

# PRODUCT INFORMATION FILE\*

RégimA

## Zone Pigment Perfector

Prepared: March 2016  
(Label and packaging update June 2021)

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

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## **INTRODUCTION**

### **PRODUCT DESCRIPTION**

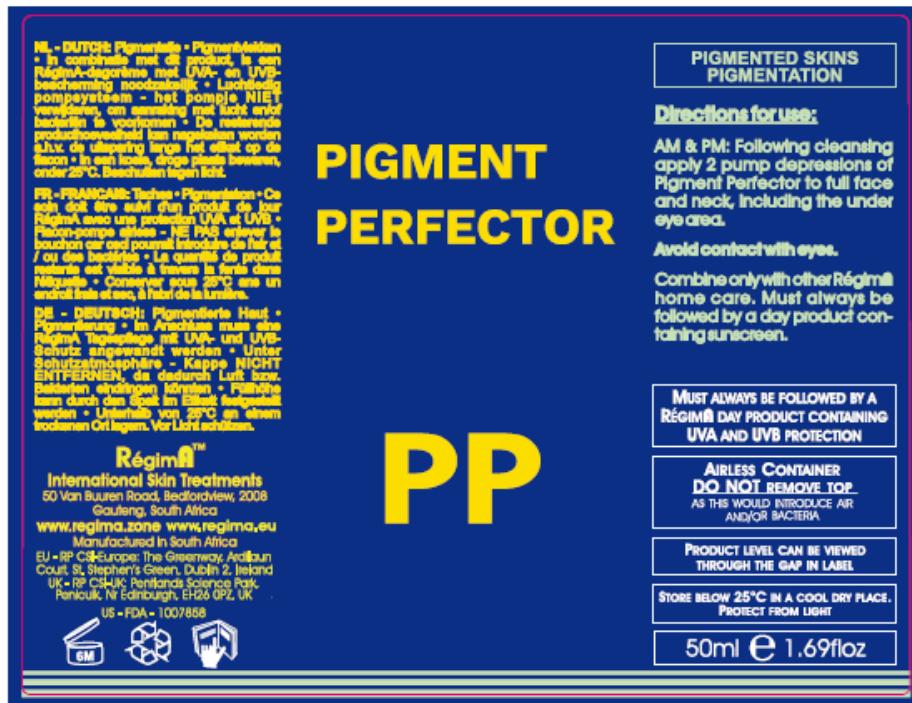
**Product Name: Zone Pigment Perfector**

Product type	Skin lightening and skin tone enhancing cream
Form	Cream
Colour	Pale Yellow
Pack size	50 mL
Pack type	WSZ Airless Bottle
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	CIPP001
Normal use	Leave-on face cream

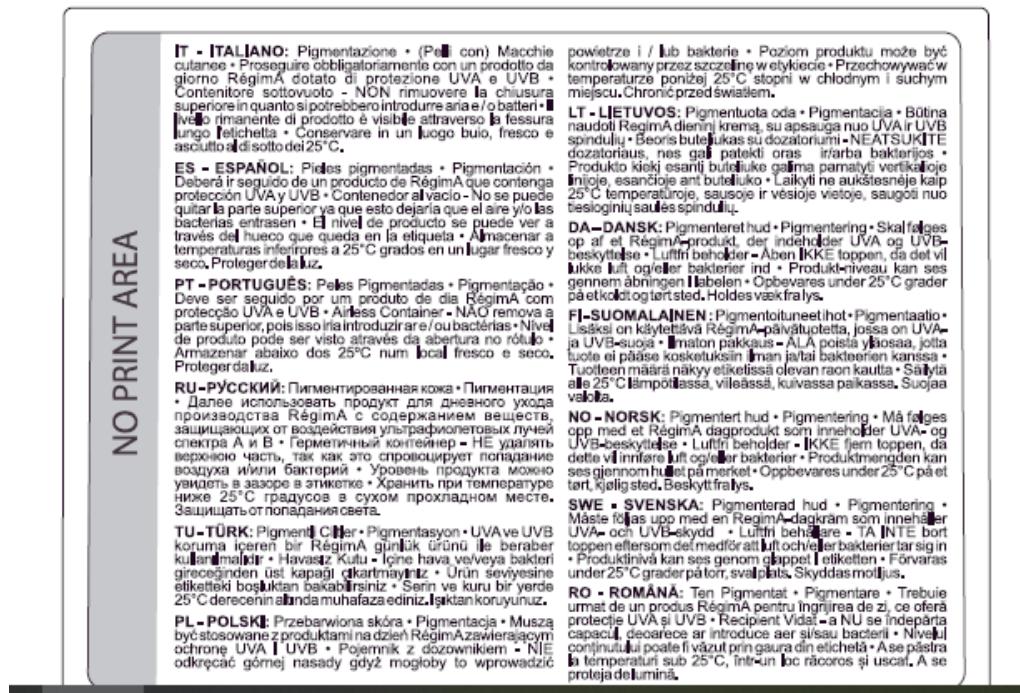
**Pictures of the Item: On following page**

## Container label

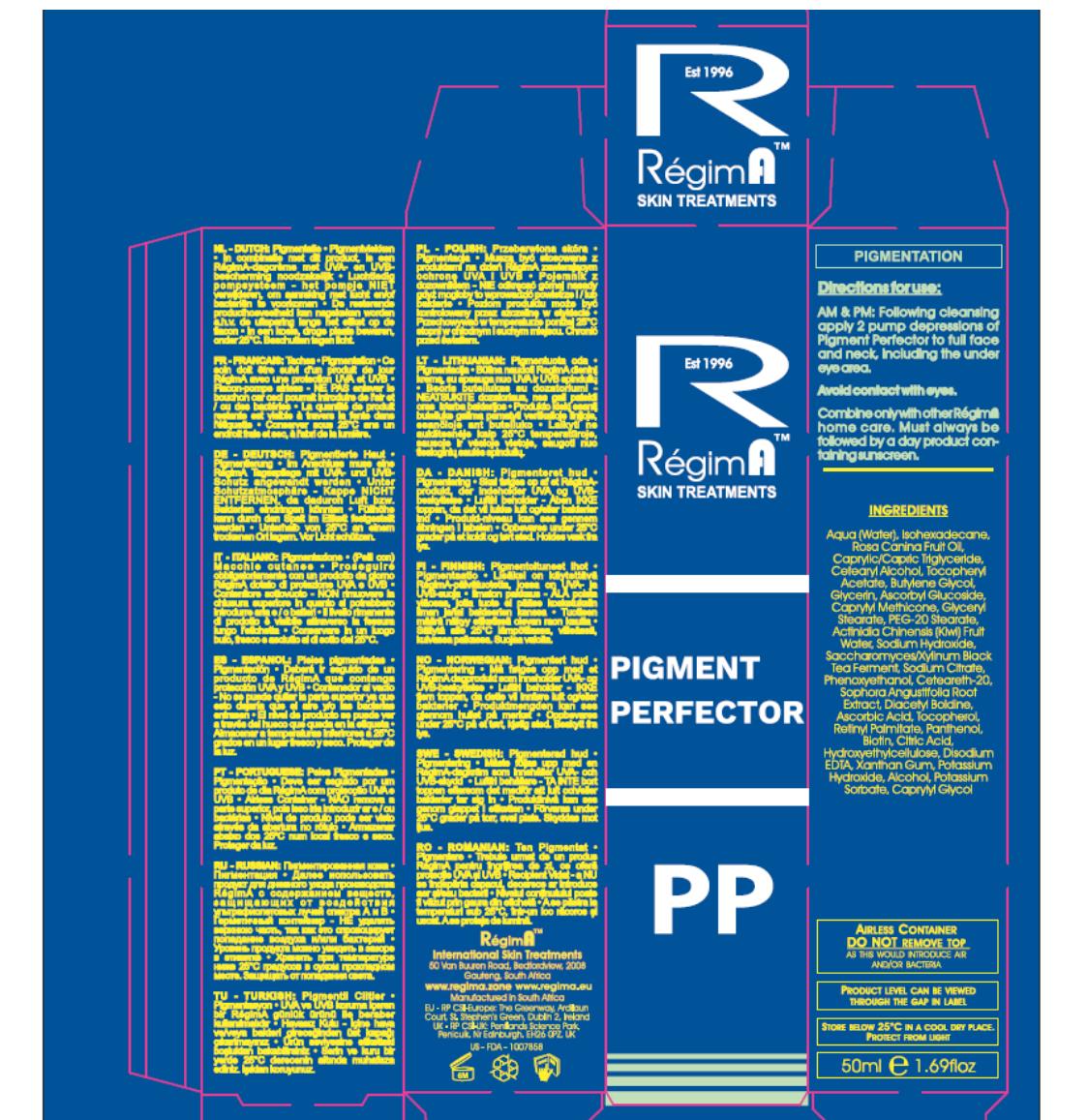
### Top layer



### Base layer



## Carton label



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

**Product claims:**

This product claims to promote enhanced skin lightening and a more radiant, even skin tone.

