Solvent	In House	Deionised Water
3	Cetearyl Olivate	5	5	85116-80-9	285-532-3	Emulsifying	Textron Tecnica (CJP Chemicals)	Olivem® 1000
	Sorbitan Olivate	2.5		92202-01-2/ 223706-40-9	296-033-5			
4	Water (Aqua)	3.5875	5	7732-18-5	231-791-2	Solvent / Humectant/ Masking/ Skin Conditioning/ Viscosity Controlling/	Silab (Meganede)	Remoduline™
	Butylene Glycol	1.25		107-88-0	203-529-7			
	Citrus Aurantium Amara Flower Extract	0.1125		72968-50-4/ 68916-04-1	277-143-2			
	Phenoxyethanol	0.025		122-99-6	204-589-7			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Ethylhexylglycerin	0.025		70445-33-9	408-080-2	Refreshing/Preservative		
5	Shea Butter Glycerides	5	5	68424-61-3/ 194043-92-0	270-312-1	Emulsifying/ Emulsion Stabilising/ Skin conditioning/ Surfactant/ Viscosity Controlling	Olcea (Savannah Fine Chemicals)	Olcea® Creamy Shea
6	Butylene Glycol	2	4	107-88-0	203-529-7	Humectant/ Masking/ Skin Conditioning/ Solvent/ Viscosity Controlling	Silab (Meganede)	Pro-Sveltyl® OP
	Water (Aqua)	1.966		7732-18-5	231-791-2			
	Nelumbo Nucifera Leaf extract	0.34		85085-51-4	285-379-2			
7	Hydrogenated Olive Oil	2.07	3	68334-28-1/ 226993-75-5	269-820-6	Skin Conditioning/ Viscosity Controlling/ Masking/ Perfuming	Textron Tecnica (CJP Chemicals)	Oliwax
	Olea Europaea Fruit Oil	0.633		8001-25-0	232-277-0			
	Olea Europaea Oil Unsaponifiables	0.297		8001-25-0/ 156798-12-8	232-277-0			
8	Olea Europaea Fruit Oil	2	2	8001-25-0	232-277-0	Masking/ Perfuming/ Skin Conditioning	Textron Tecnica (CJP Chemicals)	Olive Oil Extra Virgin
9	Glycerin	2	2	56-81-5	200-289-5	Humectant/ Perfuming/ Skin Protecting/ Viscosity Controlling	Various	Refined Glycerine
10	Persea Gratissima Oil	2	2	8024-32-6	232-428-0	Skin Conditioning	Textron Tecnica (CJP Chemicals)	Cold Pressed refined Avocado Oil
11	Phenoxyethanol	0.9	1	122-99-6	204-589-7	Preservative/	Dr. Straetmans	Verstatil® PC

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Caprylyl Glycol	0.1		1117-86-8	214-254-7	Humectant/ Skin Conditioning/ Emollient	(Meganede)	
12	Water (Aqua)	0.05	1	7732-18-5	231-791-2	Solvent / Skin Conditioning/ Skin Protecting	Silab (Meganede)	Filmexel ®
	Kappaphycus alvarezii extract	0.475		1220882-73-4	310-127-6			
	Caesalpinia spinosa fruit extract	0.475		39300-88-4	254-409-6			
13	Citrus bergamia peel oil expressed (also known as the perfuming name: Citrus Reticulata, X C. Sinensis Peel Extract)	1	1	93686-22-7	297-672-2	Perfuming	FD Copeland (CJP Chemicals)	Bergamot Oil
14	Xanthan Gum	0.3	0.3	11138-66-2	234-394-2	Binding/ Emulsifying/ Emulsion Stabilising/ Gel Forming/ Skin Conditioning/ Surfactant/ Viscosity Controlling	CP Kelco (Tranarc)	Keltrol ® T Plus
15	Tocopherol	0.1	0.1	54-28-4 (gamma)/ 16698-35-4 (beta)/ 10191-41-0 (DL)/ 119-13-1/ 1406-18-4/ 1406-66-2/	200-201-5/ 240-747-1/ 233-466-0/ 204-299-0/ 215-798-8/ 218-197-9/ 200-412-2	Antioxidant/ Masking/ Skin Conditioning	DSM Nutritional Products (Chempure)	dl-α-Tocopherol

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
				2074-53-5 (DL)/ 59-02-9 (D)/ 7616-22-0				
16	Water (Aqua)	51.6	51.6	7732-18-5	231-791-2	Solvent	In House	Deionised Water

# CAS/EC not assigned

Ingredient order for the label: Water (Aqua), Prunus Amygdalus Dulcis Oil, Shea butter Glycerides, Butylene Glycol, Olea Europaea Fruit Oil, Cetearyl Olivate, Sorbitan Olivate, Hydrogenated Olive Oil, Glycerin, Persea Gratissima Oil, Citrus Bergamia Peel Oil Expressed, Phenoxyethanol, Olus Oil, Caesalpinia Spinosa fruit Extract, Kappaphycus alvarezii extract, Nelumbo Nucifera Leaf extract, Xanthan Gum, Olea Europaea Oil Unsaponifiables, Limonene, Citrus Aurantium Amara Flower Extract, Tocopherol, Linalool, Caprylyl Glycol, Citral, Ethylhexylglycerin, Linalyl Acetate, Alpha-Pinene.

Red font denotes ingredients present at less than 1% which may be listed in any order.

Below are the allergens and their respective concentrations in the fragrance that are required to be listed in Article 19 Paragraph 1(d) & (g (ii)) of EC 1223/2009 when present at levels >0.001% in a leave-on product.

#### Fragrance allergens\*

<b>INCI (EU) Name</b>	<b>CAS number</b>	<b>EC number</b>	<b>Concentration % w/w</b>	<b>Comment</b>
Limonene	5989-27-5	227-813-5	0.2735	Annex III/88*
Linalyl Acetate	115-95-7	204-116-4	0.5379	Low to medium risk allergen as outlined by the SCCS Opinion on fragrance allergens 2*
Linalool	78-70-6	201-134-4	0.1005	Annex III/84*
Citral	5392-40-5	226-394-6	0.0301	Annex III/70*
Alpha -Pinene	80-56-8	201-291-9	0.029	Medium risk allergen as outlined by the SCCS Opinion on fragrance allergens 2*

\* Regulation (EC) No 1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetic products, Annex III; List of substances which cosmetic products must not contain except subject to the restrictions laid down, page 128.

2\* SCCS Opinion on Fragrance allergens in cosmetic products, 15<sup>th</sup> plenary meeting, June 2012, Section 7, Table 7-1, page 47.

#### A.2 Physical /chemical characteristics and stability of the cosmetic product

Physical and chemical characteristics of the ingredients have been listed in the safety data sheets which are maintained electronically by the Responsible Person and are available on request. A cross reference to the SDS tradename and electronic reference number has been shown in the base formula table.

#### Physical and Chemical Characterization of the product

1 Physical state	Cream
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	w/o mixture
3 organoleptic properties (colour, odour, whenever relevant)	Off white colour, smooth consistency with characteristic odour (Bergamot Oil perfuming agent)
4 pH (Initial result at 25°C)	6.01
5 viscosity (Initial result at 25°C)	30,000 cPs
6 thermal stability (glass bottle)	40°C for 12 weeks
7 Specific gravity (Initial result at 25°C)	0.951 g/ml

## **Stability of the product**

A shelf-life of 6 months after opening has been allocated to this product.

An on-going stability study of the product in the packaging will be available to support the shelf-life. A stability test of the product in glass jars confirmed stability at 25°C (room temperature) for 12 weeks. Additional testing was performed at 5°C, 40°C and 50°C.

### **Stability testing at 5°C**

During testing at 5°C an increase in viscosity was noted from week 1 to week 2 and in week 8 and week 12, the increase was noted to be 21%, 33%, 32% respectively.

### **Stability testing at 40°C**

During testing at 40°C a change in appearance was noted in week 4; the product appeared slightly darker, this continued until week 12. Additionally, a decrease in pH was noted as 16%, 24%, 39% and 39% in weeks 2 to 12 respectively. A decrease in viscosity was noted from week 1 to 8 with the decrease being 94%, 63%, 47% and 20% respectively, an 40% increase was then noted in week 12.

The appearance of the cream was noted as slightly darker from week 4 through to week 12. It was determined that a warning be placed on the product indicating users to keep in a cool place

### **Stability testing at 50°C**

Accelerated stability testing performed at 50°C indicated a significant change in the physical parameters outlined in the test from week 1, where a decrease in the pH was noted to be 20%, 27%, 38%, 46% and 47% from week 1 to 12 respectively. A decrease in viscosity was noted in week 1 and 4; 52% and 40% respectively.

From week 4; the creams appearance was noted as 'slightly darker' in comparison to the initial observation of off white, this change in appearance was noted through to week 12 where the consistency was also noted to be lumpy. Additionally, from week 8 the characteristic odour appeared stronger and this was continued through to week 12 of testing. A warning will be put in place for the user to keep in a cool dark place.

With normal storage and the consumer complying with additional warnings placed on the packaging, it is not expected that the product will deviate from specifications outlined. The stability report is presented in Appendix 4.

The Accelerated Aging Rate (AAR) was calculated to estimate the shelf life of the product. The AAR is calculated using the following equation;

$Q_{10}^A = ((\text{Accelerated Aging Temp.} - \text{Ambient Temp.})/10)$  where  $Q_{10}$  is the Accelerated Aging Factor with an industry standard of 2.

$$\therefore AAR = 2^A ((50 - 25)/10) = 5.66$$

The study was performed over 12 weeks, 84 days, therefore  $84 \times 5.66 =$  approximately 475 days using the Accelerated Aging scenario. This has confirmed the shelf life of 6 months which has been assigned to this product.

### **A.3 Microbiological Quality**

A PET test has been performed according to USP method 38 and confirms the effectiveness of the preservative for a period of 28 days. The certificate has been presented in Appendix 2.

### **A.4 Impurities, traces, information about the packaging material**

None of the ingredients of this product contained impurities at a level which would require notification.

A statement on the suitability of the product packaging is shown below.

The *Chubby Chunky Airless Containers* are made from 100ml; Low density polyethylene (LDPE) and AS/PP and 200ml; Polypropylene (PP) and Low-density polyethylene (LDPE). The pump in the 100ml is made from. The components of the packaging material and suitability of use criteria are included in a certificate in Appendix 4. This is maintained electronically with the PIF by the Responsible Person and is available on request.

