

PRODUCT INFORMATION FILE*

RégimA

O₂ 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

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INTRODUCTION

PRODUCT DESCRIPTION

Product Name: O₂ 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	Directions: 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



International Skin Treatments
50 Van Buuren Road, Bedfordview, 2008
Gauteng, South Africa
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



RÉGIMÀ IS AGAINST ANIMAL TESTING

RégimA

Spa ZONE

O₂-RADIANCE

LUMINOSITY

MASQUE

ALL SKIN TYPES

Directions for use:
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.

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 25°C IN A COOL DRY PLACE. PROTECT FROM LIGHT

150 ml e 5 fl oz

Ingredients

Aqua (Water), Propylene Glycol, Ananas Sativus (Pineapple) Fruit Extract, Propylene Glycol, Carica Papaya (Papaya) Fruit Extract, Glycine Soja (Soybean) Oil, Catearyl Olivae, Sorbitol Olivae, Olea Europaea (Olive) Fruit Oil, Hydrolyzed Lucine Protein, Octenylsuccinate, Hydrogenated Olive Oil, Olea Europaea (Olive) Fruit Oil, Olea Europaea (Olive) Oil Unsaponifiables, Trapaenum Malus Flower Leaf/Stem Extract, Saccharomyces Xylinum Black Tea Ferment, Glycerin, Hydroxyethylcellulose, Persae Grateiosa (Avocado) Oil, Kappaphycus Alveolate Extract, Cassipouia Spicata Fruit Extract, Tocopherol, Xanthan Gum, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Phenylethanol, Caprylyl Glycol.



Régim[®]

SKIN TREATMENTS

ALL SKIN TYPES

Directions for use:

To be used as part of a Régim[®] in-salon treatment.

Cleanse with Régim[®]. 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[®] Cleanser. Follow with appropriate Régim[®] after treatment products.

MUST NOT be combined with any other product range.



IBPN
INTERNATIONAL BOARD OF PROFESSIONAL NUTRITIONISTS

O₂-RADIANCE

LUMINOSITY MASQUE

STRICTLY FOR PROFESSIONAL USE



Régim[®]
International Skin Treatments

80 Van Rensburg Road, Beckenham, 3009
Gauteng, South Africa

www.regim.co.za

Manufactured in South Africa

50 x 50p CHM (Lapses the Guarantee, Refill Unit Grant & Merchandise Returnability) and 100 x 50p CHM (Lapses the Guarantee, Refill Unit Grant & Merchandise Returnability) P/B

100 x 100p = 1007885



150 ml e 5 fl oz

IF 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 25°C IN A COOL, DRY PLACE. PROTECT FROM LIGHT

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:

O₂ 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 Olivat	2	4	85116-80-9	285-532-3	Emulsifying	Textron Tecnica (CJP Chemicals)	Olivem® 1000
	Sorbitan Olivat	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/	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
	Olea Europaea Oil Unsaponifiables	0.3		8001-25-0/ 156798-12-8	232-277-0	Masking/ Perfuming		
9	Water (Aqua)	2.8935	3	7732-18-5	231-791-2	Solvent/ Skin Conditioning/ Preservative	Silab (meganede)	Oxygenskin [®]
	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)	Filmixel®
	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-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				
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 Olivat, Persea Gratissima Oil, Sorbitan Olivat, 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, Tropaelum 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

O₂ 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 ²)	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= 885cm² (Skincare: 565cm²- Face surface area + 320cm² -Neck surface area). The figures used are adapted from SCCS Notes of the Guidance for the testing of Cosmetic Ingredients and their Safety Evaluation, 9th Revision, Section 4.2, Table 1, page 76

** The frequency of application O₂ 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 [#]	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 Olivatate 85116-80-9	2	4.17	0.01	0.00084
Persea Gratissima Oil 8024-32-6	2	4.17	0.01	0.00083
Sorbitan Olivatate 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
Olea Europaea Oil Unsaponifiables 8001-25-0	0.3	4.17	0.01	0.00012

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor [#]	Daily ingredient exposure or SED (mg/kg bw/day)
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
Tropaelum 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 O₂ 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 ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	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 ₂ 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 Olivat 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 Olivat is present in O ₂ 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 Olivat 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 ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	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 α) 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 ₂ 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 ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	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 ₂ 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 ₂ 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 ₂ 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								

Ingredient (INCI name & CAS number)	Hazard ID and list ^a	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED ^b	MoS ^c	comment
		males and females where the test substance was applied for 24 hours for a total of 9 induction 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 ₂ 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								

^a 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.

^b all possible routes of exposure should be considered

^c 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:

O₂ 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

O₂ 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 O₂ Radiance Luminosity Masque will cause damage to human health when used as directed.

It is therefore concluded that O₂ 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 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 face masque.

List of References

SCCS Notes of Guidance for the Testing of Cosmetic Substances and Their Safety Evaluation, 9th 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 ZA15/209535

The management system of

Prime Product Manufacturing (Pty) Ltd

Necsa, Building VB5, Pelindaba, 0126, Pretoria,
Gauteng, South Africa

Has been assessed and certified as meeting the requirements of

ISO 22716

Cosmetics – Guidelines on Good Manufacturing Practices (GMP)

(First edition 2007-11-15)

For the following activities

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

The responsibility for the quality of the individual batches of the cosmetic products labelled, packed and stored lies with the organization

This certificate is valid from 6 August 2015 until 5 August 2018 and remains valid subject to satisfactory surveillance audits
Re certification audit due before 10 December 2017
Issue 1. Certified since 6 August 2015

Authorised by


Pieter Venter
Certification Manager
SGS Belgium NV, Systems and Services Certification
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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

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 (Lyrall)	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:

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.

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 (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 cleansers, 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 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.