

# PRODUCT INFORMATION FILE\*

RégimA

## SpaZone Marine Replenishing Peptide Masque

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

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

# TABLE OF CONTENTS

## Contents

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

## INTRODUCTION

### PRODUCT DESCRIPTION

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

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

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

## Container label

### Marine Replenishing Peptide Masque – 150ml



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



**RÉGIMA IS AGAINST ANIMAL TESTING**

# RégimA Spa ZONE

## MARINE REPLENISHING PEPTIDE MASQUE

**ALL SKIN TYPES**

**Directions for use:**  
To be used as part of a RégimA in-salon treatment.  
Following a RégimA Peel or facial apply eye care and desired serums, particularly O<sub>2</sub>-Purifyer. Then apply a thin layer of Masque with fingertips to face and neck, avoiding the eye area.  
This is a leave-on Decadent Masque designed to provide 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**

150 ml e 5 fl oz

## Marine Replenishing Peptide Masque – 150ml

# Régim<sup>®</sup>

## SKIN TREATMENTS

### Ingredients

Aqua (Water), Coesepinia Spinosa Oligosaccharides, Coesepinia Spinosa Gum, Glycerin, Propylene Glycol, PEG-60 Almond Glycolide, Hydrolyzed Viola tricolor Extract, Glyoxyl, Ophiopogon Japonicus Root Extract, Rapipeptide-Acylated Extract (and), Coesepinia Spinosa Fruit Extract, Citabomes, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Sodium Hyaluronate, Phenylethanol, Caprylyl Glycol

Bursting with moisture, this Ultra Rich Gel glides onto the skin, this luxurious texture beautifully calming and replenishing as the skin devours active ingredients extracted from seeds of the Andean Mountains, rich in galacto-manno-oligosaccharides.

There is more, derived from Wild Ransy, stimulating synthesis of aquaporins, proteins in cell membranes, boosting hyaluronic acid and epidermal lipids, increasing moisture retention, with the bonus of biopolymers from Red Algae, lifting and firming. This is anti-ageing excellence.

### ALL SKIN TYPES

**Directions for use:**  
To be used as part of a Régim<sup>®</sup> in-salon treatment.

Following a Régim<sup>®</sup> Peel or facial apply eye care and desired serums, particularly O<sub>2</sub>-Purifier. Then apply a thin layer of Masque with fingertips to face and neck, avoiding the eye area.

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

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

### Spa<sup>®</sup> ZONE

STRICTLY FOR PROFESSIONAL USE

### MARINE REPLENISHING PEPTIDE MASQUE

150 ml e 5 fl.oz

**IBPN**  
International Beauty Products Network  
South Africa

100% VEGAN  
100% CRUELTY FREE  
100% PARABEN FREE

**WARNING: AIRLESS CONTAINER DO NOT REMOVE TOP**  
AS THIS WOULD EXPOSE TO AIR AND/OR BACTERIA

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

**STORE BELOW 25°C IN A COOL, DRY, DARK, 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 claims to provide immediate and long-lasting deep hydration.