# **COSMETIC PRODUCT SAFETY REPORT**

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

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

### Zone Pigment Perfector base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Aqua (Water)	10	14.195	7732-18-5	231-791-2	Active/Antioxidant/Buffering	Hayashibara (Savannah Fine Chemicals)	AA2G Solution
	Ascorbyl Glucoside	2		129499-78-1	425-980-0			
	Sodium Hydroxide	1.875		1310-73-2	215-185-5			
	Sodium Citrate	0.3		68-04-2 6132-04-3	200-675-3			
	Citric Acid	0.02		77-92-9 5949-29-1	201-069-1			
2	Isohexadecane	7		93685-80-4	297-628-2	Emollient	Croda Chemicals	Arlamol HD
3	Cetearyl Alcohol	4	5	67762-27-0 8005-44-5	267-008-6	Emollient/Emulsifying	Croda Chemicals	Cosmowax D
	Ceteareth-20	1		68439-49-6	-			
4	Butylene Glycol	2.585	5	107-88-0	203-529-7	Active/Humectant	Gattefossé (Inc cosmetics)	Synerlight 2
	Actinidia Chinensis (Kiwi) Fruit Water	1.875		92456-63-8	296-241-6			
	Alcohol	0.375		64-17-5	200-578-6			
	Sophora Angustifolia Root Extract	0.15		0131-19-4	290-329-8			
	Ascorbic Acid	0.015		50-81-7	200-066-2			
5	Rosa Canina Fruit Oil	5	5	84603-93-0 84603-93-0	283-652-0	Emollient	Seatons (Croda)	Rose Hip Oil
6	Glyceryl Stearate	2	4	31566-31-1	250-705-4 286-490-9	Emulsifying	Croda Chemicals	Arlacel 165
	PEG-20 Stearate	2		9004-99-3	-			
7	Caprylic/Capric Triglyceride	3.996	4	73398-61-5 65381-09-1	277-452-2 265-724-3	Skin conditioning	Sederma (Croda)	Lumiskin
	Diacetyl Boldine	0.004		73951-75-4	-			
8	Saccharomyces/Xylinum Black Tea Ferment	1.32	3	100085-62-9	309-204-7	Active Ingredient	Sederma (Croda)	Kombuchka
	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		24634-61-5 590-00-1	246-376-1			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Citric Acid	0.4		77-92-9 5949-29-1	201-069-1			
	Sodium Citrate	0.9		68-04-2 6132-04-3	200-675-3			
	Biotin	0.002		58-85-5	200-399-3			
9	Tocopheryl Acetate	3	3	7695-91-2 58-95-7	231-710-0 200-405-4	Antioxidant	DSM Nutritional Products (Chempure)	DL-Alpha-Tocopheryl Acetate
10	Glycerin	2	2	56-81-5	200-289-5	Humectant	Organic Chemical Corporation	Glycerine
11	Caprylyl Methicone	2	2	17955-88-3	241-881-3	Skin conditioning	Momentive (Savannah Fine Chemicals)	Silsoft 034
12	Phenoxyethanol	0.975	1.5	122-99-6	204-589-7	Preservative	Acti-Chem	Microcare PHG
	Caprylyl Glycol	0.525		1117-86-8	214-254-7			
13	Panthenol	0.5	0.5	81-13-0	201-327-3	Active/Skin conditioning	Zhejiang Xinfu Biochemical	D-Panthenol
14	Aqua (Water)	0.4	0.5	7732-18-5	231-791-2	Solvent/Buffering	Tangshan Sunfar Silicon Industries Co.Ltd	Potassium Hydroxide
	Potassium Hydroxide	0.1		1310-58-3	215-181-3			
15	Retinyl palmitate	0.2775	0.5000	79-81-2	201-228-5	Skin conditioning	DSM	Vitamin A Palmitate 1.0 MIU/g (stabilized with tocopherol)
	Caprylic/Capric Triglyceride	0.0050		73398-61-5	277-452-2			
	Tocopherol	0.2175		10191-41-0	240-747-1			
16	Xanthan Gum	0.2	0.2	11138-66-2	234-394-2	Binding/Emulsifying/ Emulsion Stabilising	Jungbunzlauer	Xanthan Gum
17	Disodium EDTA	0.2	0.2	139-33-3 6381-92-6	205-358-3	Chelating/ Viscosity controlling	Trilon BD	EDTA Na2
18	Tocopherol	0.1	0.1	10191-41-0	200-201-5	Antioxidant	DSM Nutritional	DL-Alpha-Tocopherol

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
							Products (Chempure)	
19	Aqua (Water)	42.305	42.305	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

# not assigned

Ingredient order for the label: Aqua (Water), Isohexadecane, Rosa Canina Fruit Oil, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Tocopheryl Acetate, Butylene Glycol, Glycerin, Ascorbyl Glucoside, Caprylyl Methicone, Glyceryl Stearate, PEG-20 Stearate, Actinidia Chinensis (Kiwi) Fruit Water, Sodium Hydroxide, Saccharomyces/Xylinum Black Tea Ferment, Sodium Citrate, Phenoxyethanol, Ceteareth-20, Caprylyl Glycol, Panthenol, Citric Acid, Alcohol, Tocopherol, Retinyl Palmitate, Disodium EDTA, Xanthan Gum, Sophora Angustifolia Root Extract, Potassium Hydroxide, Hydroxyethylcellulose, Ascorbic Acid, Diacetyl Boldine, Potassium sorbate, Biotin.

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>

\*Zone Pigment Perfector does not contain a fragrance

#### **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 presented in the report appendices as 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 ...)	o/w emulsion
3 organoleptic properties (colour, odour, whenever relevant)	Pale yellow cream with a characteristic odour
4 pH (at 25°C)	ca. 5.02
5 viscosity (at 25°C)	ca. 53120 cPs
6 thermal stability (glass bottle)	Stable at 50°C for 8 weeks
7 Specific gravity	ca. 0.940 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 bottles has confirmed stability at 50°C for 8 weeks at which time point the cream was separating and a slight increase in pH (not measured at 8 & 12 weeks). The pH value did not affect the safety and tolerability of the product.

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

A PET test has been performed according to USP method 31 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 WSZ airless pump bottle body is made from acrylonitrile-styrene resin (SAN) with a polyethylene liner. The pump is 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**

Zone Pigment Perfector is a product designed to promote enhanced skin lightening and a more radiant, even skin tone. It is a leave-on product that in normal circumstances will be used twice daily on the face and neck including the under eye area.

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

Site of application	Full face and neck (including under eye area)
Surface area of application (cm <sup>2</sup> )	565 cm <sup>2</sup> (note there are no default values for the neck)
Volume of product applied (ml)	0.50 ml (2 pump depressions)
Frequency of application/use per day	2
Target population	Adult
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	1 ml exposure daily Estimated exposure based on 60 kg adult = 16.67 mg/kg bw /day
Dermal absorption information	Unknown
other	

## 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)
Aqua (Water) 7732-18-5	52.705	16.67	1	8.786E+00
Isohexadecane 93685-80-4	7	16.67	1	1.167E+00
Rosa Canina Fruit Oil 84603-93-0	5	16.67	1	8.335E-01
Cetearyl Alcohol 67762-27-0	4	16.67	1	6.668E-01
Caprylic/Capric Triglyceride 73398-61-5	4.001	16.67	1	6.670E-01
Tocopheryl Acetate 7695-91-2	3	16.67	1	5.001E-01
Butylene Glycol 107-88-0	2.585	16.67	1	4.309E-01
Glycerin 56-81-5	2.3	16.67	1	3.834E-01
Ascorbyl Glucoside 129499-78-1	2	16.67	1	3.334E-01
Caprylyl Methicone 17955-88-3	2	16.67	1	3.334E-01
Glyceryl Stearate 31566-31-1	2	16.67	1	3.334E-01
PEG-20 Stearate 9004-99-3	2	16.67	1	3.334E-01
Actinidia Chinensis (Kiwi) Fruit Water 92456-63-8	1.875	16.67	1	3.126E-01
Sodium Hydroxide 1310-73-2	1.875	16.67	1	3.126E-01
Saccharomyces/Xylinum Black Tea Ferment 100085-62-9	1.32	16.67	1	2.200E-01
Sodium Citrate 68-04-2	1.2	16.67	1	2.000E-01
Phenoxyethanol 122-99-6	1.005	16.67	1	1.675E-01

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)
Ceteareth-20 68439-49-6	1	16.67	1	1.667E-01
Caprylyl Glycol 1117-86-8	0.525	16.67	1	8.752E-02
Panthenol 81-13-0	0.5	16.67	1	8.335E-02
Citric Acid 77-92-9	0.42	16.67	1	7.001E-02
Alcohol 64-17-5	0.375	16.67	1	6.251E-02
Retinyl Palmitate 79-81-2	0.2775	16.67	1	4.626E-02
Disodium EDTA 139-33-3	0.2	16.67	1	3.334E-02
Xanthan Gum 11138-66-2	0.2	16.67	1	3.334E-02
Sophora Angustifolia Root Extract 0131-19-4	0.15	16.67	1	2.501E-02
Potassium Hydroxide 1310-58-3	0.1	16.67	1	1.667E-02
Tocopherol 10191-41-0	0.3175	16.67	1	5.293E-02
Hydroxyethylcellulose 9004-62-0	0.045	16.67	1	7.502E-03
Ascorbic Acid 50-81-7	0.015	16.67	1	2.501E-03
Diacetyl Boldine 73951-75-4	0.004	16.67	1	6.668E-04
Potassium sorbate 24634-61-5	0.003	16.67	1	5.001E-04
Biotin 58-85-5	0.002	16.67	1	3.334E-04

# 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.

## 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
Isohexadecane 93685-80-4	A	2014 CIR Compendium, safe when formulated to be non-irritating, IJT 31(S3): 269-295, 2012								
Rosa Canina Fruit Oil 84603-93-0	A	2014 CIR Compendium, safe up to 19%, Final report 03/2013 (CIR)								
Cetearyl Alcohol 67762-27-0	A	2014 CIR compendium, safe at use up to 25% JACT 7(3):359-413, 1988 confirmed 12/05								
Caprylic/Capric Triglyceride 73398-61-5	A	2014 CIR Compendium, safe at use up to 84%, JEPT 4(4): 105-20, 1980 confirmed 06/01, IJT 22(S1): 1-35, 2003								
Tocopheryl Acetate 7695-91-2	A	2014 CIR compendium, safe at use up to 36% (100% in Vitamin E oil) IJT 21(S3):51-116, 2002								
Butylene Glycol 107-88-0	A	Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006								
Glycerin 56-81-5	A	GRAS#, FDA approved food additive, FDA approved over the counter (OTC) for skin								
Ascorbyl Glucoside 129499-78-1	A	2014, CIR Compendium, safe at use up to 10%, IJT 24(2): 51-111, 2005								
Caprylyl Methicone 17955-88-3	A	Read across to stearoxy dimethicone: 2014, CIR Compendium, safe at use up to 3%, IJT 22(S2): 11-35, 2003 and alkyl methicones are considered safe as used in cosmetic formulations. FDA: has approved products which contain this ingredient.								
Glyceryl Stearate 31566-31-1	A	Safe up to 50%; JACT 1(4), 169-192, 1982								
PEG-20 Stearate 9004-99-3	A	Safe up to 4%; JACT 2(7). 17-60, 1983 and confirmed 11/02 International Journal of Toxicology 24(S1), 74-80, 2005								
Actinidia Chinensis (Kiwi) Fruit Water 92456-63-8	A	Safe, FDA approved food additive #GRAS								
Sodium Hydroxide 1310-73-2	B	Safe for restricted use according to CosIng Annex III/15a								

