

# 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: 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


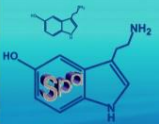
## Container label


Commented [HM1]: Triple check labels

### Neck + Breast Refining Complex – 50ml



Neck + Breast Complex - 50ml



# NECK + BREAST REFINING COMPLEX

**ALL SKIN TYPES**

Directions for use:  
AM & 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 a RégimA day product containing sun protection.

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

DISCONTINUE USE IF IRRITATION OCCURS

DO NOT USE IF PREGNANT OR BREASTFEEDING

MUST ALWAYS BE FOLLOWED BY A RÉGIM A PRODUCT CONTAINING UVA AND UVB PROTECTION

**AIRLESS CONTAINER - DO NOT REMOVE TOP**  
AS THIS WOULD INCREASE 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

50 ml. e 1.69 fl. oz.

**RégimA™**  
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 CSL Europe: The Greenway, Ardilaun Court, St. Stephen's Green, Dublin 2, Ireland  
UK - RP CSL-UK: Pentlands Science Park, Pentlands, Nt Edinburgh, EH26 0PZ, UK  
US - FDA - 1007898

REGIM A IS AGAINST ANIMAL TESTING

### 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 Olivat	2.5	5	85116-80-9	285-532-3	Emulsifying	Textron Tecnica (CJP Chemicals)	Olivem® 1000
	Sorbitan Olivat	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			
4	Water (Aqua)	4.35	5	7732-18-5	231-791-2	Solvent/ Skin Conditioning	Silab (Meganede)	Fermiskin™
	Pentylene Glycol	0.375		5343-92-0	226-285-3			
	Lentinus Edodes Extract	0.275		223748-90-1	310-127-6			
5	Olea Europaea Fruit Oil	4	4	8001-25-0	232-277-0	Masking/ Perfuming/ Skin Conditioning	Textron Tecnica (CJP Chemicals)	Olive Oil Extra Virgin
6	Water (Aqua)	2.916	3	7732-18-5	231-791-2	Solvent/ Skin Protecting/ Preservative / Skin Conditioning	Silab (Meganede)	Retilactyl D®
	Hydrolyzed pepper fruit extract	0.063		84929-41-9	284-524-7			
	Phenoxyethanol	0.015		122-99-6	204-589-7			
	Ethylhexylglycerin	0.006		70445-33-9	408-80-2			
7	Rosa Canina Fruit Oil	3	3	84696-47-9/ 84603-93-0	283-652-0	Emollient/ Skin Conditioning	Seatons (Croda)	Rose Hips Oil
8	Ribes Nigrum Seed Oil	3	3	68606-81-5/ 97676-19-2	271-749-0	Emollient	Textron Tecnica (CJP Chemicals)	Blackcurrant Seed Oil



No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
9	Hydrogenated Olive Oil	1.95	3	226993-75-5/ 68334-28-1	269-820-6	Skin Conditioning/ Viscosity Controlling/ Masking/ Perfuming/ Skin Conditioning	Textron Tecnica (CJP Chemicals)	Oliwax
	Olea Europaea Fruit Oil	0.825		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

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
16	Xanthan Gum	0.25	0.25	11138-66-2	234-394-2	Binding/ Emulsifying/ Emulsion Stabilising/ Gel Forming/ Skin Conditioning/ Surfactant/ Viscosity Controlling	CP Kilco (Tranarc)	Xanthan 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 Olivat, Sorbitan Olivat, 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

<i>INCI (EU) Name</i>	<i>CAS number</i>	<i>EC number</i>	<i>Concentration % w/w</i>	<i>Comment</i>
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, breast 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 and 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, breast and décolleté totaled 25% (1/4) of the trunk of an adult giving a surface area 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 Olivatate 85116-80-9	2.5	53.27	1	1.332
Sorbitan Olivatate 223706-40-9	2.5	53.27	1	1.332
Persea Gratissima Oil 8024-32-6	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)
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