### **A.5 Normal and reasonably foreseeable use**

Target Cellulite Silhouette Contouring Complex is a product designed to moisturise the skin. It is a leave-on cream that in normal circumstances will be used twice daily on the entire body, mainly the thighs, buttocks, abdomen, inner knees, groin and arm pits.

### **A.6 Exposure to the Cosmetic Product**

Site of application	Entire body (excluding the head)
Surface area of application (cm <sup>2</sup> )	15,670
Volume of product applied (mg)	7,820*
Frequency of application/use per day	2.28/day**
Target population	Adults
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	7.82g applied daily Relative daily exposure of 130.33 mg/kg bw/day based on a 60kg adult
Dermal absorption information	None
other	NA

\*Volume of product applied = 7.82g (7820 mg). This volume of application was determined as follows; Skin Care, Body Lotion, estimated daily amount applied; 7.82g. This figure has been extracted from adapted from SCCS Notes for

Guidance for the testing of Cosmetic Ingredients and their safety Evaluation, 9<sup>th</sup> Revision, Section 4.2, Table 2, page 79.

\*\*Frequency of application for Target Cellulite Silhouette Contouring Complex = 2.28/day. The frequency of application has been adapted from the following; Skincare, Body Lotion frequency of application of 2.28/day. This figure has been extracted from SCCS Notes for Guidance for the testing of Cosmetic Ingredients and their safety Evaluation, 9<sup>th</sup> Revision, Section 4.2, Table 1, page 76.

### A.7 Exposure to the Substances

Daily Systemic Exposure Dosage (SED) is the daily amount of a cosmetic substance applied based on the concentration of that particular substance, the percutaneous absorption and the nominal human body weight (60 kg) and this is shown in the table below.

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Prunus Amygdalus Dulcis Oil 8007-69-0	11.40612	130.33	1	14.87
Shea Butter Glycerides 68424-61-3	5	130.33	1	6.52
Butylene Glycol 107-88-0	3.25	130.33	1	4.24
Olea Europaea Fruit Oil 8001-25-0	2.633	130.33	1	3.432
Cetearyl Olivate 85116-80-9	2.5	130.33	1	3.258
Sorbitan Olivate 92202-01-2	2.5	130.33	1	3.258
Hydrogenated Olive Oil 68334-28-1	2.07	130.33	1	2.698
Glycerin 56-81-5	2	130.33	1	2.607
Persea Gratissima Oil 8024-32-6	2	130.33	1	2.607
Citrus bergamia peel oil expressed 93686-22-7	1	130.33	1	1.303
Phenoxyethanol 122-99-6	0.925	130.33	1	1.206
Olus Oil 68956-68-3	0.588	130.33	1	0.766
Caesalpinia spinosa fruit extract 39300-88-4	0.475	130.33	1	0.619
Kappaphycus alvarezii extract	0.475	130.33	1	0.619

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
1220882-73-4				
Nelumbo Nucifera Leaf extract 85085-51-4	0.34	130.33	1	0.443
Xanthan Gum 11138-66-2	0.3	130.33	1	0.391
Olea Europaea Oil Unsaponifiables 8001-25-0	0.297	130.33	1	0.387
Citrus Aurantium Amara Flower Extract 5989-27-5	0.1125	130.33	1	0.147
Tocopherol 54-28-4	0.10588	130.33	1	0.138
Caprylyl Glycol 1117-86-8	0.1	130.33	1	0.130
Ethylhexylglycerin 70445-33-9	0.025	130.33	1	0.033

# 100% dermal absorption is used as Target Cellulite Silhouette Contouring Complex is a leave on product.

## A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	Comment
Prunus Amygdalus Dulcis Oil 8007-69-0	A									2014 CIR Compendium. For use up to 77%, Final amended report 03/11 available from CIR; JACT 2(5):85-99, 1983; re-review IJT 24 (S1):98-101, 2005.
Shea Butter Glycerides 68424-61-3	A									For use up to 6.5%, Final report 09/12/2017 available from CIR
Butylene Glycol 107-88-0	A									2014 CIR Compendium. For use up to 89%, JACT 4(5):223-48, 1985 confirmed 02/04 IJT 25 (S2), 2006.
Olea Europaea Fruit Oil 8001-25-0	A									2014 CIR Compendium. For use up to 100%, final report 03/11 available from CIR.
Cetearyl Olivate 85116-80-9	A									2014 CIR Compendium. For use up to 3%; Safe for use in cosmetics when formulated to be non-irritating, Final report 03/2013 available from CIR.
Sorbitan Olivate 92202-01-2	A									2014 CIR Compendium. For use up to 7.5%, IJT 21 (S1):93-112, 2002.
Hydrogenated Olive Oil 68334-28-1	A									2014 CIR Compendium. For use up to 12%, Final report 03/11 available from CIR.
Glycerin 56-81-5	A									Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin.
Persea Gratissima Oil 8024-32-6	A									2014 CIR Compendium. For use up to 98%, final amended report 03/11 available from CIR; JEPT 4(4):93-103, 1980 (original) re-review IJT 22(S1):1-35, 2003.
Citrus Bergamia Peel Oil Expressed	B									Supplier IFRA certificate of conformity supplied and presented in Appendix 3. Maximum allowable concentration in product is 19.91% (Category 4C – Body creams), actual concentration in Target Cellulite Silhouette Contouring Complex is 1%. All allergen components are declared in Section A.1. fragrance allergen table. It was determined that <i>Citrus Bergamia Peel Oil Expressed</i> is expected to be safe for use in Target Cellulite Silhouette Contouring Complex.
Phenoxyethanol 122-99-6	A									2014 CIR Compendium. For use up to 1%, JACT 9(2):259-77, 1990.

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	Comment
Olus Oil 68956-68-3	A									A read across was performed to Vegetable Oil as Olus Oil is an expressed oil of vegetable origin that primarily consists of triglycerides of fatty acids. 2014 CIR Compendium. For use up to 31%, Final report 03/11 available from CIR.
Caesalpinia spinosa fruit extract 39300-88-4	A									A read across was performed on Caesalpinia spinosa fruit extract to Caesalpinia Spinosa gum. Caesalpinia Spinosa fruit Gum for use up to 0.5%, Final report 03/12 available from CIR. Caesalpinia spinosa fruit extract is present in Target Cellulite Silhouette Contouring Complex at a level of 0.475%, it is therefore expected to be safe for use in the product formulation.
Kappaphycus alvarezii extract 1220882-73-4	#									A secondary assessment was performed on Kappaphycus alvarezii extract where the proprietary ingredient sulphated galactan; Carrageenan was evaluated. Carrageenan is isolated from red seaweeds with molecular weights of between 200,000 and 400,000, with dermal penetration evaluated as being limited due to the large size of the molecule. Carrageenan is GRAS by the US FDA under the Code of Federal Regulations (21 CFR 182.7255) and is also approved as food additive ingredient. Carrageenan has also been considered safe for food use with no ADI and Considered acceptable for use topically. It is therefore expected to be safe for use in Target Cellulite Silhouette Contouring Complex. Secondary assessment in presented in Appendix 4.
Nelumbo Nucifera Leaf extract 85085-51-4										Limited publicly available information is available on Nelumbo Nucifera Leaf extract; therefore, a secondary assessment was performed on Nelumbo Nucifera Leaf extract to determine its safety. The assessment showed that the commercially recommended oral dose of Nelumbo Nucifera Leaf extract ranged from 1,000 – 3,000 mg daily. The relative daily exposure was calculated to range from 16.6mg/kg bw/day to 50 mg/kg bw/day, this equated to 38-115 times less than the level present in Target Cellulite Silhouette Contouring Complex (0.433 mg/kg bw/day), which in addition, is applied dermally where absorption is expected to be less than the oral route. It was determined that Nelumbo Nucifera Leaf extract is expected to be safe for use as formulated. The secondary assessment for Nelumbo Nucifera Leaf extract is present in Appendix 4. RegimA has provided additional information on Pro-Sveltyl® from Silab; the report and assessment are presented in Appendix 4.
Xanthan Gum 11138-66-2	A									2014 CIR Compendium. For use up to 6%, Final report 09/12 available from CIR.
Olea Europaea Oil Unsaponifiables	A									2014 CIR Compendium. For use up to 3%, Final report 03/11 available from CIR.

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	Comment
8001-25-0										

<p>Citrus Aurantium Amara Flower Extract 72968-50-4</p>	<p>A</p>	<p>For use up to 0.0325% in leave on formulations. Final report 12/06/2016 available from CIR website.</p> <p>Citrus Aurantium Amara (Bitter Orange) Flower Extract is present in Target Cellulite Silhouette Contouring Complex at 0.1125%. Citrus Aurantium Amara (Bitter Orange) Flower Extract was found to be non-irritating in human subjects during dermal irritation studies when leave on formulations were comprised of up to 0.001%. HRIPT of Citrus Aurantium Amara (Bitter Orange) Flower Extract at concentrations of up to 0.0225% were found not to be not sensitizing. Citrus Aurantium Amara (Bitter Orange) Flower Extract is safe for use when formulated to be non-irritating and non-sensitizing. A read across to Citrus Aurantium Amara (Bitter Orange) flower Oil was also performed to determine its dermal sensitization potential. Tests performed on Citrus Aurantium Amara (Bitter Orange) flower Oil found it not to be sensitizing at 4% in petrolatum; Final report 12/06/2016 available from CIR.</p> <p>Additionally, a Toxtree assessment was performed to determine the safety of Citrus Aurantium Amara Flower Extract, the assessment utilised the Cramer Rules and Revised Cramer Decision Tree along with a QSAR Skin Irritation/Skin Corrosion assessment.</p> <p>The results indicated a Low (Class I) classification in both the Cramer Rules and Revised Cramer Decision Tree, a Low (Class II) classification using the Cramer Rules describes a substance of simple chemical structure with known metabolic pathways and innocuous end products which suggest a low order of oral toxicity. The Threshold of Toxicological Concern has been established as 1,800 µg/day - 30µg/kg bw/day. The Revised Cramer Decision Tree Low (Class I) classification describes a substance with simple chemical structures and for which efficient modes of metabolism exist which suggests a low order of oral toxicity, the 5<sup>th</sup> percentile NOEL was established as 3.0 mg/kg bw/day with a human exposure threshold of 1.8 mg/person/day. A QSAR Skin Irritation/Skin Corrosion assessment indicated an unknown result.</p> <p>Citrus Aurantium Amara (Bitter Orange) Flower Extract is present in formulation at 0.147 mg/kg bw/day, lower than that outlined in the above assessments, it was therefore determined to be safe for use when used as directed.</p> <p>Bitter orange is regulated by the Food and Drug Administration (FDA). Although <i>C. aurantium</i> is listed in its Poisonous Plants Database, <i>C. aurantium</i> orange oil extract, peel, flowers, and leaf are listed in the food</p>
---	----------	--