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
Saccharomyces/Xylinum Black Tea Ferment 100085-62-9	#									Traditional food item, GRAS, contains preservative to control possible bacterial contamination.
Sodium Citrate 68-04-2	A									2014 CIR Compendium, safe for use up to 10%, IJT 33 (S2): 16-46, 2014
Phenoxyethanol 122-99-6	B									Safe for use when included up to 1%, CosIng Annex V/29
Ceteareth-20 68439-49-6	B									Safe when formulated to be non-irritating; 2014 CIR Compendium, Final Report 12/10 (CIR); International Journal of Toxicology 18(S3), 41-49, 1999 and International Journal of Toxicology 31 (S2), 169-244, 2012
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
Panthenol 81-13-0	A									Safe up to 25%, JAQCT 6(1): 139-62, 2006
Citric Acid 77-92-9	A									2014 CIR Compendium, safe for use up to 39%, IJT 33 (S2): 16-46, 2014
Alcohol 64-17-5	A									2014 CIR Compendium, safe for use up to 99% (when denatured). IJT 27 (S1):1-43, 2008
Retinyl Palmitate 79-81-2	A									Safe up to 5%; JACT, 6(3), 279-320, 1987; confirmed 06/06
Disodium EDTA 139-33-3	A									2014 CIR Compendium safe up to 1%, IJT 21(S2):95-142, 2002
Helianthus Annuus (Sunflower) Seed Oil 8001-21-6	A									2014 CIR Compendium, safe for use up to 96%, Final Report 03/11
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
Sophora Angustifolia Root Extract 0131-19-4	## <sup>1</sup>		HET CAM method tested- moderately irritating	No		Tested in a human patch test with Synerlight	Not available	2.501E- 02	Not available	

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
						2, no reaction noted				
Potassium Hydroxide 1310-58-3	B									
Tocopherol 10191-41-0	A									
Hydroxyethylcellulose 9004-62-0	A									
Ascorbic Acid 50-81-7	A									
Diacetyl Boldine 73951-75-4	##									
Potassium sorbate 24634-61-5	A									
Biotin 58-85-5	A									

<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.

## other; read-across to information on the boldo plant and boldine confirms predicted safe use at SED (see Appendix 4)

##<sup>1</sup> other; read-across to information on members of the Sophora family confirms predicted safe use at SED (see Appendix 4)

### **Fragrances:**

Zone Pigment Perfector does not contain a fragrance.

### **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**

RégimA Zone is an award winning company based in South Africa whose awards include:

- Professional Beauty Best Training Industry Award concurrently in 2013 and 2014.
- Best Supplier of Skin Care in the Industry 2015
- Best Product Range 2015 in South Africa' and the 'Best New Product 2015' by the Pharmaceutical and Cosmetic Review Magazine for the Innovation, Formulation, Packaging, Marketing and Regulations categories.

RégimA has a very strong reputation for both the efficacy and consumer acceptability for their skin care products which are sold only to doctors, salons and spas.

Zone Pigment Perfector was released in 2014. Over the period October 2014 to February 2015 2107 units have been sold and there have been no adverse reactions reported to RégimA International Skin Treatments.

## **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 Zone Pigment Perfector will cause damage to human health when used as directed.

It is therefore concluded that Zone Pigment Perfector can be placed on the market in the EU as a skin conditioning product.

#### Review of human data on the product

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

#### Statement of tolerability

The product has been used under the guidance of a plastic and reconstructive surgeon, Richard J Van Der Poel, for more than a year.

Richard J Van Der Poel reports:

#### "Instructions for use

- Length of time product should be used for: This would become a permanent part of the skincare routine for patients with a pigmentation problem.
- This would be part of a patients home care routine. It does not require clinic supervision.
- Guidance as to how the product is applied to the skin: To be applied am and pm under day cream containing sun protection and under night cream. It is a leave on product.
- Where the product is applied: To be applied to face and neck if affected by pigmentation, avoiding the eye area if sensitive.

#### Tolerance in patients

- Pigment Perfector has been well tolerated by my patients for more than a year.

#### Side effects

- There may be a tingling sensation on application when applied to very dry or dehydrated skins. This is expected to subside quickly.

### **Adverse reactions**

- There have been no adverse reactions with any of my patients who have used Pigment Perfector on a continual basis.

### **Summary**

Pigment Perfector has been well tolerated by my patients and there have been no reports of any adverse reactions.”

The statement is included in Appendix 4.

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

Avoid contact with eyes.

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

AM & PM: Following cleansing apply 2 pump depressions of Zone Pigment Perfector to full face and neck, including the under eye area. Combine with only with other RegimA home care.

### **B.3 Reasoning**

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

This product is intended for external use in adults only.

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

Shirley Hudson (safety assessor)  
BSc, University of Aberdeen  
CBiol, MBS  
Member of the British Toxicology Society  
20+ years as a practicing toxicologist in the pharmaceutical and chemical industries.

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

A handwritten signature in black ink, appearing to read "Shirley H", is placed over a horizontal line. To the right of the signature is a vertical line forming a small rectangular box.

## **List of References**

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

## METHOD OF MANUFACTURE / GMP CERTIFICATION





## **PROOF OF EFFECT CLAIMED**

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

## **ANIMAL TESTING STATEMENT**

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

The statement below is a confirmation of the company policy:

# **RégimA Skin Treatments**

CK92/05371/23

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### Animal Testing Compliance Statement

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

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

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

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

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

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

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

## **Appendix 4: Miscellaneous**

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

# PRODUCT INFORMATION FILE\*

*RegimA*

*Zone Quantum Elastin-  
Collagen Revival*

Prepared: June 2017  
(Label and packaging update June 2021)

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

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## **INTRODUCTION**

### **PRODUCT DESCRIPTION**

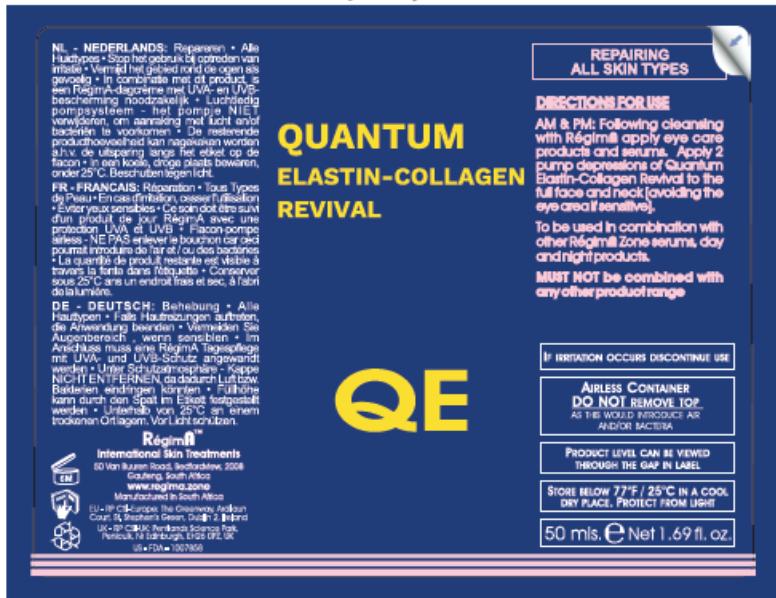
**Product Name:** Zone Quantum Elastin-Collagen Revival

Product type	Moisturizer for dry/dehydrated skins
Form	Cream
Colour	Off white
Pack size	15 ml and 50 ml
Pack type	WSZ Airless Bottle
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	QUEL 002
Normal use	Leave-on face cream

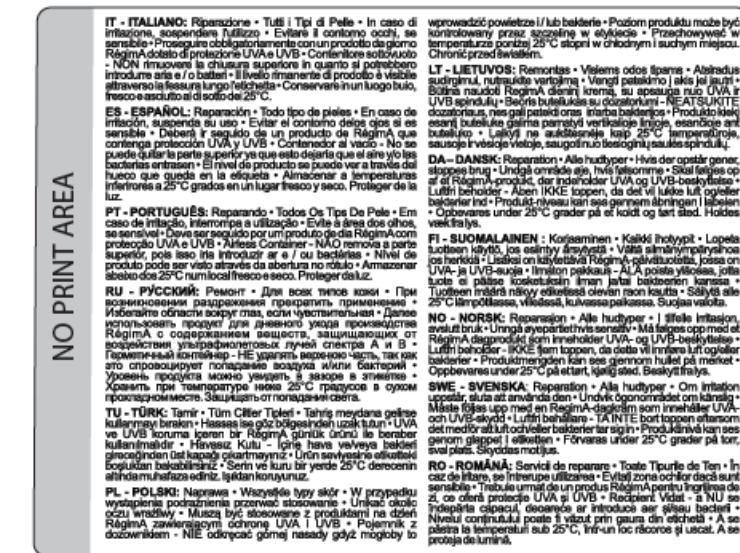
**Pictures of the Item: On following page**

