

PRODUCT INFORMATION FILE*

RegimA

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

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

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

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INTRODUCTION

PRODUCT DESCRIPTION

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

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

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

Pictures of the Item: On following page

Container label

Instant Facial Lifting Wonder Serum



Instant Facial Lifting - 50ml

RégimA™
International Skin Treatments
50 Van Buuren Road, Bedfordview, 2008
Gauteng, South Africa
www.regima.zone
Manufactured in South Africa

EU - RP CS-Europe: The Greenway, Ardoun Court, St. Stephen's Green, Dublin 2, Ireland
UK - RP CS-UK: Penlands Science Park, Penicuik, Nt Edinburgh, EH26 0PZ, UK
US - FDA - 1007858

RÉGIMA IS AGAINST ANIMAL TESTING




INSTANT FACIAL LIFTING WONDER SERUM

ALL SKIN TYPES - A MUST FOR SMOKERS

Directions for use:
AM: Cleanse with RégimA, apply eye care products. Apply a few drops of Lifting Serum to face, neck and décolleté. Allow Serum to dry to a film before applying other desired RégimA serums and daily care. Layering of products provides ultimate anti-aging excellence.
MUST NOT be combined with any other product range

AIRLESS CONTAINER - DO NOT REMOVE TOP
AS THIS WOULD INTRODUCES 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

50ml e Net 1.69 fl. oz.

O2 Purifyer Face + Body Enhancing Serum


Ingredients
Aqua (Water), PEG-60 Almond Glycerides, Sodium Lactate, Butylene Glycol, Butyrospermum parkii (Shea Butter) Seedcake Extract, Hydrolyzed Candida Saitoana Extract, Glycerin, Kappaphycus Alvarezii Extract, Caesalpinia Spinosa Fruit Extract, Carbomer, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Xanthan Gum, Sodium Hydroxide, Phenoxylethanol, Caprylyl Glycol

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US - FDA - 1007858

RÉGIMA IS AGAINST ANIMAL TESTING



O₂-PURIFYER FACE + BODY ENHANCING SERUM

**ALL SKIN TYPES
A MUST FOR SMOKERS**

Directions for use:
To be used as part of a RégimA in-salon treatment.
Following a RégimA Peel or facial, apply eye care then a layer of O₂-Purifyer Serum to all treated areas. Allow to dry to a film, one may then, if desired, also apply a thin layer of Marine Replenish Masque with fingertips to face and neck, avoiding the eye area, to finalise a purifying, hydrating, replenishing treatment.
This O₂-Purifyer may also be applied to all areas of the body to help with firming and purifying, particularly following Luxury Body Enhancing Treatment, or prior to SpaZone Cellulite or Slimming complexes.
These products are designed as leave-on providing firming with immediate and long-lasting deep hydration.
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

200 ml e 6.7 fl. oz.

Carton label

Instant Facial Lifting Wonder Serum

Ingredients

Aqua (Water), PEG-40 Almond Glycolides, Sodium Lactate, Butylene Glycol, Butyrospermum parkii (Shea Butter) Seedcake Extract, Hydrolyzed Candida Saccarosa Extract, Glycerin, Kappaphycus Alveolate Extract, Cassipouita Spicata Fruit Extract, Cabiome, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Xanthan Gum, Sodium Hydroxide, Phenylethanol, Caprylyl Glycol

Instant Facial Lifting - 50ml

0 781718 199261

RégimATM
International Skin Treatments
50 Van Buren Road, Seacombe, 2009, Gauteng, South Africa
www.regima.com
Manufactured in South Africa
EUROCEUT Europe, The Netherlands, P.O. Box 10, 2000 AA, Rotterdam, The Netherlands
Phone: +31 (0)10 437 40 00
Fax: +31 (0)10 437 40 01

RégimA AGAINST ANIMAL TESTING

This multifaceted Purifying Serum creates a biomimetic, flexible, non-occlusive film on the skin producing an immediate attenuation of facial wrinkles with a visible lifting effect.

A synergy of high tech active ingredients also target skin's natural detoxification mechanisms, actively fighting against ageing chemical pollutants such as nicotine.

Amongst these exciting actives is a purified fungi, obtained from a fermentation process and designed to target the body's detoxification process, called autophagy. This is the means by which the body eliminates toxins, autophagy being the body's recycling programme, playing a critical role in reducing inflammation and slowing down the ageing process.

This super smooth cooling Serum may be used daily, particularly if one smokes or works in the city.