		<p>additive database, an inventory often referred to as "Everything" Added to Food in the United States (EAFUS). Additionally, bitter orange peel, oil, oleoresins, and extracts are Generally Recognized as Safe (GRAS) as a direct additive to food. <a href="#">Citrus Aurantium Amara Flower Extract NTP Toxicological Literature Review</a></p> <p>As Citrus Aurantium Amara (Bitter Orange) Flower Extract is present at a higher percentage to that outlined in the CIR Compendium a warning will be placed on the label to direct the consumer to stop use if irritation occurs. It is not expected to cause irritation when used as directed.</p>
Tocopherol 54-28-4	A	2014 CIR Compendium. For use <= 5%. IJT 21(S3):51-116, 2002; Final report 03/2014 available from CIR.
Caprylyl Glycol 1117-86-8	A	2014 CIR Compendium. For use up to 5%, IJT 31 (S2):147-168, 2012.
Ethylhexylglycerin 70445-33-9	A	For use up to 8%, IJT 32(Suppl. 3):5-21, 2013

<sup>a</sup> Some ingredients are excluded from a formal risk assessment where a recognized authority has published a review of the ingredient under similar conditions of use and concluded on safe use at the level of inclusion in the cosmetic product (Hazard ID=A). Hazard ID category B is for recognized authority reviews of the ingredient under similar conditions of use with restricted use or where the ingredient is contained in the annexes to Regulation (EC) No 1223/2009 (Hazard ID=B). Where hazard ID A or B is reported, the maximum allowed usage concentration should be stated.

<sup>b</sup> all possible routes of exposure should be considered

<sup>c</sup> A MoS of greater than 100 is considered to represent safe use

# Food item, hazard and exposure data not required.

**Fragrances:**

Target Cellulite Silhouette Contouring Complex contains a fragrance called Bergamot Oil. The fragrance allergens are presented in Section A.1. with the IFRA certificate and certificate of conformity presented in Appendix 3.

**A.9 Undesirable Effects and Serious Undesirable Effects**

No undesirable effects are anticipated based on the product being used as directed on the body twice daily. The areas of the body that Target cellulite Silhouette Contouring Complex is targeted towards includes thighs, buttocks, abdomen, inner knees, behind knees, groin, armpits, up to neck.

**A.10 Information on the Cosmetic Product**

Target Cellulite Silhouette Contouring Complex was released in September 2017. Over the period September 2017 to April 2019 760 units have been sold and there have been no adverse reactions reported to RégimA.

## B: Part Cosmetic Product Safety Assessment

### B.1 Assessment Conclusion

#### Review of the ingredients

After analysis of all the available information including:

- formulation
- toxicological profile of the ingredients and their concentration in the product
- Product data sheets supplied by the ingredient manufacturer

It is not expected that Target Cellulite Silhouette Contouring Complex will cause damage to human health when used as directed.

It is therefore concluded that Target Cellulite Silhouette Contouring Complex can be placed on the market in the EU as a face and body serum.

#### Review of human data on the product

There are no human tests such as a patch test, for this product.

### B.2 Label Warnings and Instructions for Use

Directions for use are given on the product label and outer packaging of both the 100ml and 200 ml packaging, this is presented in Appendix 4.

#### Directions

**Target Cellulite Silhouette Contouring Complex 100ml:** AM or PM: Cleanse the body of any cream and oil. If the body is warm following a bath or shower this aids penetration. Massage briskly a layer of Complex to all areas prone to cellulite, thighs, buttocks, abdomen and inner knees. Then very gently areas of lymph drainage (where toxins are eliminated) are covered, targeting mainly behind knees, groin, armpits, up to neck. Leave treatment on.

**Target Cellulite Silhouette contouring Complex 200ml:** To be used as part of a RégimA in-salon treatment.

Cleanse the body of cream and oil, except SpaZone O<sub>2</sub> Purifyer Serum if undertaking a combined treatment. Ensure the body is warm as this will aid penetration.

Massage briskly a layer of Complex to all areas prone to cellulite, thighs, buttocks, abdomen and inner knees. Then very gently ensure areas of lymph drainage are

covered, targeting mainly behind knees, groin, armpits, up to neck. Leave treatment on. One may apply Slimming Sculpting Solution to target areas over the top.

**Warnings:**

**Target Cellulite Silhouette Contouring Complex 100ml**

'MUST NOT be combined with any other product range'

'Airless container DO NOT remove top as this would introduce air and/or bacteria'

'Product level can be viewed through the gap in label'

'Store below 77°F/25°C in a cool dry place. Protect from light'

'If irritation occurs, discontinue use'

**Target Cellulite Silhouette contouring Complex 200ml:**

'Strictly for Professional use'

'Airless container DO NOT remove top as this would introduce air and/or bacteria'

'Product level can be viewed through the gap in label'

'Store below 77°F/25°C in a cool dry place. Protect from light'

'MUST NOT be combined with any other product range'

'If irritation occurs, discontinue use'

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for their skin moisturising properties and with good local tolerance when used as directed. There are no reasons to anticipate tolerance problems with use.

This product is intended for external use in adults only.

### **B.4 Assessors Credentials and Approval of Part B**

Shirley Hudson (safety assessor)

BSc, University of Aberdeen

*CBiol, MSB*

20+ years as a practicing toxicologist in the pharmaceutical and chemical industries

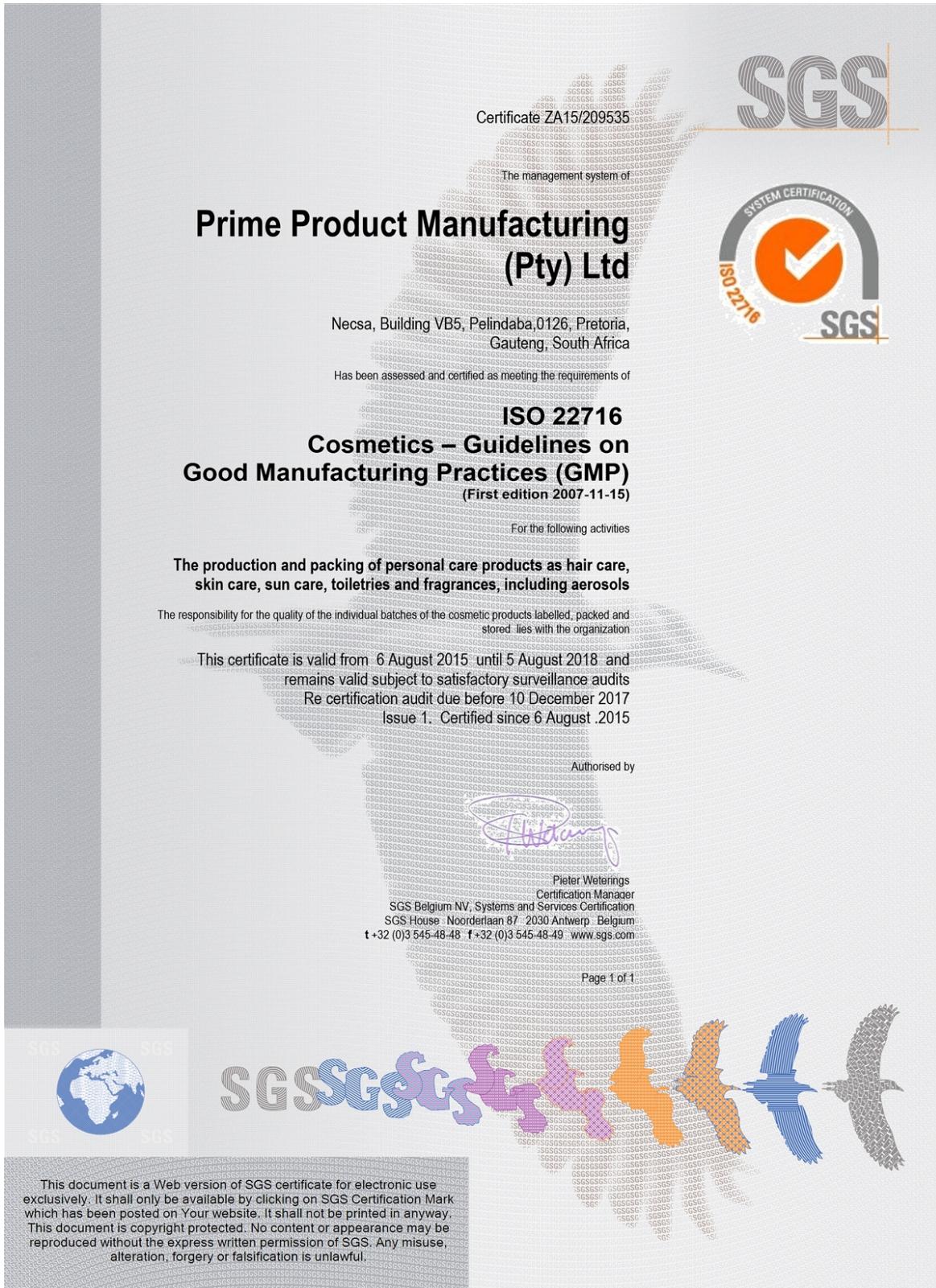
A handwritten signature in black ink, appearing to read "Shirley H".

After analysing of all of the available information including the product formulation and toxicological profile of the ingredients, I conclude that according to the current state of scientific knowledge, this product is not expected to result in any significant damage to human health and can be safely marketed for the intended and foreseeable use as a body lotion.

### **List of References**

SCCS Notes of Guidance for the Testing of Cosmetic Substances and Their Safety Evaluation, 9<sup>th</sup> Revision, 29 September 2015 (SCCS/1564/15)  
European Commission database on cosmetic ingredients (CosIng)  
<http://ec.europa.eu/consumers/cosmetics/cosing/>  
Cosmetic ingredient review <http://www.cir-safety.org/>

## METHOD OF MANUFACTURE / GMP CERTIFICATION



## **PROOF OF EFFECT CLAIMED**

This product claims to *target cellulite, facilitates progressive elimination of oedema (fluid retention), stimulates microcirculation by vaso-dilatation and decongestion. Sacred Locus breaks down fat storage, limits formation of new fat cells. Natural biopolymer has a tensor, lifting, anti-wrinkle effect, smoothing and visibly elasticizing, improving contour, plus the look and feel of lack lustre skin.*

RégimA have provided a report from the manufacturers Silab (Meganede) on the active ingredient Pro-Sveltyl® an ingredient that claims anti-cellulite and draining properties. The product Pro-Sveltyl® contains the active ingredient named *Nelumbo nucifera* which is better known as Sacred Lotus. The Pro-Sveltyl® properties include;

- *In Vivo* (Human) studies have demonstrated the anti-cellulitis action, the draining effect and the slenderizing properties of Pro-Sveltyl®. The test was performed at 4% versus a placebo where it was found that Pro-Sveltyl® significantly reduced skin surface irregularities which resulted from the presence of cellulitis, drains zones of edema and reduces the circumference of the thighs, abdomen and hips.
- Reducing fat storage by activating lipolysis and boosting the synthesis of SIRT-1
- Limits adipose tissue inflammation by stimulating the expression of adiponectin
- Preserving fibrous architecture by inhibiting the activity of adipocyte MMP-2 and MMP-9
- *In Vitro* studies have shown its effects on fat storage, adipose tissue inflammation and on fibrous matrix of adipose tissue.