## Container label

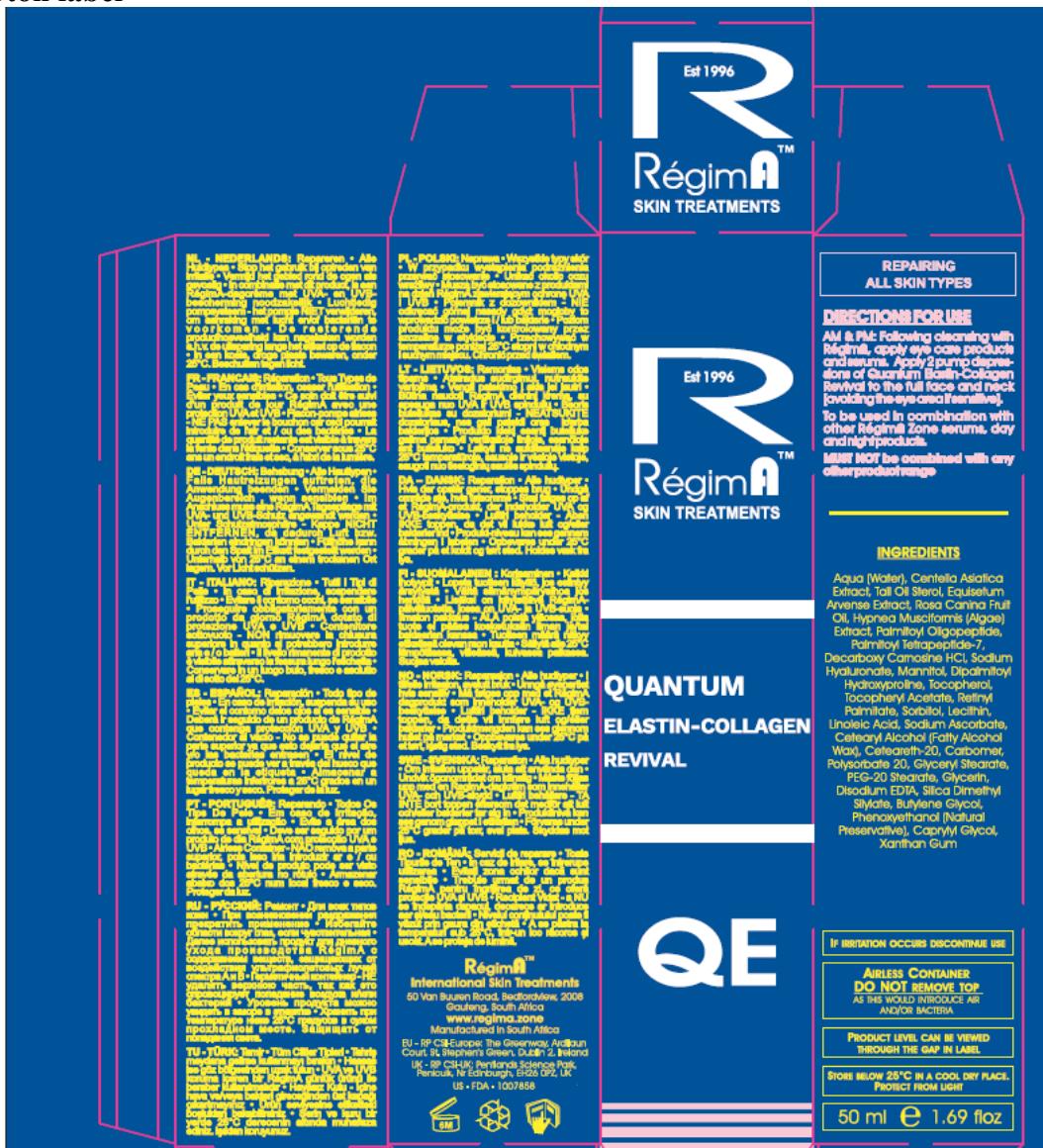
### Top layer



### Base layer



## Carton label



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

**Product claims:**

This product claims to help in the nourishment of dry or dehydrated skins and help skin feel firmer appear smoother and more youthful.

# **COSMETIC PRODUCT SAFETY REPORT**

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

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

### Quantum Elastin-Collagen Revival base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Vegetable Oil	7	7	68956-68-3	273-313-5	Skin Conditioning	Textron Téchnica (SBCM)	Wheat Germ Oil
2	Butylene Glycol	4.875	5	107-88-0	203-529-7	Skin Conditioning	Greentech (Natchem)	Cosmelene of Centella
	Centella Asiatica Extract	0.125		84696-21-9	283-640-5			
3	Aqua (Water)	4.3175	5	7732-18-5	231-791-2	Emulsifying/ Skin Conditioning/ Emollient/ Binding/ Humectant/ Moisturising/ Stabilising/ Cleansing/ Antioxidant/ Buffering/ Perfuming/ Antimicrobial/ Viscosity Controlling/ Astringent	Merck	RonaCare ASC III
	Hydrogenated Lecithin	0.1975		92128-87-5	295-786-7			
	Dipalmitoyl Hydroxyproline	0.095		41672-81-5	255-490-0			
	Lecithin	0.1975		8002-43-5	232-307-2			
	Phenoxyethanol	0.0495		122-99-6	204-589-7			
	Mannitol	0.02		69-65-8	200-711-8			
	Beta Sitosterol	0.0495		83-46-5	201-480-6			
	Linoleic Acid	0.0245		60-33-3	200-470-9			
	Tocopherol	0.0245		1406-18-4	215-798-8			
	Sodium Ascorbate	0.0245		134-03-2	205-126-1			
4	Cetearyl Alcohol	3.5	5	67762-27-0	267-008-6	Emollient/ Emulsifying/ Emulsion Stabilising	Croda Chemicals	Cosmowax D
	Ceteareth-20	1.5		68439-49-6	#			
5	Butylene Glycol	4.25	5	107-88-0	203-529-7	Skin Conditioning/ Solvent/ Astringent/ Soothing	Greentech (Natchem)	Cosmelene Horsetail
	Aqua (Water)	0.65		7732-18-5	231-791-2			
	Equisetum Arvense Extract	0.1		71011-23-9	275-123-8			
6	Rosa Canina Fruit Oil	5	5	84696-47-9/ 84603-93-0	283-652-0	Emollient/ Skin Conditioning	Seatons (Croda)	Rosehip Oil
7	Aqua (Water)	5	5	7732-18-5	231-791-2	Solvent	In-House	Deionised water

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
8	Glyceryl Stearate	2	4	31566-31-1	250-705-4/ 286-490-9	Emollient/ Emulsifying/ Humectant/ Surfactant	Croda Chemicals	Arlacel 165
	PEG-20 Stearate	2		9004-99-3	#			
9	Glycerin	1.57	3	56-81-5	200-289-5	Skin Conditioning/ Emulsion Stabilising/ Viscosity Controlling/ Emulsifying/ Surfactant/ Keratolytic/ Humectant	Sederma (Croda)	Matrixyl 3000
	Aqua (Water)	0.75		7732-18-5	231-791-2			
	Butylene Glycol	0.6		107-88-0	203-529-7			
	Carbomer	0.03		9003- -01- 4	#			
	Polysorbate 20	0.015		9005-64-5	#			
	Palmitoyl Tripeptide-1	0.003		147732-56-7	#			
	Palmitoyl Tetrapeptide-7	0.00015		221227-05-0	#			
	Sodium Lactate	0.03		72-17-3/ 867-56-1	200-772-0/ 212-762-3			
10	Aqua (Water)	2.904	3	7732-18 -5	231-791-2	Skin Protecting/ Preservative/ Skin Conditioning	Silab (Meganede)	Deglysome
	Hypnea Musciformis Extract	0.0075		223751-71-1	607-050-8			
	Phenoxyethanol	0.0015		122-99-6	204-589-7			
	Ethyhexylglycerin	0.006		70445-33-9	408-080-2			
11	Tocopheryl acetate	3	3	7695-91-2/ 58-95-7	231-710-0/ 200-405-4	Antioxidant/ Skin Conditioning	DSM Nutritional Products	DL-Alpha-Tocopheryl Acetate
12	Decarboxy Carnosine HCL	0.3	3	57022-38-5	415-470-6	Skin Conditioning/ Humectant/ Visocsity Controlling	Exsymol (Akulu Marchon)	Alistin P5
	Butylene Glycol	0.2454		107-88-0	203-529-7			
	Phenoxyethanol	0.03		122-99-6	204-589-7			
	Aqua (Water)	2.4246		7732-18 -5	231-791-2			
13	Aqua (Water)	2.2578	3	7732-18-5	231-791-2	Skin Protecting/ Viscosity Controlling/ Humectant/ Plasticiser/ Cleansing/ Smoothing/	Infinitec (Fusion Chemicals)	Nano LPD's Asiatic Centella
	Glycerin	0.18		56-81-5	200-289-5			
	Sorbitol	0.18		50-70-4	200-061-5			
	Centella Asiatica Extract	0.18		84696-21-9	283-640-5			
	Lecithin	0.144		8002-43-5	232-307-2			
	Xanthan Gum	0.018		11138-66-2	234-394-2			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
13	Phenoxyethanol	0.018		122-99-6	204-589-7	Soothing/ Emollient/ Emulsifying/ Binding/ Emulsifying/ Emulsion Stabilising/ Chelating		
	Caprylyl Glycol	0.015		1117-86-8	214-254-7			
	Disodium EDTA	0.0054		139-33-3	205-358-3			
	Glyceryl Caprylate	0.0018		26402-26-6	247-668-1			
14	Butylene Glycol	2	2	107-88-0	203-529-7	Humectant/ Skin Conditioning	Various	Butylene Glycol
15	Phenoxyethanol	0.75	1.5	122-99-6	204-589-7	Emollient/ Humectant/ Skin Conditioning	Acti-Chem	Microcare PHG
	Caprylyl Glycol	0.75		1117-86-8	214-254-7			
16	Silica Dimethyl Silyate	1	1	68611-44-9	271-893-4	Anticaking/ Antifoaming/ Emollient/ Emulsion Stabilising/ Viscosity Controlling	Evonik Degussa (Protea Speciality Chemicals)	Aerosil R 972
17	Retinyl Palmitate	0.37	0.5	79-81-2	201-228-5	Skin Conditioning	DSM Nutritional Products	Vitamin A Palmitate
	BHT	0.015		128-37-0	204-881-4			
	Helianthus Annuus Seed Oil	0.115		8001-21-6	232-273-9			
18	Xanthan Gum	0.3	0.3	234-394-2	11138-66-2	Binding/ Emulsifying/ Emulsion Stabilising/ Skin Conditioning/ Viscosity Controlling	Jungbunzluer	Xanthan Gum
19	Sodium Hyaluronate	0.2	0.2	9067-32-7	#	Humectant/ Skin Conditioning	Contipro Biotech (Cosmetic Ingredients)	Hysilk
20	Tocopherol	0.1	0.1	10191-41-0	233-466-0	Antioxidant/ Masking/ Skin Conditioning	DSM Nutritional Products	DL-Alpha-Tocopherol

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
21	Aqua (Water)	38.4	38.4	7732-18-5	231-791-2	Solvent	In-House	Deionised water

# not assigned

Ingredient order for the label: Butylene Glycol, Vegetable Oil, Rosa Canina Fruit Oil, Cetearyl Alcohol, Tocopheryl acetate, Glyceryl Stearate, PEG-20 Stearate, Glycerin, Ceteareth-20, Silica Dimethyl Silyate, Phenoxyethanol, Caprylyl Glycol, Retinyl Palmitate, Lecithin, Xanthan Gum, Centella Asiatica Extract, Decarboxy Carnosine HCL, Sodium Hyaluronate, Hydrogenated Lecithin, Sorbitol, Tocopherol, Helianthus Annuus Seed Oil, Equisetum Arvense Extract, Dipalmitoyl Hydroxyproline, Beta Sitosterol, Carbomer, Sodium Lactate, Linoleic Acid, Sodium Ascorbate, Mannitol, BHT, Polysorbate 20, Hypnea Musciformis Extract, Ethylhexylglycerin, Disodium EDTA, Palmitoyl Tripeptide-1, Glyceryl Caprylate, Palmitoyl Tetrapeptide-7.