# **COSMETIC PRODUCT SAFETY REPORT**

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

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

### Marine replenishing peptide masque base formula

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



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

# not assigned

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

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

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

#### **Fragrance allergens**

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

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

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

### Physical and Chemical Characterization of the product

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

### Stability of the product

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

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

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

### A.3 Microbiological Quality

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

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

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

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

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

### A.5 Normal and reasonably foreseeable use

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

### A.6 Exposure to the Cosmetic Product

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

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

## A.7 Exposure to the Substances

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

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

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

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

## A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Almond Oil PEG-6 Esters 124046-50-0	A	2014 CIR Compendium. Safe for use in cosmetics when formulated to be non-irritating. Almond Oil PEG-6 esters is the product of transesterification of Prunus Amygdalus dulcis (Almond) Oil and PEG-G. The limits of the outlined reactants are stated as up to 77% and 51% respectively, where Almond oil was determined to be non-irritating and PEG-6 safe for use in cosmetics. Full amended report 09/12 available from CIR; IJT 33 (Suppl 4):13-39, 2014. It was determined that the use of Almond Oil PEG-6 Esters is safe to use Marine Replenishing Peptide Masque at the level of 5%.								
Propylene Glycol 57-55-6	A	2014 CIR Compendium. For use up to 50%. JACT 13(6):437-91, 1994; IJT 21(2) 245-260, 2012.								
Glycerin 56-81-5	A	Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin.								
Phenoxyethanol 122-99-6	A	2014 CIR Compendium, for use up to 1%. JACT 9(2):259-77, 1990.								
Cyclohexane 110-82-7	B	<p>Available data on Cyclohexane indicated that it has a low order of toxicity, no ADI has been established according to JECFA report 23/19. Evaluation of certain food additives. Twenty-third Report of the Joint FAO/WHO Expert Committee on Food Additives. (1981). <i>Food and Cosmetics Toxicology</i>, 19, p381.</p> <p>Cyclohexane is almost completely absorbed by the oral and inhalation route with dermal absorption of pure liquid cyclohexane in contact with the skin being 5%, this percentage is significantly reduced use Marine Replenishing Peptide Masque due to Cyclohexane being present in the formulation at 0.8% therefore the dermal absorption would be reduced. Cyclohexane is considered to be a skin irritant with the properties being delayed and persistent while it was not considered to be sensitizer. The NOAEL ranged from 250 ppm to 2,000 ppm in a number of animal and human toxicity testing. Taking 250ppm as the worst case scenario NOAEL the MoS was calculated to be 7485. It is considered that a value above 100 is generally considered to be safe. Cyclohexane is present at a level of 0.0334 mg/kg bw/day in use Marine Replenishing Peptide Masque, considerable lower than the level outlined as a NOAEL and therefore safe for use. Cyclohexane, Summary Risk Assessment Report. (2004). <i>European Commission Joint Research</i></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
		<i>Centre, Institute for health and Consumer Protection, European Chemicals Bureau, special Publication 1.04.22, pp 1-15. This report is presented in Appendix 4.</i>								
Sodium hydroxide 1310-73-2	A	For use up to 6.9% in leave on cosmetics. Restricted to use in formulations where pH must be below pH 11. The pH of Marine Replenishing Peptide Masque is indicated on the stability report as pH 4.01. Human dermal irritation studies indicated irritation caused by sodium Hydroxide at levels as low as 0.5, with dermal sensitization HRIPT challenge test sodium hydroxide was not sensitizing when induced up to 1% and when challenged at 0.125% irritation was observed. Final report 12/15, available CIR website. The pH of Marine replenishing Peptide Masque indicated a pH of 4.01 ; lower than pH 11 outlined. With the combination of sufficient pH and Sodium Hydroxide present in formulation at 0.8%, no serious undesirable effects are expected when used as directed.								
Hydrolysed caesalpinia Spinosa Gum 39300-88-4	A	For use up to 0.4% in leave on formulations, it is currently present in formulation at 0.7%. A read across to Caesalpinia Spinosa Gum toxicology was performed and the assessment found that the skin irritation potential was low and determined to be non-irritating. Hydrolysed Caesalpinia Spinosa Gum is classed as a Galactomannan, which are large molecules with a molecular weight of greater than 50,000 g/mole and often exceed 2,000,000 g/mole, therefore systemic safety is not considered as the dermal absorption potential is reduced. Caesalpinia Spinosa Gum has been approved for use as a food ingredient by the JECFA and an ADI has not been specified. IJT 34 (Suppl. 1):35-65, 2015. It was determined that the inclusion of Hydrolysed Caesalpinia Spinosa Gum in Marine Replenishing Peptide Masque will not cause any serious undesired effects when used as directed.								
Ophiopogon japonicus root extract 952500-62-8	##	A secondary assessment has been performed for <i>Ophiopogon japonicus</i> (OJ) root extract. A clinical trial (n=858) outlined a dose of 11,800 mg (196.6 mg/kg bw/day) which is 14,246 times lower than the concentration in the outlined product (0.0138 mg/kg bw/day). Mild adverse effects were noted in the high dose intravenous group (60ml/day); the effects included mild insomnia, dry mouth and stomach discomfort. No serious undesired effects are expected with the use of OJ in Marine Replenishing Peptide Masque when used as directed.								



Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Caesalpinia Spinosa Gum 39300-88-4	A	Safe when used up to 0.5%, CIR compendium 2014. Final report 03/12 available from CIR. Caesalpinia Spinosa Gum is present in Marine Replenishing Peptide Masque at a level of 0.2% and it was determined that at this level no serious undesirable effects are expected when used as desired.								
Hydrolysed Viola Tricolor extract 84012-42-0	##	A secondary assessment was performed on Hydrolysed Viola Tricolor extract. According to the EMA final assessment, the worst case dose of Hydrolysed Viola Tricolour was outlined to be 37.5 mg/kg bw/day, 6421 times greater than the stated amount in Marine Replenishing Peptide Masque. It was therefore concluded to be safe for use by adolescents and adults only. A read across was performed to a product called <i>ABS Viola Tricolor PF</i> , with INCI name of <u>Hydrolyzed Viola Tricolor</u> where <i>In vitro</i> toxicological tests concluded that Hydrolysed Tricolor was a nether a dermal nor ocular irritant. It is not expected that the presence of Hydrolysed Viola tricolor extract at a concentration of 0.14% (at 0.00584 mg/kg bw/day) would cause any serious undesired effects when used as directed.								
Caprylyl Glycol 1117-86-8	A	2014 CIR Compendium. For use up to 5%, IJT 31 (S2):147-168,2012.								
Caesalpinia Spinosa Fruit Pod Extract 39300-88-4	##	A read across was performed to Caesalpinia spinosa gum, where it was approved for use as a food ingredient by JECFA with no specific ADI assigned for man. The read across was performed to Caesalpinia Spinosa Gum due to both ingredients originating from the same plant family; Caesalpiniaceae. The fruit pod extract is similar to the gum as they are both largely contain polysaccharide's. It was determined that Caesalpinia Spinosa Fruit Pod Extract was safe for use in Marine Replenishing Peptide Masque due to its low level inclusion ( 0.095%) and a read across to Caesalpinia Spinosa Gum determining it approved as a food ingredient.								
Kappaphycus Alvarezii Extract 1220882-73-4	##	A secondary assessment was performed on Kappaphycus Alvarezii Extract where the proprietary ingredient sulphated galactan; Carrageenan was evaluated. Carrageenan is isolated from red seaweeds with molecular weights of between 200,000 and 400,000, with dermal penetration evaluated as being limited due to the large size of the molecule. Carrageenan is GRAS by the US FDA under the Code of Federal Regulations (21 CFR 182.7255) and is also approved as food additive ingredient. Carrageenan has also been considered safe for food use with no ADI and Considered acceptable for use topically It is expected that Kappaphycus Alvarezii Extract is safe for use in Marine Replenishing Masque.								