These properties have been confirmed by *In vitro* and *In vivo* (Human studies), this report is presented in Appendix 4.

## **ANIMAL TESTING STATEMENT**

To the best of our knowledge, the manufacturer and his suppliers have not carried out or commissioned any animal testing for the purpose of developing new cosmetic products.

The statement below is a confirmation of the company policy:

## **RégimA Skin Treatments**

CK92/05371/23

VAT No. 4590131043

**Tel: 011 615 2869 or 011 622 7827**

**Fax: 011 616 8008**

**Cell: 0836537020**

**e-mail: [jax@regima.com](mailto:jax@regima.com)**

**POSTAL ADDRESS: PO BOX 9523 Edenglen 1613**

**PHYSICAL ADDRESS: 20 River Road Morninghill Bedfordview 2007 RSA**

---

### Animal Testing Compliance Statement

This letter is to serve as testimony as to the practice of animal testing, and confirm that RégimA Skin Treatments has not, nor will not engage in any practice that involves animal testing in any form.

RégimA Skin Treatments hereby confirms neither the manufacturer nor RégimA Skin Treatments itself have commissioned or carried out any form of animal testing during the course of product development. This applies to any and all activities performed as part of the development process, including, but not restricted to: R&D, stability testing, safety and toxicology assessments, suitability studies or any other facet related to the product's development.

## **Appendix 1: Safety Data Sheets or Ingredient Specifications**

Safety data sheets and technical data sheets for the ingredients are maintained electronically with the PIF by the Responsible Person. They are available on request.

## **Appendix 2: Microbial Challenge Test**

A microbial challenge test is maintained electronically with the PIF by the Responsible Person. It is available on request.

## Appendix 3: Certificates of Allergen Content



### Allergen Analysis

Compound Name : BERGAMOT OIL {BOL-BE01}

Code Number : RCP-76695

flavour ingredient	CAS No.	Concentration present as a percentage (%) or 'A' for absent in flavour		
		Added as such	From natural & other sources	Total
alpha-iso-Methylionone	127-51-5	A	A	A
Amyl Cinnamal	122-40-7	A	A	A
Amylcinnamyl Alcohol	101-85-9	A	A	A
Anise Alcohol	105-13-5	A	A	A
Benzyl Alcohol	100-51-6	A	A	A
Benzyl Benzoate	120-51-4	A	A	A
Benzyl Cinnamate	103-41-3	A	A	A
Benzyl Salicylate	118-58-1	A	A	A
Butylphenyl Methylpropional (Lilial)	80-54-6	A	A	A
Cinnamal	104-55-2	A	A	A
Cinnamyl Alcohol	104-54-1	A	A	A
Citral	5392-40-5	3.00	0.01	3.01
Citronellol	106-22-9	A	A	A
Coumarin	91-64-5	A	A	A
Eugenol	97-53-0	A	A	A
Evernia Furfuraceae (Tree Moss) Extract	90028-67-4	A	A	A
Evernia Prunastri (Oak Moss) Extract	90028-68-5	A	A	A
Famesol	4602-84-0	A	A	A
Geraniol	106-24-1	A	A	A
Hexyl Cinnamal	101-86-0	A	A	A
Hydoxycitronellal	107-75-5	A	A	A
Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde (Lyral)	31906-04-4	A	A	A
Isoeugenol	97-54-1	A	A	A
Limonene	5989-27-5	A	27.35	27.35
Linalool	78-70-6	10.00	0.05	10.05
Methyl 2-Octynoate	111-12-6	A	A	A

The information contained herein is true and accurate to the best of our knowledge. All information is valid until revisions are issued. We will not therefore accept liability for misuse of this data resulting in damage or loss.



## IFRA Conformity Certificate

Compound Name : BERGAMOT OIL {BOL-BE01}  
Code Number : RCP-76695

We certify that the above compound is in compliance with the standards of the INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA-47th amendment, published June 2013), provided it is used at a maximum concentration level of:

IFRA category (*)	Maximum level of use (%) (w/w) (**)
1A,1B (***)	1.33 (***)
2	1.66
3A	6.64
3B	6.64
3C	6.64
3D	6.64
4A	19.91
4B	19.91
4C	19.91
4D	19.91
5	9.96
6 (***)	33.19 (***)
7A	3.32
7B	3.32
8A	46.47
8B	46.47
9A	100.00
9B	100.00
9C	100.00
10A	82.97
10B	82.97
11A	100.00
11B	100.00

(\*) See annex for definition of IFRA categories

(\*\*) Usage limit N/A = Not Applicable; no IFRA restrictions

(\*\*\*) IFRA would recommend that any material used to impart perfume or flavour in products intended for human ingestion should consist of ingredients that are in compliance with appropriate regulations for foods and food flavourings

For other kinds of application or use at higher concentrations, a new safety evaluation may be needed; please contact F.D. Copeland and Sons Ltd.

The IFRA Standards regarding restrictions are based on safety assessments by the Panel of Experts of the RESEARCH INSTITUTE FOR FRAGRANCE MATERIALS (RIFM) and are enforced by the IFRA Scientific Committee.

Evaluation of individual Fragrance ingredients is made according to the safety standards contained in the relevant section of the IFRA Code of Practice.

It is the ultimate responsibility of our customer to ensure the safety of the final product (containing this fragrance) by further testing if need be.

The information contained herein is true and accurate to the best of our knowledge. All information is valid until revisions are issued. It is your responsibility to ensure that the usage of the fragrance ingredients and the levels of such usage are permitted at all times according to the relevant laws and regulations

## ANNEX: Definition of IFRA categories

Finished Product Types	IFRA category
Lip products of all types (solid and liquid lipsticks, balms, clear or coloured, lipwax, etc.) Toys	1A (**)
Waxes for mechanical hair removal	1B
Deodorant and Antiperspirant Products of all types (pump spray, aerosol spray, stick, roll-on, under-arm and body, etc.) Fragranced Bracelets	2
Hydroalcoholic Products applied to recently shaved skin - EdT	3A
Hydroalcoholic Products applied to recently shaved skin- Fine fragrance	3B
Eye Products of all types (eye shadow, mascara, eyeliner, eye make-up, etc.) including eye care Men's Facial Creams and Balms; Baby Creams, Lotions, Oils; Body Paint for Children	3C
Tampons	3D
EdT: Hydroalcoholic Products applied to unshaved skin, Ingredients of Perfume Kits, Scent Pads, Foil Packs, Scent Strips for Hydroalcoholic Products	4A
Hydroalcoholic Products applied to unshaved skin - Fine fragrance	4B
Hair styling aids sprays of all types (pumps, aerosol sprays etc.), Hair Deodorant Body Creams, Oils, Lotions, Fragrancing Creams of all types (except baby creams, lotions and oils) Fragrance Compounds for Cosmetic Kits, Foot Care Products, Body Paint for Adults	4C
Fragrancing cream	4D
Women's Facial Creams/Facial Make-up, Hand Cream, Facial Masks Hand Sanitisers, Wipes or Refreshing Tissues for Face, Neck, Hands, Body Baby Powder and Talc Hair Permanent and Other Hair Chemical Treatments (e.g. relaxers) but not hair dyes, Dry Shampoo or Waterless Shampoo	5
Mouthwash, including Breath Sprays, Toothpaste	6 (**)
Intimate Wipes, Baby Wipes	7A
Insect Repellent (intended to be applied to the skin)	7B
Make-up Removers of all types (not including face cleansers) Hair Styling Aids Non-Spray of all types (mousse, gels, leave-in conditioners, etc.) Nail Care, Powders and talcs (not including baby powders and talcs)	8A
Hair Dyes	8B
Shampoos of all types (including baby shampoos), Conditioner (Rinse-Off), Face Cleansers of all types (washes, gels, scrubs, etc.), Liquid Soap, Bar Soap (Toilet Soap), Depilatory(not including waxes for mechanical hair removal), Shaving Creams of all types (stick, gels, foams, etc.) Body Washes of all types (including baby washes) and Shower Gels of all types Bath Gels, Foams, Mousses, Salts, Oils and other products added to bathwater	9A
Feminine Hygiene – pads, liners, Toilet Paper Wheat bags	9B
Other' Aerosols (Ind. air freshener sprays and air freshener pump sprays, but not deodorants / antiperspirants, hair styling aids spray and animal sprays) Facial Tissues, Napkins, Paper Towels	9C
Handwash Laundry Detergents of all types including concentrates Machine Wash Laundry Detergents (liquids, powders, tablets etc.) including laundry bleaches and concentrates Fabric Softeners of all types including fabric softener sheets, Hand Dishwashing Detergent Including concentrates Hard Surface Cleaners of all types (bathroom and kitchen cleaners, furniture polish etc.) Other Household Cleaning Products (fabric cleaners, soft surface cleaners, carpet cleaners etc.) Dry Cleaning Kits, Shampoo for pets	10A
Diapers, Toilet Seat Wipes	10B
All non-skin contact including: Air Fresheners and Fragrancing of all types (concentrated aerosol air fresheners, plug-ins, solid substrate, membrane delivery, ambient, electrical...) excluding aerosol products, Liquid refills for air fresheners (cartridge systems), Scent delivery system using a dry air technology that releases a fragrance without sprays, aerosols or heated oils (technology of nebulization), Air delivery systems Candles, Joss Sticks, Incense, Air freshening crystals, Fragranced lamp ring, Scent pack, Machine Only Laundry Detergent (e.g. liquitabs), Toilet Blocks, Insecticides (mosquito coil, paper, electrical, for clothing etc.) excluding aerosols Fuels, Paints, Floor wax, Plastic articles (excluding toys)	11A
All incidental skin contact including: Pot pourri, powders, fragrancing sachets, Incense, Reed diffusers, Liquid refills for airfresheners (non-cartridge systems) Odoured Distilled Water (that can be added to steam irons), Machine Dishwash Detergent and Deodorizers Deodorizers/Maskers not intended for skin contact (e.g. fabric drying machine deodorizers, carpet powders) Treated Textiles (e.g. starch sprays, fabric treated with fragrances after wash, deodorizers for textiles or fabrics, tights with moisturizers) Infused socks, Scratch and sniff (sampling technology) Shoe Polishes, Cat litter, Animal Sprays (all types)	11B

(\*\*) This IFRA certificate does not include a GRAS-FEMA conformity check

## **Appendix 4: Miscellaneous**

The stability report, packaging material information and product carton insert are maintained electronically with the PIF by the Responsible Person. They are available on request.