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>

\*Zone Quantum Elastin-Collagen Revival does not contain a fragrance

#### **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 ...)	Cream
3 organoleptic properties (colour, odour, whenever relevant)	Off white cream with a characteristic odour
4 pH (at 25°C)	Ca. 4.77
5 viscosity (at 25°C)	Ca. 14400 cPs
6 thermal stability (glass bottle)	Stable at 50°C for 8 weeks
7 Specific gravity	Ca 0.960 g/ml

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

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

An on-going stability study of the product in the packaging will be available to support the shelf-life. A stability test of the product in glass bottles has confirmed stability at 50°C for 8 weeks at which time point the cream began separating and there was a slight increase in pH (not measured at 8 and 12 weeks). The pH value did not affect the safety and tolerability of the product.

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

A PET test has been performed according to USP method 31 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 WSZ airless pump bottle body is made from acrylonitrile-styrene resin (SAN) with a polyethylene liner. The pump is 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**

Zone Quantum Elastin-Collagen Revival is a product designed to help in the nourishment of dry or dehydrated skins and help skin feel firmer, appear smoother and more youthful. It is a leave-on product that in normal circumstances will be used twice daily on the face and neck, avoiding the eye area if sensitive.

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

Site of application	Full face and neck (excluding under eye area)
Surface area of application (cm <sup>2</sup> )	565 cm <sup>2</sup> (note there are no default values for the neck)
Volume of product applied (ml)	0.5 ml (2 pumps depressions)
Frequency of application/use per day	2
Target population	Adult
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	1 ml exposure daily Estimated exposure based on 60 kg adult = 16.67 mg/kg bw /day
Dermal absorption information	Unknown
other	

## 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)
Butylene Glycol 107-88-0	11.9704	16.67	1	9.45
Vegetable Oil 68956-68-3	7	16.67	1	2.00
Rosa Canina Fruit Oil 84696-47-9	5	16.67	1	1.17
Cetearyl Alcohol 67762-27-0	3.5	16.67	1	0.83
Tocopheryl acetate 7695-91-2	3	16.67	1	0.58
Glyceryl Stearate 31566-31-1	2	16.67	1	0.50
PEG-20 Stearate 9004-99-3	2	16.67	1	0.33
Glycerin 56-81-5	1.75185	16.67	1	0.33
Ceteareth-20 68439-49-6	1.5	16.67	1	0.29
Silica Dimethyl Silylate 68611-44-9	1	16.67	1	0.25
Phenoxyethanol 122-99-6	0.849	16.67	1	0.17
Caprylyl Glycol 1117-86-8	0.765	16.67	1	0.14
Retinyl Palmitate 79-81-2	0.37	16.67	1	0.13
Lecithin 8002-43-5	0.3415	16.67	1	0.062
Xanthan Gum 11138-66-2	0.318	16.67	1	0.057
Centella Asiatica Extract 84696-21-9	0.305	16.67	1	0.053
Decarboxy Carnosine HCL 57022-38-5	0.3	16.67	1	0.051
Sodium Hyaluronate 9067-32-7	0.2	16.67	1	0.05

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Hydrogenated Lecithin 92128-87-5	0.1975	16.67	1	0.033
Sorbitol 50-70-4	0.18	16.67	1	0.033
Tocopherol 10191-41-0	0.1245	16.67	1	0.03
Helianthus Annuus Seed Oil 8001-21-6	0.115	16.67	1	0.021
Equisetum Arvense Extract 71011-23-9	0.1	16.67	1	0.019
Dipalmitoyl Hydroxyproline 41672-81-5	0.095	16.67	1	0.017
Beta Sitosterol 83-46-5	0.0495	16.67	1	0.016
Carbomer 9003-01-4	0.03	16.67	1	0.008
Sodium Lactate 72-17-3	0.03	16.67	1	0.01
Linoleic Acid 60-33-3	0.0245	16.67	1	0.01
Sodium Ascorbate 134-03-2	0.0245	16.67	1	0.0041
Mannitol 69-65-8	0.02	16.67	1	0.0041
BHT 128-37-0	0.015	16.67	1	0.0033
Polysorbate 20 9005-64-5	0.015	16.67	1	0.0025
Hypnea Musciformis Extract 223751-71-1	0.0075	16.67	1	0.0025
Ethylhexylglycerin 70445-33-9	0.006	16.67	1	0.0013
Disodium EDTA 139-33-3	0.0054	16.67	1	0.001
Palmitoyl Tripeptide-1 147732-56-7	0.003	16.67	1	0.0009
Glyceryl Caprylate 26402-26-6	0.0018	16.67	1	0.0005
Palmitoyl Tetrapeptide-7 221227-05-0	0.00015	16.67	1	0.0003

# 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.

## 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
Butylene Glycol 107-88-0	A									Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006
Vegetable Oil 68956-68-3	A									2014 CIR Compendium, safety of vegetable oil as used in cosmetic formulations has been established, GRAS
Rosa Canina Fruit Oil 84696-47-9	A									2014 CIR Compendium, safe up to 19%, Final report 03/2013 (CIR)
Cetearyl Alcohol 67762-27-0	A									2014 CIR compendium, safe at use up to 25% JACT 7(3):359-413, 1988 confirmed 12/05
Tocopheryl acetate 7695-91-2	A									2014 CIR compendium, safe at use up to 36% (100% in Vitamin E oil) IJT 21(S3):51-116, 2002
Glyceryl Stearate 31566-31-1	A									Safe up to 50%; JACT 1(4), 169-192, 1982
PEG-20 Stearate 9004-99-3	A									Safe up to 4%; JACT 2(7). 17-60, 1983 and confirmed 11/02 International Journal of Toxicology 24(S1), 74-80, 2005
Glycerin 56-81-5	A									GRAS#, FDA approved food additive, FDA approved over the counter (OTC) for skin
Ceteareth-20 68439-49-6	B									Safe when formulated to be non-irritating; 2014 CIR Compendium, Final Report 12/10 (CIR); International Journal of Toxicology 18(S3), 41-49, 1999 and International Journal of Toxicology 31 (S2), 169-244, 2012
Silica Dimethyl Silylate 68611-44-9	A									Safe when formulated and delivered in the final product not to be irritating or sensitizing to the respiratory tract; IJT 32(S1):5-24, 2013
Phenoxyethanol 122-99-6	B									Safe for use when included up to 1%, CosIng Annex V/29
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
Retinyl Palmitate	A									Safe up to 5%; JACT, 6(3), 279-320, 1987; confirmed 06/06

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
79-81-2										
Lecithin 8002-43-5	A									
Xanthan Gum 11138-66-2	A									
Centella Asiatica Extract 84696-21-9	C	-	Non- irritant	Non- irritant	Safe at 0.024% inclusion rate	Not genotoxic	10	9.60x10- 6	1.04x106	NOAEL based on reproduction toxicity effects in male rats
Decarboxy Carnosine HCL 57022-38-5	A									
Sodium Hyaluronate 9067-32-7	A									
Hydrogenated Lecithin 92128-87-5	A									
Sorbitol 50-70-4	A									
Tocopherol 10191-41-0	A									
Helianthus Annuus Seed Oil 8001-21-6	A									
Equisetum Arvense Extract	A									

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
71011-23-9										herba in 2016 (EMA/HMPC/278089/2015) and concluded that the benefit-risk assessment for Equisetum arvense preparations included in the monograph is positive under the specified conditions of use and at the therapeutic dosages. The therapeutic dosages investigated were several orders of magnitude larger than the SED of 0.017 mg/kg bw/day for this product, and on this basis it is considered that there are no safety concerns regarding the inclusion of this ingredient in the product.
Dipalmitoyl Hydroxyproline 41672-81-5	A									Read across to the two constituents of dipalmitoyl hydroxyproline 1. Palmitic acid and 2. Hydroxyproline. Palmitic acid is safe for use up to 25% (2014 CIR Compendium; JACT 6(3):321-401, 1987 confirmed 06/05. Hydroxyproline is a natural occurring component of collagen in the body with the same structure as the amino acid proline. On the basis of the safety of the two constituents and the high molecular weight of the molecule (ca. 607.961 g/mol-it is unlikely to be systemically absorbed), safe use can be expected.
Beta Sitosterol 83-46-5	A									Safe in the present practices of use and concentration. Safety Assessment of Phytosterols as Used in Cosmetics, Final Report 01/2014.
Carbomer 9003-01-4	A									Safe when used up to 2%, JACT 1(2)109-41, 1982 confirmed 11/02 IJT 22(S1):1-35, 2003
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. Included in formulation at 0.03%.
Linoleic Acid 60-33-3	A									Read across to oleic acids as linoleic acid is an oleic acid; safe in the present practices of use and concentration in cosmetics; Final Report on the Safety Assessment of Oleic Acid, Lauric Acid, Palmitic Acid, Myristic Acid, and Stearic Acid, JACT 6(3):321-401, 1987 confirmed 06/05 IJT 25(S2), 2006
Sodium Ascorbate 134-03-2	A									2014 CIR Compendium safe for use up to 0.3%; IJT 24(2):51-111, 2005
Mannitol 69-65-8	A									Safe to use at the present practices of use and concentrations, GRAS, FDA approved.
BHT	A									Safe up to 0.5%, International Journal of Toxicology 21(S2), 19-94, 1992; EFSA Journal 10(3), 2588,

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
128-37-0		2012								
Polysorbate 20 9005-64-5	A									
Hypnea Musciformis Extract 223751-71-1	#									
Ethylhexylglycerin 70445-33-9	A									
Disodium EDTA 139-33-3	A									
Palmitoyl Tripeptide- 1 147732-56-7	B									

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

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

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

# Food item, hazard and exposure data not required.

**Fragrances:**

Zone Quantum Elastin-Collagen Revival does not contain a fragrance.

**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**

Zone Quantum Elastin-Collagen Revival was released in 2016. Over the period December 2016 to January 2017, 1158 units of the 15ml product and 3382 units of the 50 ml product have been sold and there have been no adverse reactions reported to RegimA.

## **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 Zone Quantum Elastin-Collagen Revival will cause damage to human health when used as directed.

It is therefore concluded that Zone Quantum Elastin-Collagen Revival can be placed on the market in the EU to help the nourishment of dry or dehydrated skins and help skin feel firmer appear smoother and more youthful.

#### 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 insert (Appendix 4).

AM & PM: following cleansing with Regima apply eye care products and serums. apply 2 pump depressions of Quantum Elastin-Collagen Revival to the full face and neck [avoiding the eye area if sensitive]. To be used in combination with other RegimA Zone serums, day and night products [if irritation occurs, discontinue use].

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for their nourishment of dry or dehydrated skins and help skin feel firmer appear smoother and more youthful properties and with good local tolerance. There are no reasons to anticipate tolerance problems with use.

This product is intended for external use in adults only.