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
Ethylhexylglycerin 70445-33-9	A	2014 CIR Compendium. Safe for use up to 2% in leave on formulations. The skin irritation and sensitization potential of a foundation containing 0.4% ethylhexylglycerin in a RIPT with 108 males and females was evaluated where the test substance was applied for 24 hours for a total of 9 induction applications. There was 109 participants in the challenge phase where the test sites were scored at the time of patch removal, 24 and 48 hours later. It was determined that the foundation was neither a skin irritant nor a sensitizer. IJT 32 (Suppl. 3):5-21, 2013.								
Methylparaben 99-76-3	A	2014 CIR Compendium. For use up to 0.4% if used alone; parabens mixture up to 0.8%. IJT 27(S4):1-82, 2008 JACT 3(5):147-209. 1984 (original report). Methylparaben is present in Marine Replenishing Peptide Masque in a paraben mixture and therefore is allowed a maximum value of 0.8% in formulation.								
Butylparaben 94-26-8	A	2014 CIR Compendium. For use up to 0.4% if used alone; parabens mixture up to 0.8%. IJT 27(S4):1-82, 2008 JACT 3(5):147-209. 1984 (original report). Butylparaben is present in Marine Replenishing Peptide Masque in a paraben mixture and therefore is allowed a maximum value of 0.8% in formulation.								
Ethylparaben 120-47-8	A	2014 CIR Compendium. For use up to 0.4% if used alone; parabens mixture up to 0.8%. IJT 27(S4):1-82, 2008 JACT 3(5):147-209. 1984 (original report). Ethylparaben is present in Marine Replenishing Peptide Masque in a paraben mixture and therefore is allowed a maximum value of 0.8% in formulation.								
Propylparaben 94-13-3	A	2014 CIR Compendium. For use up to 0.4% if used alone; parabens mixture up to 0.8%. IJT 27(S4):1-82, 2008 JACT 3(5):147-209. 1984 (original report). Propylparaben is present in Marine Replenishing Peptide Masque in a paraben mixture and therefore is allowed a maximum value of 0.8% in formulation.								
Citrus Bergamia Peel Oil Expressed	B	Supplier IFRA Certificate of conformity for Bergamot Oil is supplied and presented in Appendix 3. The maximum allowable concentration; Category 5 - Women's facial creams is 9.96 % w/w . The actual concentration in the formulation is 0.5%. The allergen components are declared in section A.1. Fragrance Allergen table. Citrus Bergamia Peel Oil Expressed will be indicated in the label along with its fragrance components. It has been determined that the use of Bergamot Oil is safe for use in Marine Replenishing Peptide Masque.								

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

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

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

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

# Food item, hazard and exposure data not required

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

**Fragrances:**

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

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

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

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

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

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

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

#### Review of the ingredients

After analysis of all the available information including:

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

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

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

#### Review of human data on the product

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

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

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

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

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

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

#### **Warnings:**

**50ml Bottle:**

'Must NOT be combined with any other product range'

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

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

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

'Strictly for professional use'

**150ml Bottle:**

'Must NOT be combined with any other product range'

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

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

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

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

### B.3 Reasoning

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

This product is intended for external use in adults only.

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

Shirley Hudson (safety assessor)

BSc, University of Aberdeen

CBiol, MSB

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

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, 9<sup>th</sup> Revision, 29 September 2015 (SCCS/1564/15)

European Commission database on cosmetic ingredients (Cosing)

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

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

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

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

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

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



## METHOD OF MANUFACTURE / GMP CERTIFICATION

**SGS**

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  
SGS Belgium NV, Systems and Services Certification  
SGS House - Noorderlaan 87 - 2030 Antwerp - Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Page 1 of 1



SGS



SGS

This document is a Web version of SGS certificate for electronic use  
exclusively. It shall only be available by clicking on SGS Certification Mark  
which has been posted on Your website. It shall not be printed in anyway.  
This document is copyright protected. No content or appearance may be  
reproduced without the express written permission of SGS. Any misuse,  
alteration, forgery or falsification is unlawful.

## **PROOF OF EFFECT CLAIMED**

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

## **ANIMAL TESTING STATEMENT**

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

The statement below is a confirmation of the company policy:

## **RégimA Skin Treatments**

CK92/05371/23

VAT No. 4590131043

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

**Fax: 011 616 8008**

**Cell: 0836537020**

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

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

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

---

### Animal Testing Compliance Statement

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

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



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

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

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

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

## Appendix 3: Certificates of Allergen Content

### Allergen Analysis

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

*Code Number* : RCP-76695

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



## **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.