# PRODUCT INFORMATION FILE\*

RégimA

Urban Stress Protect + Detox  
Clarifying Masque

Prepared: September 2018  
(Label & packaging update August 2021)

\*As required under Article 11 of the European Cosmetics Regulation EC No. 1223/2009

# TABLE OF CONTENTS

## Contents

INTRODUCTION .....	3
PRODUCT DESCRIPTION .....	3
COSMETIC PRODUCT SAFETY REPORT .....	7
Part A: Cosmetic Product Safety Information.....	7
A.1 Quantitative and qualitative composition of the cosmetic product:.....	7
A.2 Physical /chemical characteristics and stability of the cosmetic product .....	12
A.3 Microbiological Quality.....	14
A.4 Impurities, traces, information about the packaging material .....	14
A.5 Normal and reasonably foreseeable use.....	14
A.6 Exposure to the Cosmetic Product .....	14
A.7 Exposure to the Substances .....	15
A.8 Toxicological Profile of the Substances .....	17
A.9 Undesirable Effects and Serious Undesirable Effects.....	22
A.10 Information on the Cosmetic Product .....	22
B: Part Cosmetic Product Safety Assessment .....	23
B.1 Assessment Conclusion .....	23
B.2 Label Warnings and Instructions for Use .....	23
B.3 Reasoning .....	25
B.4 Assessors Credentials and Approval of Part B.....	25
List of References.....	25
METHOD OF MANUFACTURE / GMP CERTIFICATION.....	26
PROOF OF EFFECT CLAIMED .....	27
ANIMAL TESTING STATEMENT.....	27
Appendix 1: Safety Data Sheets or Ingredient Specifications .....	28
Appendix 2: Microbial Challenge Test .....	29
Appendix 3: Certificates of Allergen Content .....	30
Appendix 4: Miscellaneous .....	33

## **INTRODUCTION**

### **PRODUCT DESCRIPTION**

**Product Name:** Urban Stress Protect + Detox Clarifying Masque

Product type	Face Clarifying Masque
Form	Light cream
Colour	Off white
Pack size	150 ml (5 fl oz)
Pack type	Polypropylene
Dispenser type	Airless container
Part of a set	No
Manufacturer code	DCFM 002
Normal use	<b>Directions:</b> Cleanse with RégimA, apply a thin layer of Masque with fingertips to face and neck, avoiding the eye area. Allow 15-20 minutes for penetration and action. Remove thoroughly with RégimA cleanser. Follow with appropriate RégimA after treatment products

**Pictures of the Item: On following page**

Container label

**Régim<sup>®</sup>**  
**Spa<sup>®</sup> ZONE**

**URBAN STRESS  
PROTECT + DETOX  
CLARIFYING MASQUE**

**ALL SKIN TYPES**

**Directions for use:**  
To be used as part of a Régim<sup>®</sup> in-salon treatment.  
Cleanse with Régim<sup>®</sup>, apply a thin layer of Masque with fingertips to face and neck, avoiding the eye area. Allow 15-20 minutes for penetration and action. Remove thoroughly with Régim<sup>®</sup> Cleanser. Follow with appropriate Régim<sup>®</sup> after treatment products.

**MUST NOT be combined with any other product range**

**STRICTLY FOR PROFESSIONAL USE**

**AIRLESS CONTAINER DO NOT REMOVE TOP AS THIS WOULD INTRODUCE AIR AND/OR BACTERIA**

**PRODUCT LEVEL CAN BE VIEWED THROUGH THE GAP IN LABEL**

**STORE BELOW 77°F / 25°C IN A COOL DRY PLACE. PROTECT FROM LIGHT**

**150 ml. e Net 5 fl. oz.**

**IBPN technology<sup>®</sup>**  
Infiltrating BioPolymer Network  
SILAB

NCC(C(=O)c1ccccc1)Cc2c(c(O)cc3[nH]c4ccccc4n2)C(=O)c5ccccc5

**Régim<sup>™</sup>**  
**International Skin Treatments**  
50 Van Buuren Road, Bedfordview, 2008  
Gauteng, South Africa  
[www.regima.zone](http://www.regima.zone)  
Manufactured in South Africa  
EU - RP CSI-Europe; The Greenway, Ardilaun  
Court, St. Stephen's Green, Dublin 2, Ireland  
UK - RP CSI-UK; Penicuik Science Park,  
Penicuik, Nr Edinburgh, EH26 0PZ, UK  
US - FDA - 1007858

6M



## Carton label



**Batch code:** The batch number is printed onto the underside of the carton and the container at the point of manufacturing and filling, therefore it is not visible on the label as represented in this PIF. The batching is automated, so the batch code and date is printed onto the carton and container as they are filled and boxed.

**Product claims:**

This product has no direct claims.

## **COSMETIC PRODUCT SAFETY REPORT**

### **Part A: Cosmetic Product Safety Information**

#### **A.1 Quantitative and qualitative composition of the cosmetic product:**

### Urban Stress Protect +Detox Clarifying Masque base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Kaolin	15	15	1332-58-7	310-194-1	Abrasive/ Absorbent/ Anticaking/ Bulking/ Cosmetic Colourant/ Opacifying	Protea	Kaolin (Clay Mineral)
2	Butyrospermum Parkii Butter	5	5	194043-92-0/ 91080-23-8/ 68920-03-6	293-515-7/ 272-911-3	Skin Conditioning/ Viscosity Controlling	BASF (Chemgrit)	Cetiol® SB 45
3	Argilla	4.675	5	12199-37-0	235-374-6	Abrasive/ Bulking/ Humectant/ Opacifying/ UV Absorber/ UV Filter/ Buffering	Vanderbilt (IMCD)	Veegum® Ultra
	Titanium Dioxide	0.15		13463-67-7	236-675-5			
	Potassium Bitartrate	0.15		868-14-4	212-769-1			
	Quartz	0.025		14808-60-7	238-878-4			
4	Cetearyl Olivate	2.5	5	85116-80-9	285-532-3	Emulsifying	B&T Srl (Millchem)	Olivem® 1000
	Sorbitan Olivate	2.5		223706-40-9/ 92202-01-2	296-033-5			
5	Olea Europaea Fruit Oil	4	4	8001-25-0	232-277-0	Masking/ Perfuming/ Skin conditioning	Textron Technica (CJP Chemicals)	Olive Oil Extra Virgin
6	Glycerin	4	4	56-81-5	200-289-5	Humectant/ Perfuming/ Skin Protecting/ Viscosity Controlling	Organic Chemical Corporation	Refined Glycerine

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
7	Hydrogenated Olive Oil	1.803	3	226993-75-5/ 68334-28-1	269-820-6	Skin Conditioning/ Viscosity Controlling/ Masking/ Skin Conditioning	B&T Srl (Millchem)	Oliwax
	Olea Europaea Fruit Oil	0.9		8001-25-0	232-277-0			
	Olea Europaea Oil Unsaponifiables	0.297		8001-25-0/ 156798-12-8	232-277-0			
8	Water (Aqua)	2.8665	3	7732-18-5	231-791-2	Skin Conditioning/ Solvent / Skin Protecting/ Preservative	Silab (Meganede)	Celldetox®
	Hydrolysed Candida Saitoana Extract	0.1125		1151559-87- 3	232-387-9			
	Phenoxyethanol	0.015		122-99-6	204-589-7			
	Ethylhexylglycerin	0.006		70445-33-9	408-080-2			
9	Water (Aqua)	2.874	3	7732-18-5	231-791-2	Solvent/ Skin Conditioning/ Skin Protecting/ Emollient/ Humectant/	Silab (Meganede)	Mitokinyl®
	Yeast Extract	0.096		8013-01-2/ 68876-77-7	232-387-9			
	1,2-Hexanediol	0.015		6920-22-5	230-029-6			
	Caprylyl Glycol	0.015		1117-86-8	214-254-7			
10	Persea Gratissima Oil	2	2	8024-32-6	232-428-0	Skin Conditioning	Textron Technica (CJP Chemicals)	Avocado Oil
11	Phenoxyethanol	0.901	1	122-99-6	204-589-7	Preservative / Emollient/ Humectant/ Skin Conditioning	Dr Straetmans (Meganede)	Verstatil® PC
	Caprylyl Glycol	0.099		1117-86-8	214-254-7			
12	Xanthan Gum	0.8	0.8	11138-66-2	234-395-2	Binding/ Emulsifying/ Emulsion Stabilising/ Gel Forming/ Skin Conditioning/ Surfactant/	CP Kelco( Tranarc)	Keltrol T- Plus

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
						Viscosity Controlling		
13	Citrus bergamia peel oil expressed (also known as the perfuming name: Citrus Reticulata, X C. Sinensis Peel Extract)	0.5	0.5	93686-22-7	297-672-2	Perfuming	FD Copeland (CJP Chemicals)	Bergamot Oil
14	Kappaphycus Alvarezii extract	0.19	0.4	1220882-73-4	310-127-6	Skin Protecting/ Skin Conditioning/ Solvent	Silab (Meganede)	Filmexel ®
	Caesalpinia Spinosa Fruit Extract	0.19		39300-88-4	254-409-6			
	Water (Aqua)	0.02		7732-18-5	231-791-2			
15	Tocopherol	0.1	0.1	54-28-4(gamma)/ 16698-35-4 (beta)/ 10191-41-0(DL)/ 119-13-1/ 1406-18-4/ 1406-66-2/ 2074-53-5 (DL)/ 59-02-9/ 7616-22-0	200-201-5/ 240-747-1/ 233-466-0/ 204-299-0/ 215-798-8/ 218-97-9/ 200-412-2	Antioxidant/ Masking/ Skin Conditioning	DSM Nutrient Products (chempure)	dl- $\alpha$ -Tocopherol
16	Water (Aqua)	43.2	48.2	7732-18-5	231-791-2	Solvent	Inhouse	Deiolinsed water

# not assigned

Ingredient order for the label: Water(Aqua), Kaolin, Butyrospermum Parkii Butter, Olea Europaea Fruit Oil, Argilla, Glycerin, Sorbitan Olivate, Cetearyl Olivate, Persea Gratissima Oil, Hydrogenated Olive Oil, Phenoxyethanol, Xanthan Gum, Citrus bergamia peel oil expressed, Olea Europaea Oil Unsaponifiables, Caesalpina Spinosa Fruit Extract, Kappaphycus Alvarezii extract, Potassium Bitartrate, Titanium Dioxide, Limonene, Caprylyl Glycol, Hydrolysed Candida Saitoana Extract, Tocopherol, Yeast Extract, Linalool, Quartz, Citral, 1,2-Hexanediol, Ethylhexylglycerin, Citral, Limonene, Linalool, Linalyl Acetate, Alpha-Pinene.