<sup>#</sup> 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
										<p>mating until weaning of pups produced no adverse effects on the reproductive efficiency of the parents (F<sub>0</sub> generation), or the growth, fertility, or reproductive performance of the untreated F<sub>1</sub> generation. No histological changes occurred in the tissues of either the F<sub>1</sub> or F<sub>2</sub> 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<sub>1</sub> and the F<sub>2</sub> 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.</p> <p>Final report 12/09/2014 available from CIR website.</p>
Ribes Nigrum Seed Oil 68606-81-5	A									<p>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.</p> <p>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.</p> <p>No signs of toxicity or gastric ulceration was observed.</p> <p>2g/kg/day = 2,000mg/kg/day 1.34g/kg/day = 1,340 mg/kg/day <a href="#">EMA/HMPC/745347/2016</a></p> <p>The use of a conversion factor was required in order to obtain a mg/kg bw/day value which could then be used to assess the safety of Ribes Nigrum. The EFSA Guidance on default values stated that the conversion factor that is to be used in subacute rat studies is a factor of 0.12 this allows for the conversion of mg/kg to mg/kg bw/day. Therefore;</p> <p>2,000 mg/kg bw/day x 0.12 = 240 mg/kg bw/day 1,340 m/kg bw/day = 160.8 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
		<p><a href="#">EFSA Journal 2012;10(3):2579</a></p> <p>The EMA has stated that there is no data is available on the use of Ribes Nigrum L leaves in fertility, pregnancy and lactation, therefore, use of Ribes nigrum L., folium cannot be recommended during pregnancy and lactation.</p> <p>Ribes Nigrum Seed Oil 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 Ribes Nigrum Seed Oil 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 (Rosa Canina) Fruit oil during pregnancy and breastfeeding it is therefore advisable to avoid its application to the skin.								
Cetearyl Olivatate 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 Olivatate during pregnancy and breastfeeding it is therefore advisable to avoid its application to the skin.								
Sorbitan Olivatate 223706-40-9	A	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 Olivatate, 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.								

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
		A maternal toxicity MoS was calculated to be 751 (Maternal NOAEL 1000mg/kg bw/day ÷ SED 1.332 mg/kg bw/day), 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 give 0.25, 1.25 and 2.5% Phenoxyethanol in their diet. An additional 40 mice of each sex was 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>								

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>In another phase of the study, the final litters obtained from the continuous breeding phase of the study were one to 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
		<p>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 (plant secretion) of the <i>Caesalpinia Spinosa</i>.</p> <p>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.</p> <p>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 &lt;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.</p>								
Kappaphycus alvarezii extract 1220882-73-4	2#	<p>A secondary assessment was performed on <i>Kappaphycus Alvarezii</i> extract. A read across was performed to carrageenan as most carrageenans 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</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
		formulated. There is no reliable information on the safety of taking Kappaphycus Alvarezii extract during pregnancy and breastfeeding it is therefore advisable to avoid its application to the skin during these times.								
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 <sub>3</sub> H <sub>8</sub> O <sub>2</sub> ) and Pentylene Glycol (C <sub>5</sub> H <sub>10</sub> O <sub>2</sub> ) differ by C <sub>2</sub> H <sub>2</sub> . 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 <sup>®</sup> ; an aqueous mycelial extract of <i>Lentinula edodes</i> (formally <i>Lentinus Edodes</i> ). Lentinex <sup>®</sup> consists of approximately 98% water and 2% dry matter; containing β-Glucan Lactan, free glucose and N-containing constituents). <i>Lentinus Edodes</i> is present in RégimA Neck + Breast Refining Complex as Silab's ingredient Fermiskin <sup>®</sup> , where the composition is stated as Water (87%), Pentylene Glycol (7.5%) and Lentinus Edodes Extract (5.5%). A proposed intake of Lentinex <sup>®</sup> was estimated at 2.5mL; containing 1mg Lentinan (β-glucan)/ml that corresponds to 41.7 µg/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 <sup>®</sup> 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 <sup>®</sup> ) 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 <sup>®</sup> has eluded to it being nonirritating, sensitizing and no toxicity associated with acute toxicity testing. Presented in Appendix 4. Lentinus								

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
		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 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.								



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
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 application to the skin during these times.								
Hydrolyzed pepper fruit extract 84929-41-9	B	<p>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 <i>in vitro</i> or <i>in vivo</i> 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%. <a href="#">Pepper (Piper), P. nigrum ext. REACH dossier</a></p> <p>Piperine is a naturally occurring alkaloid that is the major pungent compound found in spices including <i>Piper nigrum</i> L., a 90-day toxicity study in rats has established a NOAEL of 5mg/kg bw/day. A MoS of 1901 has been calculated; 5mg/kg bw/day ÷ SED of 0.00263 mg/kg bw/day = 1901. A MoS of greater than 100 is generally recognized as safe. Norwegian Scientific Committee for Food Safety (2016). <i>Risk assessment of "other substances" -Piperine</i>.</p> <p>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).</p> <p>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). <i>Risk assessment of "other substances" -Piperine</i>. While the product is considered safe when used and directed and adverse</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
		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 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

A handwritten signature in dark ink, appearing to read 'Shirley H', with a long horizontal flourish extending to the right.

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



**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 claims to:

1. Fortify firmness and tonicity while lightening uneven skin colour
  - 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
  - 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
  - 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.
  - 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**

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### 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.



### 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,dear 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 Pads, 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 pad, Machine Dry Laundry Detergent (e.g. liquid/sol), 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/Masks 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-Methyllanone	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
Citronellal	106-22-9	A	A	A
Coumarin	91-64-5	A	A	A
Eugenol	97-53-0	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
Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde (Lylal)	31906-04-4	A	A	A
Isoeugenol	97-54-1	A	A	A
Limonene	5989-27-5	A	27.35	27.35
Linalol	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.