**ALL SKIN TYPES
A Must For Smokers**

Directions for use:

AM - Cleanse with RégimA, apply eye care products. Apply a few drops of Lifting Serum to face, neck and décolleté. Allow Serum to dry to a film before applying other desired RégimA serums and daily care. Layering of products provides ultimate anti-ageing excellence.

MUST NOT be combined with any other product range

ANALYST CONSUMER DO NOT REMOVE TOP
AS THIS WOULD INTRODUCE AIR INTO THE PRODUCT

PRODUCT LEVEL CAN BE VIEWED THROUGH THE GAP IN LAMB

STORE BELOW 72°F / 25°C IN A COOL, DRY PLACE. PROTECT FROM LIGHT

INSTANT FACIAL LIFTING WONDER SERUM

50 ml. e Net 1.69 fl. oz.

O2 Purifier Face + Body Enhancing Serum

Ingredients

Aqua (Water), PEG-40 Almond Glycolides, Sodium Lactate, Butylene Glycol, Butyrospermum parkii (Shea Butter) Seedcake Extract, Hydrolyzed Candida Saccarosa Extract, Glycerin, Kappaphycus Alveolate Extract, Cassipouita Spicata Fruit Extract, Cabiome, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Xanthan Gum, Sodium Hydroxide, Phenylethanol, Caprylyl Glycol

O₂-PURIFIER

FACE + BODY ENHANCING SERUM

RégimATM
International Skin Treatments
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A synergy of high tech active ingredients also target skin's natural detoxification mechanisms, actively fighting against ageing chemical pollutants such as nicotine.

Amongst these exciting actives is a purified fungi, obtained from a fermentation process and designed to target the body's detoxification process, called autophagy. This is the means by which the body eliminates toxins, autophagy being the body's recycling programme, playing a critical role in reducing inflammation and slowing down the ageing process.

Regular treatments to include this super smooth cooling Serum are recommended, particularly if one smokes or works in the city.

**ALL SKIN TYPES
A Must For Smokers**

Directions for use:

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

Following a RégimA Face or Facial, apply eye care then a layer of O₂-Purifier Serum to all treated areas. Allow to dry to a film, one may then, if desired, also apply a thin layer of Marine Respiration Masque with fingertips to face and neck, avoiding the eye area, to finish a purifying, hydrating, replenishing treatment.

This O₂-Purifier may also be applied to all areas of the body to help with firming and purifying, particularly following Lumin Body Enhancing Treatment, or prior to SpaZone Cellulite or Slimming complexes.

These products are designed as leave-on providing firming with immediate and long-lasting deep hydration.

MUST NOT be combined with any other product range

STRICTLY FOR PROFESSIONAL USE

ANALYST CONSUMER DO NOT REMOVE TOP
AS THIS WOULD INTRODUCE AIR INTO THE PRODUCT

PRODUCT LEVEL CAN BE VIEWED THROUGH THE GAP IN LAMB

STORE BELOW 72°F / 25°C IN A COOL, DRY PLACE. PROTECT FROM LIGHT

O₂-PURIFIER FACE + BODY ENHANCING SERUM

200 ml. e 6.7 fl. oz.

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

Product claims:

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

COSMETIC PRODUCT SAFETY REPORT

Part A: Cosmetic Product Safety Information

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

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

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

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

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

not assigned

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

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

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

Fragrance allergens*

<i>INCI (EU) Name</i>	<i>CAS number</i>	<i>EC number</i>	<i>Concentration % w/w</i>	<i>IFRA Standard</i>	<i>Comment</i>
Citral	5392-40-5	226-394-6	0.0301		Above 0.001% limit for leave on product
Limonene	5989-27-5	227-813-5	0.2735	d-, l- and dl- limonene and natural products containing substantial amounts of it, should only be used when the level of peroxides is kept to the lowest practical level, for instance by adding antioxidants at the time of production. Such products should have a peroxide value of less than 20 millimoles peroxides per liter, determined according to the FMA method.	Entire product has less than 20 mmoles/L. The product also contains antioxidants tocopherol and tocopheryl acetate and the preservative phenoxyethanol. Above 0.001% limit for leave on product
Linalool	78-70-6	201-134-4	0.1005		Above 0.001% limit for leave on product

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

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

Physical and Chemical Characterization of the product

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

Stability of the product

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

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

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

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

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

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

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

A.3 Microbiological Quality

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

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

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

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

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

A.5 Normal and reasonably foreseeable use

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

A.6 Exposure to the Cosmetic Product

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

* The total surface area for application of Instant facial lifting Wonder Serum is 16235 cm² (Skincare; Face surface area = 565 cm² and Skincare; Body Lotion surface area = 15670cm²). These figures are extracted from the SCCS guidelines for the testing of Cosmetic Ingredients and their Safety Evaluation, 9th revision, Section 4.2 , Table 1, page 76.