Red font denotes ingredients present at less than 1% which may be listed in any order.

Below are the allergens and their respective concentrations in the fragrance that are required to be listed in Article 19 Paragraph 1(d) & (g (ii)) of EC 1223/2009 when present at levels >0.001% in a leave-on product.

#### Fragrance allergens

<b>INCI (EU) Name</b>	<b>CAS number</b>	<b>EC number</b>	<b>Concentration % w/w</b>	<b>Comment</b>
Citral	5392-40-5	226-394-6	0.01505	Annex III/70*
Limonene	5989-27-5	227-813-5	0.1368	Annex III/88*
Linalool	78-70-6	201-134-4	0.05025	Annex III/84*
Linalyl Acetate	115-95-7	204-116-4	0.26895	SCCS opinion on fragrances 2*
Alpha-pinene	80-56-8	201-291-9	0.0145	SCCS opinion on fragrances 2*

\* Regulation (EC) No 1223/2009 of the European Parliament and of the council of 30 November 2990 on cosmetic products, Annex III; List of substances which cosmetics products must not contain except subject to the restrictions laid down.

2\* SCCS opinion on Fragrance allergens in Cosmetic products, 15<sup>th</sup> plenary meeting, June 2012, Section 7, Table 7-1, Page 47.

#### A.2 Physical /chemical characteristics and stability of the cosmetic product

Physical and chemical characteristics of the ingredients have been listed in the safety data sheets which are maintained electronically by the Responsible Person and are available on request. A cross reference to the SDS tradename and electronic reference number has been shown in the base formula table, Section 7, Table 7-1, page 47.

#### Physical and Chemical Characterization of the product

1 Physical state	Cream
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Lotion
3 organoleptic properties (colour, odour, whenever relevant)	Off white colour with characteristic odour
4 pH (at 25°C)	4.24
5 viscosity (at 25°C)	89 500 cPs
6 thermal stability (glass bottle)	50 °C for 12 weeks
7 Specific gravity (at 25°C)	0.987/ml

#### Stability of the product

A shelf-life of 6months after opening has been allocated to this product.

An on-going stability study of the product in the packaging will be available to support the shelf-life. A stability test of the product in glass jars has confirmed stability at 25°C for 12 weeks.

Accelerated stability testing was performed at 40 and 50 °C for 12 weeks which further substantiated the product was stable as formulated. A reduction in viscosity was however noted across all the temperature ranges in the stability tests in week 12; 59%, 51%, 77%, 68% in 5 °C, 25 °C, 40 °C and 50 °C respectively. This reduction in viscosity in all stability test is not expected to affect the overall stability of the product as formulated.

### **A.3 Microbiological Quality**

A PET test has been performed according to USP method 38 and confirms the effectiveness of the preservative for a period of 28 days. The certificate has been presented in Appendix 2.

### **A.4 Impurities, traces, information about the packaging material**

None of the ingredients of this product contained impurities at a level which would require notification.

A statement on the suitability of the product packaging is shown below.

The Chubby Chunky Airless Container is made from Polypropylene. The pump is made from Polypropylene, high-density polypropylene and low-density-polypropylene. The components of the packaging material and specifications are included in a certificate in Appendix 4. This is maintained electronically with the PIF by the Responsible Person and is available on request.

### **A.5 Normal and reasonably foreseeable use**

Urban Stress Protect + Detox Clarifying Masque is a product designed clarify the skin. It is a wash off product that in normal circumstances will be used twice daily on the face and neck (avoiding the eye area).

### **A.6 Exposure to the Cosmetic Product**

Site of application	Face and neck
Surface area of application (cm <sup>2</sup> )	885*
Volume of product applied (mg)	250
Frequency of application/use per day	1**
Target population	Adults
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	0.5ml exposure daily Estimated exposure based on 60 kg adult = 4.17 mg/kg bw/day
Dermal absorption information	None
other	NA

\*The total surface area the Urban Stress Protect + Detox Clarifying Masque is applied too= 885cm<sup>2</sup> (Skincare: 565cm<sup>2</sup>- Face surface area + 320cm<sup>2</sup> -Neck surface area). The figures used are adapted from SCCS Notes of the Guidance for the testing of Cosmetic Ingredients and their Safety Evaluation, 9<sup>th</sup> Revision, Section 4.2, Table 1, page 76

\*\* The frequency of application for Urban Stress Protect + Detox Clarifying Masque was determined as 1 applications per day, this was determined due to the product sole use '*In Salon*' where it is applied by professionals trained by RégimA. A warning is in place on the label to indicate it's in salon use only.

### A.7 Exposure to the Substances

Daily Systemic Exposure Dosage (SED) is the daily amount of a cosmetic substance applied based on the concentration of that particular substance, the percutaneous absorption and the nominal human body weight (60 kg) and this is shown in the table below.

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Kaolin 1332-58-7	15	4.17	0.01	0.00626
Butyrospermum Parkii Butter 194043-92-0	5	4.17	0.01	0.00209
Olea Europaea Fruit Oil 8001-25-0	4.9	4.17	0.01	0.00204
Argilla 12199-37-0	4.675	4.17	0.01	0.00195
Glycerin 56-81-5	4	4.17	0.01	0.00167
Sorbitan Olivate 223706-40-9	2.5	4.17	0.01	0.00104
Cetearyl Olivate 85116-80-9	2.5	4.17	0.01	0.00104
Persea Gratissima Oil 8024-32-6	2	4.17	0.01	0.00083
Hydrogenated Olive Oil 226993-75-5	1.803	4.17	0.01	0.00075
Phenoxyethanol 122-99-6	0.916	4.17	0.01	0.00038
Xanthan Gum 11138-66-2	0.8	4.17	0.01	0.00033
Citrus bergamia peel oil expressed (also known as the perfuming name: Citrus	0.5	4.17	0.01	0.00021

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Reticulata, X C. Sinensis Peel Extract)				
Olea Europaea Oil Unsaponifiables 8001-25-0	0.297	4.17	0.01	0.0001238
Caesalpina Spinosa Fruit Extract 39300-88-4	0.19	4.17	0.01	0.0000792
Kappaphycus Alvarezii extract 1220882-73-4	0.19	4.17	0.01	0.0000792
Potassium Bitartrate 868-14-4	0.15	4.17	0.01	0.0000626
Titanium Dioxide 13463-67-7	0.15	4.17	0.01	0.00006255
Caprylyl Glycol 1117-86-8	0.114	4.17	0.01	0.00004754
Hydrolysed Candida Saitoana Extract 1151559-87-3	0.1125	4.17	0.01	0.00004691
Tocopherol 54-28-4	0.1	4.17	0.01	0.00004170
Yeast Extract 8013-01-2	0.096	4.17	0.01	0.00004003
Quartz 14808-60-7	0.025	4.17	0.01	0.00001043
1,2-Hexanediol 6920-22-5	0.015	4.17	0.01	0.00000626
Ethylhexylglycerin 70445-33-9	0.006	4.17	0.01	0.00000250

# 1% dermal absorption is used in the assessment of Urban Stress Protect +Detox Clarifying Masque. The dermal penetration factor was obtained from *Face washes, gels and scrubs*, Table 3, Dermal sensitization quantitative risk Assessment (QRA) for fragrance ingredients, Api et al, 2007.

#### A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Kaolin 1332-58-7	A									2014 CIR Compendium. For use up to 100%, IJT 28(S1):37-102, 2003.
Butyrospermum Parkii Butter 194043-92-0	A									2014 CIR Compendium. For use up to 60%, Final report 03/11 available from CIR
Olea Europaea Fruit Oil 8001-25-0	A									2014 CIR Compendium. For use up to 100%, Final report 03/11 available from CIR
Argilla 12199-37-0	B									An additional assessment was performed on Argilla. Argilla is described as naturally occurring substance in the <i>Smectite group minerals</i> with cosmetic functions including; abrasive, bulking and humectant properties. Argilla has been adopted as a trade name for 'Kaolin'; World Health Organisation, W. (2005). <i>Bentonite, Kaolin and Selected Clay Minerals</i> (EHC 231, 2005). [online] Inchem.org. Available at: <a href="http://www.inchem.org/documents/ehc/ehc/ehc231.htm#3.2.1.3">http://www.inchem.org/documents/ehc/ehc/ehc231.htm#3.2.1.3</a> [Accessed 3 Sep. 2018], a read across was then performed to Kaolin. 204 CIR Compendium. For use up to 100%, IJT 22(S1):37-102, 2003.
Glycerin 56-81-5										Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin
Sorbitan Olivate 223706-40-9	A									2014 CIR Compendium. For use up to 7.5%, IJT 21(S1):93-112, 2002
Cetearyl Olivate 85116-80-9	A									2014 CIR compendium, safe for use in cosmetics when formulated to be non-irritating, Final report 03/2013 available from CIR.
Persea Gratissima Oil 8024-32-6	A									2014 CIR Compendium. For use up to 98%, Final amended report 03/11 available from CIR; JEPT 4(4):93-103, 1980 (original) re-review IJT 22(S1):1-35, 2003.
Hydrogenated	A									2014 CIR Compendium. For use up to 12%, Final report available from CIR.