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

Shirley Hudson (safety assessor)

BSc, University of Aberdeen

CBiol, MBS

Member of the British Toxicology Society

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

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



## **List of References**

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

European Commission database on cosmetic ingredients (CosIng)

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

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

## METHOD OF MANUFACTURE / GMP CERTIFICATION



## **PROOF OF EFFECT CLAIMED**

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

## **ANIMAL TESTING STATEMENT**

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

The statement below is a confirmation of the company policy:

### **RégimA Skin Treatments**

CK92/05371/23

VAT No. 4590131043

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

**Fax: 011 616 8008**

**Cell: 0836537020**

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

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

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

#### Animal Testing Compliance Statement

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

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



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

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

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

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

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

Not applicable as this product does not contain a fragrance.

## **Appendix 4: Miscellaneous**

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

# PRODUCT INFORMATION FILE\*

RegimA

## Zone Rapid-Rejuvo Masque

Prepared: June 2017  
(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:** Zone Rapid-Rejuvo Masque

Product type	Masque to leave the skin feeling silky soft
Form	Cream
Colour	Off-white
Pack size	50ml
Pack type	WO Jar
Dispenser type	N/A
Part of a set	No
Manufacturer code	REM 004
Normal use	<b>In-salon use only.</b> Cleanse face and neck with RegimA Cleanser. Apply a pea size amount of Rapid-Rejuvo Masque, using fingertips, to face, and neck, avoiding eye area. Do not steam whilst Masque is in place. Leave for 5 to 10 minutes maximum then cleanse thoroughly to remove the Masque.

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

## Container label

## Carton label





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

**Product claims:**

This product claims to swiftly, safely, effectively, leaves the skin feeling silky soft whilst appearing revitalized with a renewed youthful glow.

# **COSMETIC PRODUCT SAFETY REPORT**

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

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

### Zone Rapid-Rejuvo Masque base formula

No	Raw Ingredient (INCI Name)	%	% (w/w)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Hydrogenated Polydecene	20	20	68037-01-4	500-183-1	Emollient/ Masking/ Perfuming/ Skin Conditioning	BP (Lipo Chemicals)	Silkflo 364 NF
2	Lactic Acid	10.8	12	79-33-4/ 50-21-5	201-196-2/ 200-018-0	Buffering/ Skin Conditioning/ Humectant	Merck KGaA	L(+)-Lactic Acid, PURAC®
	Aqua (Water)	1.2		7732-18-5	231-791-2			
3	Salicylic Acid	10	10	69-72-7	200-712-3	Keratolytic/ Masking/ Preservative/ Skin Conditioning	Salicylates & Chemicals (Fourchem)	Salicylic Acid 99%
4	Butylene Glycol	5	5	107-88-0	203-529-7	Humectant/ Masking/ Skin Conditioning/ Solvent/ Viscosity Controlling	Various	Butylene Glycol
5	Aqua (Water)	2.475	5	7732-18-5	231-791-2	Skin Conditioning/ Humectant/ Solvent/ Viscosity Controlling	Greentech (Natchem)	Meadowsw eet Medulat
	Propylene Glycol	2.47		57-55-6	200-338-0			
	Spiraea Ulmaria Flower Extract	0.055		84775-57-5	283-886-3			
6	Butylene Glycol	2.625	5	107-88-0	203-529-7	Solvent/ Skin Conditioning/	Greentech (Natchem)	Phytelene Complex
	Aqua (Water)	2.345		7732-18-5	231-791-2			

	Nasturtium Officinale Extract	0.01065		84775-70-2	283-899-4	Astringent/ Soothing/ Tonic/ Antimicrobial Cleansing/ Perfuming		EGX 247 BG
	Arctium Lappa Root Extract	0.002175		84012-13-5	281-658-8			
	Salvia Officinalis (Sage) Leaf Extract	0.002175		84082-79-1	282-			
	Citrus Limon (Lemon) Fruit Extract	0.01065		84929-31-7	284-515-8			
	Hedera Helix (Ivy) Extract	0.002175		84082-54-2	282-000-2			
	Saponaria Officinalis Extract	0.002175		84775-97-3	283-921-2			
7	Butylene Glycol	2.811	3	107-88-0	203-529-7	Humectant/ Masking/ Skin Conditioning/ Solvent/ Viscosity Controlling/ Buffering/ Solvent	ISP Vinciènce (Millchem)	Acnacidol
	10-Hydroxydecanoic Acid	0.072		1679-53-4	216-848-1			
	Sebacic Acid	0.072		111-20-6	203-845-5			
	1,10-Decanediol	0.045		112-47-0	203-975-2			
8	C14-22 Alcohols	1.9875	2.5	67762-30-5/ 629-96-9/ 661-19-8/ 27836-64-2/ 54549-26-7/ 54549-27-8/ 27836-65-3/ 100231-68-3	267-009-1/ 211-119-4/ 211-546-6/ 248-685-7/ 259-219-7/ 259-220-2/ 248-686-2/ 309-369-5	Emulsion Stabilising/ Emulsifying/ Surfactant	Seppic (Sharon Bolel Chemical Marketing)	Montanov L
	C12-20 Alkyl Glucoside	0.5		7732-18-5	231-791-2			
	Aqua (Water)	0.0075		50-99-7	200-075-1			
	Glucose	0.005						
9	Panthenol	2	2	81-13-0	201 327 3	Skin Conditioning	DSM Nutritional	D- Panthenol

							Products (Chempure)	
10	T-Butyl Alcohol	0.08	2	75-65-0	200-889-7	Perfuming/ Solvent/ Viscosity Controlling/ Emulsion Stabilising	Seppic (CJP)	SepiMax ZEN
	Aqua (Water)	0.02		7732-18-5	231-791-2			
	Polyacrylate Crosspolymer-6	1.9		#	#			
11	Phenoxyethanol	0.975	1.5	122-99-6	204-589-7	Emollient/ Humectant/ Skin Conditioning/ Preservative	Thor (Actichem)	Microcare PHG
	Caprylyl Glycol	0.525		1117-86-8	214-254-7			
12	Myristic Acid	0.004	1	544-63-8	208-875-2	Cleansing/ Emulsifying/ Perfuming/ Emulsion Stabilising/ Masking/ Refatting/ Surfactant/ Opacifying/ Surfactant	Various	Stearic Acid
	Palmitic Acid	0.543		57-10-3	200-312-9			
	Stearic Acid	0.449		57-11-4	200-313-4			
	Arachidic Acid	0.004		506-30-9	208-031-3			
13	Silica Dimethyl Silylate	1	1	68611-44-9	271-893-4	Anticaking/antifoaming/emollient/emulsion stabilizing/viscosity controlling	Evonik Degussa (Protea Speciality Chemicals)	Aerosil R 972

14	Xanthan Gum	0.5	0.5	11138-66-2	234-394-2	Binding/ Emulsifying/ Emulsion Stabilising/ Gel forming/ Skin Conditioning/ Surfactant/ Viscosity Controlling	CP Kelco (Tranarc)	Keltrol CG-T
15	Aqua (Water)	29.5	29.5	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

# not assigned

Ingredient order for the label: Aqua (Water), Hydrogenated Polydecene, Lactic Acid, Butylene Glycol, Salicylic Acid, Propylene Glycol, Panthenol, C14-22 Alcohols, Polyacrylate Crosspolymer-6, Silica Dimethyl Silylate, Phenoxyethanol, Palmitic Acid, Caprylyl Glycol, C12-20 Alkyl Glucoside, Xanthan Gum, Stearic Acid, T-Butyl Alcohol, 10-Hydroxydecanoic Acid, Sebacic Acid, Spiraea Ulmaria Flower Extract, 1,10-Decanediol, Citrus Limon (Lemon) Fruit Extract, Nasturtium Officinale Extract, Glucose, Arachidic Acid, Myristic Acid, Arctium Lappa Root Extract, Hedera Helix (Ivy) Extract, Salvia Officinalis (Sage) Leaf Extract, Saponaria Officinalis Extract.

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>

\*Zone Rapid-Rejuvo Masque does not contain a fragrance

#### **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 ...)	Cream
3 organoleptic properties (colour, odour, whenever relevant)	Off white, characteristic odour
4 pH (at 25°C)	2.37
5 viscosity (at 25°C)	45800 cPs
6 thermal stability (glass bottle)	12 weeks at 25°C
7 Specific gravity	0.981 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 bottles has confirmed stability at 25°C for 12 weeks, although the product began “sweating” at 40°C and 50°C at week 2 and therefore a warning regarding storage temperature to be below 25°C will be presented on the label.

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

A PET test has been performed according to USP method 31 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 WO jar is made from poly methyl methacrylate. The inner jar is made of polypropylene with a polyethylene lining and LDPE disc. The inner cap consists of polypropylene and the outer cap of acrylonitrile-butadiene-styrene. 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**

Zone Rapid-Rejuvo Masque is a product designed to swiftly, safely and effectively leave the skin feeling silky soft whilst appearing revitalized with a renewed youthful glow. It is a wash-off product that in normal circumstances will be applied by professional in-salon therapists who have been trained according to a RegimA program (see Appendix 4). It is used every 4-6 weeks in the salon only on the face and the neck, avoiding the eye area.