A.7 Exposure to the Substances

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

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

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

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

#2 No CAS number assigned.

A.8 Toxicological Profile of the Substances

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

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

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
		the worse case scenario dose of 2500 mg/kg bw/day. It is not expected to cause any serious undesirable effects when used as directed.								
Kappaphycus Alvarezii Extract ##	###	A secondary assessment was preformed on Kappaphycus Alvarezii Extract. A principal component of Kappaphycus alvarezii extract is sulfonated galactans also known as Carrageenan's. Carrageenan has been generally recognized as safe (GRAS) by the FDA and has also been approved as a food additive, this has been confirmed by WHO and JECFA with no ADI established. It has been determined that Kappaphycus alvarezii extract is a safe for use in Instant facial wonder serum and O ₂ Purifyer face +body enhancing serum.								
Phenoxyethanol 122-99-6	B	Safe for use when included up to 1%, JACT 9(2):259-77, 1990								
Sodium Hydroxide 1310-73-2	B	Safe for use up to 6.9 % in leave on formulations, where the pH is <11. Human dermal irritation studies indicated irritation caused by sodium Hydroxide at levels as low as 0.5, with dermal sensitization HRIPT challenge test sodium hydroxide was not sensitizing when induced up to 1% and when challenged at 0.125% irritation was observed. Final report 12/15/2015 available from CIR. Sodium Hydroxide is in Annex III/15 where the pH is restricted to pH <11. Sodium hydroxide is present in Instant Facial Lifting Wonder Serum at a level of 0.2%, with a pH of 4.6 there for all restrictions are satisfied and determined safe for use as directed.								
Sodium Lactate 72-17-3	B	Safe with restrictions: Glycolic and Lactic Acid, their common salts and their simple esters, are safe for use in cosmetic products at concentrations <=10%, at final formulation pH >=3.5, when formulated to avoid increasing sun sensitivity or when directions for use include the daily use of sun protection. IJT 17(S1):1-242, 1998. Sodium Lactate is included in formulation at 3%, at a pH of 4.6 and has been determined safe for use in Instant facial lifting wonder serum and O ₂ Purifyer Face + Body Enhancing Serum.								
Xanthan Gum 11138-66-2	A	2014 CIR Compendium safe up to 6%, Safety Assessment of Microbial Polysaccharide Gums as Use in Cosmetics, Final Report, CIR, October, 2012								

^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.

No CAS number assigned

Secondary assessment performed, presented in Appendix 4

Fragrances:

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

A.9 Undesirable Effects and Serious Undesirable Effects

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

A.10 Information on the Cosmetic Product

Instant facial lifting wonder serum and O₂ Purifyer Face + Body Enhancing Serum was released in 2017. Over the period August 2017 to August 2018 2841 units of Instant Facial Lifting Wonder Serum and 438 units of O₂ Purifyer Face + Body Enhancing Serum have been sold and there have been no adverse reactions reported to RégimA Company.

B: Part Cosmetic Product Safety Assessment

B.1 Assessment Conclusion

Review of the ingredients

After analysis of all the available information including:

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

It is not expected that Instant Facial Lifting Wonder Serum and O₂ Purifying Face + Body Enhancing Serum will cause damage to human health when used as directed.

It is therefore concluded that Instant Facial Lifting Wonder Serum and O₂ Purifying Face + Body Enhancing Serum can be placed on the market in the EU as a face and body serum.

Review of human data on the product

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

B.2 Label Warnings and Instructions for Use

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

Directions:

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

O₂ Purifier Face +Body Enhancing Serum: To be used as part of a RégimA in-salon treatment. Following a RégimA peel or facial, apply eye care then layer of O₂-Purifier Serum to all treater areas. Allow to dry to a film, one may then, if desired, also apply a thin layer of Marine Replenish Masque with fingertips to face and neck, avoiding the eye area, to finalise a purifying, hydrating, replenishing treatment.

Warnings:

Instant Facial Lifting Wonder Serum:

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

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

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

'Must not be combined with any other product range'

O₂ Purifyer Face +Body Enhancing Serum:

' Strictly for professional use'

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

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

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

'Must not be combined with any other product range'

A Silab IBPN technology® logo is present on the label signifying RégimA having a license to use FILMEXEL® in Instant Facial Lifting Wonder Serum and O₂ Purifyer Face + Body Enhancing Serum. The license and technical summary is presented in Appendix 4.