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Olive Oil 226993-75-5										
Phenoxyethanol 122-99-6	A									2014 CIR Compendium. For use up to 1%, JACT 9(2):259-77, 1990.
Xanthum Gum 11138-66-2	A									2014 CIR Compendium. For use up to 6%, Final report 09/12 available from CIR.
Olea Europaea Oil Unsaponifiables 8001-25-0	A									2014 CIR Compendium. For use up to 3%, Final report 03/11 available from CIR.
Caesalpinia Spinosa Fruit Extract 39300-88-4	2#									A secondary assessment was performed on Caesalpinia Spinosa Fruit extract, where a read across to Caesalpinia spinosa gum as performed. A typical dose range was established as being from 1-5%; Caesalpinia Spinosa Fruit extract is present in formulation at 0.19% (0.0000792 mg/kg bw/day), 5.26 times less than the worst case scenario dose. JECFA opinion on 'Tara' Gum (obtained from grinding the endosperm of the seeds of Caesalpinia spinosa; family: Leguminosae) declared Caesalpinia Spinosa Fruit extract safe for use as food ingredient with no ADI specified for man. It was then concluded that Caesalpinia Spinosa Fruit extract is safe for use in Urban Stress Protect + Detox clarifying Masque as formulated. The secondary assessment is presented in Appendix 4
Kappaphycus Alvarezii extract 1220882-73-4	2#									A secondary assessment was performed on Kappaphycus alvarezii extract where a read across was performed to Carrageenan; the read across was performed as the sulphated galactans present primarily in <i>Kappaphycus Alvarezii</i> are known as Carrageenan. Carrageenan is a large macro-molecule with ranging molecular weights of 200,000-400,000 resulting in low risk dermal penetration. Carrageenan was determined as GRAS by the US FDA and therefore safe for use in Urban Stress Protect + Detox Clarifying Masque at 0.19% (0.0000792 mg/kg bw/day) . See attached secondary assessment in Appendix 4.
Potassium Bitartrate 868-14-4	B									Determined GRAS by the FDA, referenced as Potassium Acid Tartrate. 21CFR184.1077
Titanium Dioxide	B									Titanium Dioxide was evaluated by JECFA where an ADI of 'Not Limited' was established at the 13 <sup>th</sup>

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment	
13463-67-7		JECFA (1969). TRS 733-JECFA 29/24									
Caprylyl Glycol 1117-86-8	A	2014 CIR Compendium. For use up to 5%, IJT 31 (S2):147-168, 2012									
Hydrolysed Candida Saitoana Extract 1151559-87-3	2#	A secondary assessment was performed on Hydrolysed Candida Saitoana Extract; isolated and purified form of <i>Candida Saitoana</i> , a fungus obtained from a fermentation process. The active ingredient in hydrolysed Candida Saitoana Extract has been identified as α-glucans. Limited toxicology data is available for α-glucan so a read across was performed to β-glucan due to the stereochemistry. B-glucans have a high molecular mass, thus reducing the potential for dermal absorption. During a sub-chronic oral toxicity study a no adverse effect dose of 2.5 g/kg bw/day. A worst case dose for Hydrolysed Candida Saitoana Extract was established at 41.6mg/kg bw/day. This is 888,226 times greater than the level present in Urban Stress Protect + Detox Clarifying Masque, which is 0.00004691 mg/kg bw/day. It was concluded that Hydrolysed Candida Saitoana Extract is safe for use as formulated. The secondary assessment for Hydrolysed Candida Saitoana Extract is present in Appendix 4.									
Tocopherol 54-28-4	A	2014 CIR Compendium. For use <= 5% IJT 21 (S3):51-116, 2002; Final report 03/2014 available from CIR									
Yeast Extract 8013-01-2	A	Food item (various), GRAS category (FDA) as food for human consumption.									
Quartz 14808-60-7	B	Quartz was assessed under the name Crystalline silica; where quartz is the most common form, Occupational Safety and Health administration (2002). <i>Crystalline Silica Exposure Health Hazard Information</i> . [online] Osha.gov. Available at: <a href="https://www.osha.gov/OshDoc/data_General_Facts/crystalline-factsheet.pdf">https://www.osha.gov/OshDoc/data_General_Facts/crystalline-factsheet.pdf</a> [Accessed 4 Sep. 2018]. According to the FDA Quartz has been identified as <i>Silicon dioxides</i> with a CAS number 14808-60-7 and has been considered as a GRAS substance; SCOGS Report Number: 61, NTIS Accession Number: PB301402, 1979 (FDA (1979). <i>Select Committee on GRAS Substances (SCOGS) Opinion: Silicates</i> . [online] Wayback.archive-it.org. Available at: <a href="http://wayback.archive-it.org/7993/20171031063508/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/SCOGS/ucm260849.htm">http://wayback.archive-it.org/7993/20171031063508/https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/SCOGS/ucm260849.htm</a> [Accessed 4 Sep. 2018].)									

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
1,2-Hexanediol 6920-22-5	B									For use up to 10% in dermal contact products. The sensitization potential of 1,2-hexanediol was evaluated at concentrations of 10%, 50% and 10% in acetone/olive (3:1) using the mouse local lymph node assay (following OECD 429 protocol). The results from the study indicated 1,2-Hexanediol was negative for its skin sensitization potential. A 50:50 (w/w) mixture of 1,2-Hexanediol and caprylyl glycol was evaluated in an RIPT involving 56 subjects. The test concentration was set at 20% in gel (where the effective concentration per ingredient equaled to 10%) where it was determined that the mixture did not induce skin sensitization in any of the test subjects. A leg and foot gel containing 0.5% 1,2-Hexanediol was applied to the upper back of 101 healthy subjects (males and females) in an RIPT. The test site was covered with a semi-occlusive patch that remained in place for 24h, The product did not induce skin irritation or sensitization. A safety evaluation on the skin irritation and sensitization potential of 1,2-Hexanediol utilized the in-use effect of a body wash containing 0.15% 1,2-Hexanediol for a minimum of 3 times per week over a total of 30 days. No evidence of erythema, edema or dryness was identified during the test period and it was concluded that the product containing 1,2-Hexanediol did not demonstrate a potential for skin irritation or sensitization. 1,2-Hexanediol is present in Urban Stress Protect + Detox Clarifying Masque at 0.015%; 666 times less than the maximum concentration of 10%, it is determined that the use of 1,2-Hexanediol in cosmetics. Final report ' <i>On the safety assessment of 1,2-Glycols as used in cosmetics</i> ' June 2011 available from the CIR website.
Ethylhexylglycerin 70445-33-9	A									2014 CIR Compendium. For use up to 8%, IJT 32 (S3):5-21, 2013.

<sup>a</sup> Some ingredients are excluded from a formal risk assessment where a recognized authority has published a review of the ingredient under similar conditions of use and concluded on safe use at the level of inclusion in the cosmetic product (Hazard ID=A). Hazard ID category B is for recognized authority reviews of the ingredient under similar conditions of use with restricted use or where the ingredient is contained in the annexes to Regulation (EC) No 1223/2009 (Hazard ID=B). Where hazard ID A or B is reported, the maximum allowed usage concentration should be stated.

<sup>b</sup> all possible routes of exposure should be considered

<sup>c</sup> A MoS of greater than 100 is considered to represent safe use

# Food item, hazard and exposure data not required.

2# A secondary assessment was performed on this ingredient, reports are placed in Appendix 4.

**Fragrances:**

Urban Stress Protect + Detox Clarifying Masque does contain a fragrance known as Bergamot Oil. The IFRA certificate and allergen certificate is presented in Appendix 3.

**A.9 Undesirable Effects and Serious Undesirable Effects**

No undesirable effects are anticipated based on the product being used as directed on the face and neck twice daily.

**A.10 Information on the Cosmetic Product**

Urban Stress Protect +Detox Clarifying Masque was released in June 2017. Over the period June 2017 to September 2018, 914 units have been sold and there have been no adverse reactions reported to RégimA cosmetics.

## **B: Part Cosmetic Product Safety Assessment**

### **B.1 Assessment Conclusion**

#### Review of the ingredients

After analysis of all the available information including:

- formulation
- toxicological profile of the ingredients and their concentration in the product
- Product data sheets supplied by the ingredient manufacturer

It is not expected that Urban Stress Protect + Detox Clarifying Masque will cause damage to human health when used as directed.

It is therefore concluded that Urban Stress Protect + Detox Clarifying Masque can be placed on the market in the EU as a face masque.

#### Review of human data on the product

There are no human tests such as a patch test, for this product.

### **B.2 Label Warnings and Instructions for Use**

Directions for use are given on the product label provided in Appendix 4.

**Directions:** Cleanse with RégimA, apply a thin layer of masque with fingertips to face and neck, avoiding the eye area. Allow 15-20 minutes for penetration and action. Remove thoroughly with RégimA cleanser. Follow with appropriate RégimA after treatment products.

#### **Warnings:**

'Strictly for professional use'

'Airless Container DO NOT remove top as this would introduce air and/or bacteria'

'Product level can be viewed through the gap in label'

'Store below 77°F/25°C in a cool dry place. Protect from light'

'Must not be combined with any other product range'

'Avoiding eye area'

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for their Facial masque properties and with e.g. good local tolerance. There are no reasons to anticipate tolerance problems with use.

This product is intended for external use in adults only.

### **B.4 Assessors Credentials and Approval of Part B**

Shirley Hudson (safety assessor)

BSc, University of Aberdeen

*CBiol, MSB*

20+ years as a practicing toxicologist in the pharmaceutical and chemical industries

A handwritten signature in black ink, appearing to read "Shirley H".

After analyzing of all of the available information including the product formulation and toxicological profile of the ingredients, I conclude that according to the current state of scientific knowledge, this product is not expected to result in any significant damage to human health and can be safely marketed for the intended and foreseeable use as a facial masque.

### **List of References**

SCCS Notes of Guidance for the Testing of Cosmetic Substances and Their Safety Evaluation, 9<sup>th</sup> Revision, 29 September 2015 (SCCS/1564/15)  
European Commission database on cosmetic ingredients (CosIng)  
<http://ec.europa.eu/consumers/cosmetics/cosing/>  
Cosmetic ingredient review <http://www.cir-safety.org/>

## METHOD OF MANUFACTURE / GMP CERTIFICATION



# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

**Prime Product  
Manufacturing (Pty) Ltd**

Main Site: Necsa Site, Building VB5, Elias Motsoaledi Street Ext (Church Street West), R104 Pelindaba, Madibeng Municipality, North West

has been registered by Intertek as conforming to the requirements of:

**ISO 22716:2007**

The management system is applicable to:

The production and packing of personal care products as hair care, skin care, sun care, toiletries and fragrances, including aerosols

**Certificate Number:**  
0072927-00

**Initial Certification Date:**  
07 March 2018

**Date of Certification Decision:**  
07 March 2018

**Issuing Date:**  
07 March 2018

**Valid Until:**  
06 March 2021

**Certificate  
Mark**  
coming soon



Calin Moldovean  
President, Business Assurance



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at [certificate.validation@intertek.com](mailto:certificate.validation@intertek.com) or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.