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

Site of application	Face and neck (if problematic)
Surface area of application (cm <sup>2</sup> )	565 cm <sup>2</sup>
Volume of product applied (ml)	0.25 ml (pea sized amount)
Frequency of application/use per day	1 application/4weeks (maximum)
Target population	Adult
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	0.25 ml exposure per 4-6 weeks Estimated exposure based on 60 kg adult= 4.17 mg/kg bw
Dermal absorption information	Unknown
other	None

## 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)
Hydrogenated Polydecene 68037-01-4	20	4.17	1	0.83
Lactic Acid 79-33-4	10.80	4.17	1	0.45
Butylene Glycol 107-88-0	10.44	4.17	1	0.43
Salicylic Acid 69-72-7	10	4.17	1	0.42
Propylene Glycol 57-55-6	2.47	4.17	1	0.10
Panthenol 81-13-0	2	4.17	1	0.08
C14-22 Alcohols 67762-30-5	1.99	4.17	1	0.08
Polyacrylate Crosspolymer-6 (no CAS number assigned)	1.90	4.17	1	0.08
Silica Dimethyl Silylate 68611-44-9	1	4.17	1	0.04
Phenoxyethanol 122-99-6	0.98	4.17	1	0.04
Palmitic Acid 57-10-3	0.54	4.17	1	0.02
Caprylyl Glycol 1117-86-8	0.53	4.17	1	0.02
C12-20 Alkyl Glucoside 67762-30-5	0.50	4.17	1	0.02
Xanthan Gum 11138-66-2	0.50	4.17	1	0.02
Stearic Acid 57-11-4	0.45	4.17	1	0.02
T-Butyl Alcohol 75-65-0	0.08	4.17	1	0.0033
10-Hydroxydecanoic Acid 1679-53-4	0.072	4.17	1	0.0030
Sebacic Acid 111-20-6	0.072	4.17	1	0.0030
Spiraea Ulmaria Flower Extract 84775-57-5	0.055	4.17	1	0.0023
1,10-Decanediol 112-47-0	0.045	4.17	1	0.0019

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)
Citrus Limon (Lemon) Fruit Extract 84929-31-7	0.011	4.17	1	0.00044
Nasturtium Officinale Extract 84775-70-2	0.011	4.17	1	0.00044
Glucose 50-99-7	0.005	4.17	1	0.00021
Arachidic Acid 506-30-9	0.004	4.17	1	0.00017
Myristic Acid 544-63-8	0.004	4.17	1	0.00017
Arctium Lappa Root Extract 84012-13-5	0.0022	4.17	1	0.00009
Hedera Helix (Ivy) Extract 84082-54-2	0.0022	4.17	1	0.00009
Salvia Officinalis (Sage) Leaf Extract 84082-79-1	0.0022	4.17	1	0.00009
Saponaria Officinalis Extract 84775-97-3	0.0022	4.17	1	0.00009

# 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.

## 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	NOAE L (mg/kg bw/day)	SED <sup>b</sup> 9	MoS <sup>c</sup>	comment
Hydrogenated Polydecene 68037-01-4	C	-	Non- irritant	Not a primary irritant/n on- corrosive	Non- sensitizin g	Non- irritant, non- genotoxic	1000- 6771 4620 for females in a 90- day study	0.20	22105	Safety assessment of polyene group as used in cosmetics, CIR, 2014
Lactic Acid 79-33-4	B									2014 CIR compendium, αHAs included at ca. 15% - safe up to ≤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. safe for use in salon products at concentrations ≤30%, at final formulation pH ≥3.0, in products designed for brief, discontinuous use followed by thorough rinsing from the skin, when applied by trained professionals, and when application is accompanied by directions for the daily use of sun protection <sup>1</sup> ; International Journal of Toxicology 17(S1): 1-242, 1998 Safe use in this product is supported by human usage information (see section A.10 and B.1)
Butylene Glycol 107-88-0	A									Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006
Salicylic Acid 69-72-7	A									2014 CIR Compendium, safe when formulated to avoid irritation and to avoid increasing sun sensitivity, or when increased sun sensitivity would be expected, directions for use include the daily use of sun protection. The label for this product states that sun protection (UVA and UVB) must always be used following use of this Masque. IJT 22(3):1-108. Safe use of this product is supported by human usage information and strictly in-salon use by RegimA trained professionals (see Section A.10 and B.1).
Propylene Glycol 57-55-6	A									Safe (when formulated to be non-irritating), Safety assessment of propylene glycol tripropylene glycol and PPGs as Used in Cosmetics, Fiume, M. et al., International Journal of Toxicology 31(S 2), 2012

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	NOAE L (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Panthenol 81-13-0	A									Safe up to 25%, JAQCT 6(1): 139-62, 2006
C14-22 Alcohols 67762-30-5	## <sup>1</sup>									2014 CIR Compendium, C14, is safe up to 5% (JACT 7(3):359-413, 1988 confirmed, 12/05), C16 is safe up to 50% (JACT 7(3):359-413, 1988 confirmed 12/05), C18 is safe up to 25% (JACT 4(5):1-29, 1985 confirmed 03/04 IJT 25(S2), 2006) and C22 is safe up to 50% (JACT 7(3):359-413, 1988 confirmed 12/05). The maximum concentration of C14-22 Alcohols in this product is 2.385%- which is under half of the worst case % presented in the CIR compendium, therefore it is not expected that any of the other C-alcohols would at a % unsafe for use, especially considering there is a mix of 9 alcohols in 2.385%.
Polyacrylate Crosspolymer-6 (no CAS number assigned)	C	-	Slight ly irritati ng	Non- irritant	Non- sensitizin g	Non- sensitizin g and non- irritating in humans at ~5%	Not available	Not available	Not available	Not genotoxic (negative bacterial revere mutation). Based on assumed low hazard (meets the NICNAS polymer of low concern criteria) and assessed use pattern (up to 5%)

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	NOAE L (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment	
										in cosmetics), not considered to be an unreasonable health risk	
Silica Dimethyl Silylate 68611-44-9	A	2014 CIR safe when formulated and delivered in the final product not to be irritating or sensitizing to the respiratory tract, IJT 32(S1):5-24, 2013									
Phenoxyethanol 122-99-6	B	2014 CIR Compendium safe up to 1%, JACT 9(2):259-77, 1990									
Palmitic Acid 57-10-3	A	2015 CIR Compendium, safe for use up to 25%, JACT 6(3):321-401, 1987 confirmed 06/05									
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									
C12-20 Alkyl Glucoside 67762-30-5	A	Safe for use in cosmetics when formulated to be non-irritating; International Journal of Toxicology 32 (S3): 22-48, 2013									
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									
Stearic Acid 57-11-4	A	2014 CIR compendium, safe at use over 50%, JACT 6(3):321-401, 1987 confirmed 06/05 IJT 25(S2),2006									
T-Butyl Alcohol 75-65-0	A	Safe for use up to 0.5% IJT 24(2):1-20, 2005, (Amended) JACT 8(4):627-41, 1989 (Original Report)									

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Referenc e for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAE L (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
10-Hydroxydecanoic Acid 1679-53-4	A		Component of Royal Jelly: <a href="https://www.jstage.jst.go.jp/article/cpb/55/10/55_10_1528/_pdf">https://www.jstage.jst.go.jp/article/cpb/55/10/55_10_1528/_pdf</a> . Long standing oral use of royal jelly identified for menopausal symptoms.  It is a hydroxy fatty acid (see Reference in Appendix 4- Identification of a Collagen Production-promoting Factor from an Extract of Royal Jelly and Its Possible Mechanism) and is structurally similar to hydroxystearic acid and other fatty acids i.e alpha hydroxy acids. Therefore read across to hydroxy acids is applicable (alpha hydroxy acids at worst case).  2014 CIR compendium, αHAs included at ca. 15% - safe up to ≤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. safe for use in salon products at concentrations ≤30%, at final formulation pH ≥3.0, in products designed for brief, discontinuous use followed by thorough rinsing from the skin, when applied by trained professionals, and when application is accompanied by directions for the daily use of sun protection <sup>1</sup> ; International Journal of Toxicology 17(S1): 1-242, 1998 Safe use in this product is supported by human usage information (see section A.10 and B.1)							
Sebacic Acid 111-20-6	A		2014 CIR Compendium, safe for use at up to 0.03% in leave on and up to 1% in rinse-off formulations; IJT 31 (S1):5-76, 2012							
Spiraea Ulmaria Flower Extract 84775-57-5	A		Meadowsweet, also known as Dropwort ( <i>Filipendula ulmaria</i> ): <a href="https://www.globalherbalsupplies.com/herb_information/meadowsweet.htm">https://www.globalherbalsupplies.com/herb_information/meadowsweet.htm</a> Used as a herbal medicine at up to 6g for tea preparation, considered not harmful systemically bearing in mind the long period of marketing experience without reports of adverse effects and the results of preclinical studies by the European Medicines Agency: EMA/HMPC/434892/2010. Topical tolerance of this ingredient is not a concern in a product intended as a peel for in-salon use by trained professionals.							
1,10-Decanediol 112-47-0	A		2014 CIR Compendium, safe for use up to 1%; IJT 28 (1): 5-67, 2009							
Citrus Limon (Lemon) Fruit	#		Annex II/358 R1, Furocoumarines (e.g. trioxysalen (INN), 8-methoxypсорален, 5-methoxypсорален) except for normal content in natural essences used. Restriction does not apply as this							

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	NOAE L (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Extract 84929-31-7			ingredient is a natural essence; GRAS							
Nasturtium Officinale Extract 84775-70-2	#		Watercress is a food item and systemic toxicity is acceptable. The supplier notes it is non-irritant and in consideration of its food item status, it can be assumed that watercress is safe when applied dermally.							
Glucose 50-99-7	A		Safety Assessment of Monosaccharides, Disaccharides, and Related Ingredients as Used in Cosmetics, Final Report 03/2014, Glucose is listed in Annex IV of the European Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) which “sets out substances that are exempted from the registration, evaluation and downstream user provisions of REACH as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties. GRAS.							
Arachidic Acid 506-30-9	A		Arachidic acid is a saturated long-chain fatty acid with a 20-carbon backbone. It is found naturally as a minor component of peanut oil and is formed by the hydrogenation of arachidonic acid: <a href="https://pubchem.ncbi.nlm.nih.gov/compound/Arachidic_acid#section=Top">https://pubchem.ncbi.nlm.nih.gov/compound/Arachidic_acid#section=Top</a> Hence a read across to arachidonic acid is deemed appropriate. The 2014 CIR Compendium considers that the safety of this ingredient has not yet been documented and substantiated for cosmetic use until data is generated. However, considering that Arachidic acid makes up about 1.93% of peanut oil (see Appendix 4), a commonly ingested food item, compared to 0.0004% arachidic acid in the formulation for this product, systemic safety can be assumed. The 2014 CIR Compendium also states that in a 24 h single patch test, a formulation containing 0.04% Arachidonic Acid was not a skin irritant (this is 100 time greater than the concentration in this formulation) and on this basis, it is considered acceptable for topical use in this product.							
Myristic Acid 544-63-8	A		2014 CIR Compendium, safe for use up to 50%, JACT 6(3):321-401, 1987 confirmed 06/05 IJT 25(S2), 2006; IJT 29 (S3): 162-186, 2010							
Arctium Lappa Root Extract	## <sup>1</sup>		2014 CIR Compendium, Arctium Lappa <b>Seed Oil</b> is expected as safe for use in product categories and concentrations comparable to others in these groups. Assessment report on Arctium lappa L., radix,							

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	NOAE L (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
84012-13-5										EMA/HMPC/246764/2009; a carcinogenicity study showed rats treated with a diet containing 33% of roots of <i>Arctium lappa</i> L. for 120 days had no tumours detected in any animal. Other in vivo focused on other parts of the plant, however the available data does not point to any serious concern with respect to safety. Preparations of <i>Arctium lappa</i> root can be considered as safe.
Hedera Helix (Ivy) Extract 84082-54-2	A									Used as oral medicinal use as expectorant. GRAS for topical use with warning regarding discontinue use if irritation or itching occurs. <a href="http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_HMPC_assessment_report/2012/01/WC500120648.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_HMPC_assessment_report/2012/01/WC500120648.pdf</a>
Salvia Officinalis (Sage) Leaf Extract 84082-79-1	A									Traditional use has shown that sage leaf can be recognised as safe when used in recommended dosages (up to 3g leaf steeped in water) under the conditions specified in the monograph. Also, traditional medicinal use of sage leaf has been found to fulfil the requirement of medicinal use for at least 30 years according to Directive 2004/24/EC for numerous indications including the traditional herbal medicinal product for relief of minor skin inflammations. Doc. Ref.: EMA/HMPC/330383/2008.
Saponaria Officinalis Extract 84775-97-3	A									Herbal use: long used as gentle soap, used in brewing to create 'head' on beer. Can be regarded as GRAS due to long history of external use for skin problems, psoriasis, eczema etc. Reference unavailable.