B.3 Reasoning

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

This product is intended for external use in adults only.

B.4 Assessors Credentials and Approval of Part B

Shirley Hudson (safety assessor)

BSc, University of Aberdeen

CBiol, MSB

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

A handwritten signature in dark ink, appearing to read 'Shirley H' followed by a long horizontal flourish.

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

List of References

SCCS Notes of Guidance for the Testing of Cosmetic Substances and Their Safety Evaluation, 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 Weterings
Certification Manager
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PROOF OF EFFECT CLAIMED

This product claims to help with firming and purifying and provide firming and immediate long-lasting hydration, confirmatory evidence has been provided by RégimA. SpaZone Instant Facial Lifting Wonder Serum and O₂ Purifyer Face + Body Enhancing Serum contains an active ingredient called FILMEXEL® (with active botanicals Kappaphycus Alvarezii Extract and Caesalpinia Spinosa Fruit Pod Extract), this patented dynamic ingredient is categorised as providing a non-occlusive film known as a 'Second Skin' that mimicks its properties and functions. A technical summary outlining this proof of effect along with RégimA's license to use FILMEXEL® in Instant Facial Lifting Wonder Serum and O₂ Purifyer Face + Body Enhancing Serum is presented in Appendix 4.

ANIMAL TESTING STATEMENT

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

The statement below is a confirmation of the company policy:

RégimA Skin Treatments

CK92/05371/23

VAT No. 4590131043

Tel: 011 615 2869 or 011 622 7827

Fax: 011 616 8008

Cell: 0836537020

e-mail: jax@regima.com

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
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 (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

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



IFRA Conformity Certificate

Compound Name : BERGAMOT OIL {BOL-BE01}

Code Number : RCP-76695

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

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

(*) See annex for definition of IFRA categories

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

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

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

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

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

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

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

ANNEX: Definition of IFRA categories

Finished Product Types	IFRA category
Lip products of all types (solid and liquid lipsticks, balms, clear or coloured, lipwax, etc.) Toys	1A (**)
Waxes for mechanical hair removal	1B
Deodorant and Antiperspirant Products of all types (pump spray, aerosol spray, stick, roll-on, under-arm and body, etc.) Fragranced Bracelets	2
Hydroalcoholic Products applied to recently shaved skin - EdT	3A
Hydroalcoholic Products applied to recently shaved skin- Fine fragrance	3B
Eye Products of all types (eye shadow, mascara, eyeliner, eye make-up, etc.) including eye care Men's Facial Creams and Balms; Baby Creams, Lotions, Oils; Body Paint for Children	3C
Tampons	3D
EdT: Hydroalcoholic Products applied to unshaved skin, Ingredients of Perfume Kits, Scent Pads, Foil Packs, Scent Strips for Hydroalcoholic Products	4A
Hydroalcoholic Products applied to unshaved skin - Fine fragrance	4B
Hair styling aids sprays of all types (pumps, aerosol sprays etc.), Hair Deodorant Body Creams, Oils, Lotions, Fragrancing Creams of all types (except baby creams, lotions and oils) Fragrance Compounds for Cosmetic Kits, Foot Care Products, Body Paint for Adults	4C
Fragrancing cream	4D
Women's Facial Creams/Facial Make-up, Hand Cream, Facial Masks Hand Sanitisers, Wipes or Refreshing Tissues for Face, Neck, Hands, Body Baby Powder and Talc Hair Permanent and Other Hair Chemical Treatments (e.g. relaxers) but not hair dyes, Dry Shampoo or Waterless Shampoo	5
Mouthwash, including Breath Sprays, Toothpaste	6 (**)
Intimate Wipes, Baby Wipes	7A
Insect Repellent (intended to be applied to the skin)	7B
Make-up Removers of all types (not including face cleansers) Hair Styling Aids Non-Spray of all types (mousse, gels, leave-in conditioners, etc.) Nail Care, Powders and talcs (not including baby powders and talcs)	8A
Hair Dyes	8B
Shampoos of all types (including baby shampoos), Conditioner (Rinse-Off), Face Cleansers of all types (washes, gels, scrubs, etc.), Liquid Soap, Bar Soap (Toilet Soap), Depilatory(not including waxes for mechanical hair removal), Shaving Creams of all types (stick, gels, foams, etc.) Body Washes of all types (including baby washes) and Shower Gels of all types Bath Gels, Foams, Mousses, Salts, Oils and other products added to bathwater	9A
Feminine Hygiene – pads, liners, Toilet Paper Wheat bags	9B
Other* Aerosols (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/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

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.