## **PROOF OF EFFECT CLAIMED**

This product makes no direct or implied claims and consequently no proof is required.

## **ANIMAL TESTING STATEMENT**

To the best of our knowledge, the manufacturer and his suppliers have not carried out or commissioned any animal testing for the purpose of developing new cosmetic products.

The statement below is a confirmation of the company policy:

# **RégimA Skin Treatments**

CK92/05371/23  
VAT No. 4590131043

Tel: **011 615 2869** or **011 622 7827**  
Fax: **011 616 8008**  
Cell: **0836537020**  
e-mail: [jax@regima.com](mailto:jax@regima.com)

**POSTAL ADDRESS: PO BOX 9523 Edenglen 1613**

**PHYSICAL ADDRESS: 20 River Road Morninghill Bedfordview 2007 RSA**

### Animal Testing Compliance Statement

This letter is to serve as testimony as to the practice of animal testing, and confirm that RégimA Skin Treatments has not, nor will not engage in any practice that involves animal testing in any form.

RégimA Skin Treatments hereby confirms neither the manufacturer nor RégimA Skin Treatments itself have commissioned or carried out any form of animal testing during the course of product development. This applies to any and all activities performed as part of the development process, including, but not restricted to: R&D, stability testing, safety and toxicology assessments, suitability studies or any other facet related to the product's development.

## **Appendix 1: Safety Data Sheets or Ingredient Specifications**

Safety data sheets and technical data sheets for the ingredients are maintained electronically with the PIF by the Responsible Person. They are available on request.

## **Appendix 2: Microbial Challenge Test**

A microbial challenge test is maintained electronically with the PIF by the Responsible Person. It is available on request.

## Appendix 3: Certificates of Allergen Content



### **IFRA Conformity Certificate**

**Compound Name : BERGAMOT OIL {BOL-BE01}**  
**Code Number : RCP-76695**

We certify that the above compound is in compliance with the standards of the INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA-47th amendment, published June 2013), provided it is used at a maximum concentration level of:

<b>IFRA category (*)</b>	<b>Maximum level of use (%)(w/w) (**)</b>
1A 1B (***)	1.33 (***)
2	1.66
3A	6.64
3B	6.64
3C	6.64
3D	6.64
4A	19.91
4B	19.91
4C	19.91
4D	19.91
5	9.96
6 (***)	33.19 (***)
7A	3.32
7B	3.32
8A	46.47
8B	46.47
9A	100.00
9B	100.00
9C	100.00
10A	82.97
10B	82.97
11A	100.00
11B	100.00

(\*) See annex for definition of IFRA categories

(\*\*) Usage limit N/A = Not Applicable; no IFRA restrictions

(\*\*\*) IFRA would recommend that any material used to impart perfume or flavour in products intended for human ingestion should consist of ingredients that are in compliance with appropriate regulations for foods and food flavourings

For other kinds of application or use at higher concentrations, a new safety evaluation may be needed; please contact F.D. Copeland and Sons Ltd.

The IFRA Standards regarding restrictions are based on safety assessments by the Panel of Experts of the RESEARCH INSTITUTE FOR FRAGRANCE MATERIALS (RIFM) and are enforced by the IFRA Scientific Committee.

Evaluation of individual Fragrance ingredients is made according to the safety standards contained in the relevant section of the IFRA Code of Practice.

It is the ultimate responsibility of our customer to ensure the safety of the final product (containing this fragrance) by further testing if need be.

*The information contained herein is true and accurate to the best of our knowledge. All information is valid until revisions are issued.  
It is your responsibility to ensure that the usage of the fragrance ingredients and the levels of such usage are permitted at all times according to the relevant laws and regulations.*

ANNEX: Definition of IFRA categories

<b>Finished Product Types</b>	<b>IFRA category</b>
Lip products of all types (solid and liquid lipsticks, balms, clear or coloured, lipwax, etc.) Toys	1A (**)
Waxes for mechanical hair removal	1B
Deodorant and Antiperspirant Products of all types (pump spray, aerosol spray, stick, roll-on, under-arm and body, etc.) Fragranced Bracelets	2
Hydroalcoholic Products applied to recently shaved skin - EdT	3A
Hydroalcoholic Products applied to recently shaved skin - Fine fragrance	3B
Eye Products of all types (eye shadow, mascara, eyeliner, eye make-up, etc.) including eye care Men's Facial Creams and Balms, Baby Creams, Lotions, Oils; Body Paint for Children	3C
Tampons	3D
EdT: Hydroalcoholic Products applied to unshaved skin, Ingredients of Perfume Kits, Scent Pads, Foil Packs, Scent Strips for Hydroalcoholic Products	4A
Hydroalcoholic Products applied to unshaved skin - Fine fragrance	4B
Hair styling aids sprays of all types (pumps, aerosol sprays etc.), Hair Deodorant Body Creams, Oils; Lotions; Fragrancing Creams of all types (except baby creams, lotions and oils) Fragrance Compounds for Cosmetic Kits, Foot Care Products, Body Paint for Adults	4C
Fragrancing cream	4D
Women's Facial Creams/Facial Make-up, Hand Cream, Facial Masks Hand Sanitisers, Wipes or Refreshing Tissues for Face, Neck, Hands, Body Baby Powder and Talc Hair Permanent and other Hair Chemical Treatments (e.g. relaxers) but not hair dyes, Dry Shampoo or Waterless Shampoo	5
Mouthwash, including Breath Sprays, Toothpaste	6 (**)
Intimate Wipes, Baby Wipes	7A
Insect Repellent (intended to be applied to the skin)	7B
Make-up Removers of all types (not including face cleansers) Hair Styling Aids Non-Spray of all types (mousse, gels, leave-in conditioners, etc.) Nail Care, Powders and talcs (not including baby powders and talcs)	8A
Hair Dyes	8B
Shampoos of all types (including baby shampoos), Conditioner (Rinse-Off), Face Cleaners of all types (washes, gels, scrubs, etc.), Liquid Soap, Bar Soap (Toilet Soap), Depilatory (not including waxes for mechanical hair removal), Shaving Creams of all types (stick, gels, foams, etc.) Body Washes of all types (including baby washes) and Shower Gels of all types Bath Gels, Foams, Mouses, Salts, Oils and other products added to bathwater	9A
Feminine Hygiene - pads, liners, Toilet Paper - what bags	9B
Other Aerosols (incl. air freshener sprays and air freshener pump sprays, but not deodorants / antiperspirants, hair styling aids spray and animal sprays) Facial Tissues, Napkins, Paper Towels	9C
Handwash Laundry Detergents of all types including concentrates Machine Wash Laundry Detergents (liquids, powders, tablets etc.) including laundry bleaches and concentrates Fabric Softeners of all types including fabric softener sheets, Hand Dishwashing Detergent including concentrates Hard Surface Cleaners of all types (bathroom and kitchen cleaners, furniture polish etc.) Other Household Cleaning Products (fabric cleaners, soft surface cleaners, carpet cleaners etc.) Dry Cleaning Kits, Shampoo for pets	10A
Diapers, Toilet Seat Wipes	10B
All non-skin contact including: Air Fresheners and Fragrancing of all types (concentrated aerosol air fresheners, plug-ins, solid substrate, membrane delivery, ambient, electrical...) excluding aerosol products, Liquid refills for air fresheners (cartridge systems), Scent delivery system using a dry air technology that releases a fragrance without sprays, aerosols or heated oils (technology of nebulization), Air delivery systems Candles, Joss Sticks, Incense, Air Freshener crystals, Fragranced lamp ring, Scent pack, Machine Only Laundry Detergent (e.g. liquidtabs), Toilet Blocks, Insecticides (mosquito coil, paper, electrical, for clothing etc.) excluding aerosols Fuels, Paints, Floor wax, Plastic articles (excluding aerosols)	11A
All incidental skin contact including: Pot pourri, powders, fragrancing sachets, incense, Reed diffusers, Liquid refills for airfresheners (non-cartridge systems) Odoured Distilled Water (that can be added to steam irons), Machine Dishwash Detergent and Deodorizers Deodorizers/Maskers not intended for skin contact (e.g. fabric drying machine deodorizers, carpet powders) Treated Textiles (e.g. starch sprays, fabric treated for fragrance, after-wash deodorizers for textiles or fabrics, tights with moisturizers) Infused socks, Scratch and sniff (sampling technology) Shoe Polishes, Cat litter, Animal Sprays (all types)	11B

(\*\*) This IFRA certificate does not include a GRAS-FEMA conformity check



## Allergen Analysis

Compound Name : BERGAMOT OIL {BOL-BE01}

Code Number : RCP-76695

flavour ingredient	CAS No.	Concentration present as a percentage (%) or 'A' for absent in flavour		
		Added as such	From natural & other sources	Total
alpha-Isa-Methylionane	127-51-5	A	A	A
Amyl Cinnamal	122-40-7	A	A	A
Amylcinnamyl Alcohol	101-85-9	A	A	A
Anise Alcohol	105-11-5	A	A	A
Benzyl Alcohol	100-51-6	A	A	A
Benzyl Benzoate	120-51-4	A	A	A
Benzyl Cinnamate	103-41-3	A	A	A
Benzyl Salicylate	118-58-1	A	A	A
Butylphenyl Methylpropional (Lilial)	80-54-6	A	A	A
Cinnamal	104-55-2	A	A	A
Cinnamyl Alcohol	104-54-1	A	A	A
Citral	5192-40-5	1.00	0.01	1.01
Citronellal	106-22-9	A	A	A
Coumarin	91-64-5	A	A	A
Eugenol	97-52-0	A	A	A
Evernia Furfuracea (Tree Moss) Extract	90028-67-4	A	A	A
Evernia Prunastri (Oak Moss) Extract	90028-68-5	A	A	A
Farnesol	4602-84-0	A	A	A
Geraniol	106-24-1	A	A	A
Hexyl Cinnamal	101-86-0	A	A	A
Hydroxycitronellal	107-75-5	A	A	A
Hydroxyisobutyl 3-Cyclohexene Carboxaldehyde (Lyral)	31906-04-4	A	A	A
Isoeugenol	97-54-1	A	A	A
Limonene	59-89-27-5	A	27.35	27.35
Linabool	78-70-6	1D.00	0.05	1D.05
Methyl 2-Octynoate	111-12-6	A	A	A

The information contained herein is true and accurate to the best of our knowledge. All information is valid until revisions are issued.  
We will not therefore accept liability for misuse of this data resulting in damage or loss.

## **Appendix 4: Miscellaneous**

The stability report, packaging material information and product carton insert are maintained electronically with the PIF by the Responsible Person. They are available on request.