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

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

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

# Food item, hazard and exposure data not required.



**Fragrances:**

Zone Rapid-Rejuvo Masque does not contain a fragrance.

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

No undesirable effects are anticipated based on the product being used as directed on the face and neck every 4-6 weeks.

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

Zone ‘Acne Attack’ Pro-Masque was released in 2016. Over the period June 2016 to December 2016, 2267 units have been sold and there have been no adverse reactions reported to RegimA.

## **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 Zone Rapid-Rejuvo Masque will cause damage to human health when used as directed.

It is therefore concluded that Zone Rapid-Rejuvo Masque can be placed on the market in the EU as an in-salon use masque to swiftly, safely, effectively, leaves the skin feeling silky soft whilst appearing revitalized with a renewed youthful glow.

#### 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 insert (Appendix 4).

IN-SALON: Cleanse face and neck with RegimA Cleanser. Apply a pea size amount of Zone Rapid-Rejuvo Masque, using fingertips, to face, and neck, avoiding eye area. Do not steam whilst Masque is in place. Leave for 5 to 10 minutes maximum then cleanse thoroughly to remove the Masque.

Warnings:

‘Do not apply to damaged/open skin’.

‘May sting and itch on application’.

‘Not for retail. Strictly in-salon Masque for use by a RegimA trained professional skin care therapist.

‘Must always be followed by a RegimA product containing UVA and UVB protection’.

‘Suitable for adults only- keep out of reach of children’.

‘Store below 25°C in a cool dry place. Protect from light’.

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for their properties to help congested skins properties. There are no reasons to anticipate tolerance problems with intermittent 4-6 week use. The Masque is used in-salon only, by trained staff (see Appendix 4).

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, MBS

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

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

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

## **List of References**

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

European Commission database on cosmetic ingredients (CosIng)

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

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

## METHOD OF MANUFACTURE / GMP CERTIFICATION



## **PROOF OF EFFECT CLAIMED**

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

## **ANIMAL TESTING STATEMENT**

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

The statement below is a confirmation of the company policy:

### **RégimA Skin Treatments**

CK92/05371/23

VAT No. 4590131043

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

**Fax: 011 616 8008**

**Cell: 0836537020**

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

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

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

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#### Animal Testing Compliance Statement

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

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

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

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

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

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

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

Not applicable.

## **Appendix 4: Miscellaneous**

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

# PRODUCT INFORMATION FILE\*

RegimA

## Zone Rejuvoderm Night Maintenance

Prepared: January 2018  
(Label and packaging update June 2021)

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

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## **INTRODUCTION**

### **PRODUCT DESCRIPTION**

**Product Name:** Rejuvoderm Night Maintenance

Product type	Gradual Natural Exfoliant for more sensitive or fragile skin
Form	Thick cream
Colour	Off white
Pack size	50ml
Pack type	WSZ50 Airless Bottle
Dispenser type	Pump
Part of a set	No
Manufacturer code	MNC 002
Normal use	<b><u>Salon take home product only:</u></b> PM: Cleanse with RegimA cleanser. Apply eye products and serums, then apply one full pump depression of Rejuvoderm to the face, avoiding the eye area and neck. May tingle a little on application. Do not apply to damaged/broken skin. AM: Cleanse skin thoroughly with RegimA cleanser in the morning and must always be followed by a day product containing UVA and UVB protection.

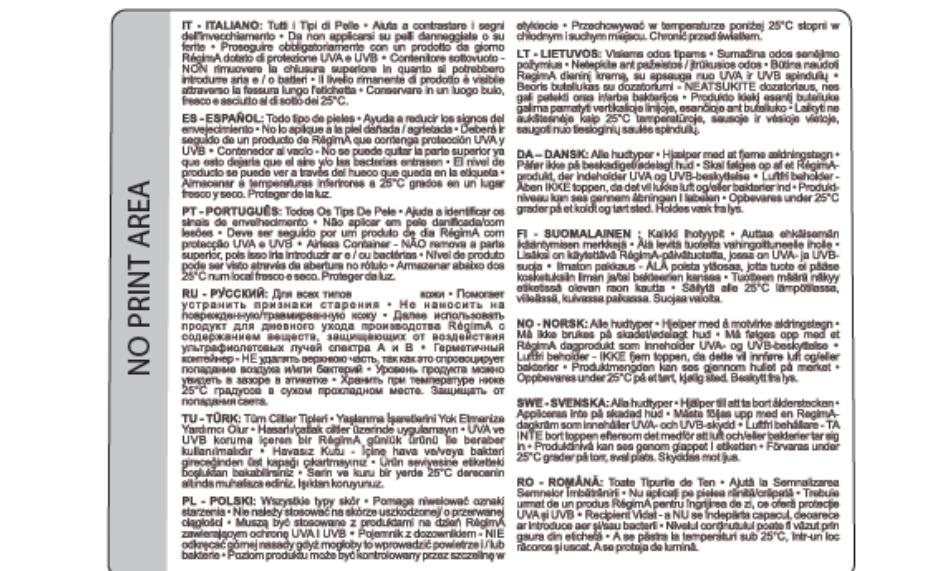
**Pictures of the Item: On following page**

## Container label

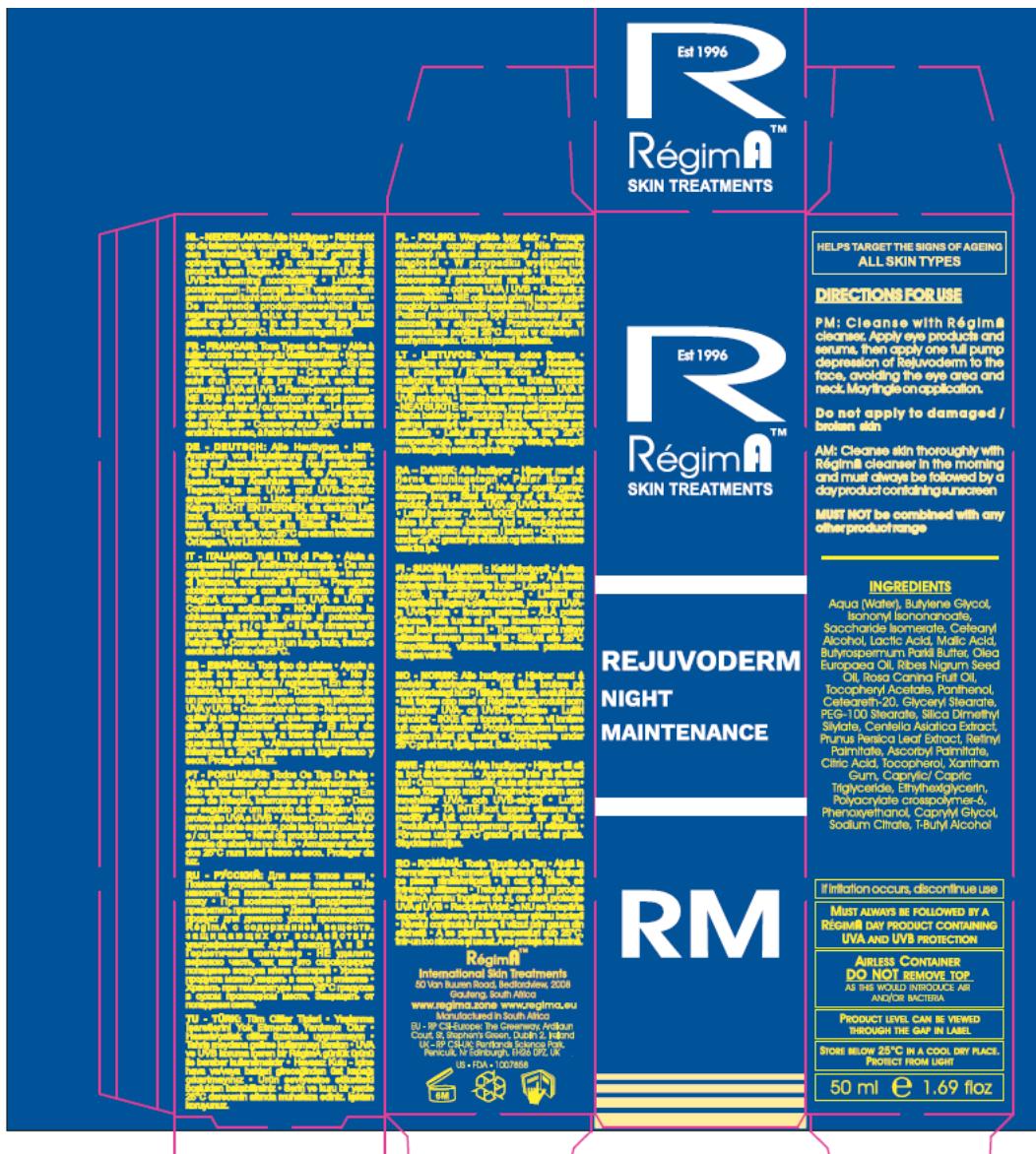
### Top layer



### Base layer



## Carton label



**Batch code:** The batch number is printed onto the underside of the carton and the container at 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 gradually and naturally exfoliate the skin.

# **COSMETIC PRODUCT SAFETY REPORT**

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

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

### Zone Rejuvoderm Night Maintenance Base Formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Cetearyl Alcohol	3.5	5	67762-27-0/ 8005-44-5	267-008-6	Emollient/ Emulsifying/ Emulsion Stabilising/ Opacifying/ Surfactant/ Viscosity Controlling/ Cleansing	Croda Chemicals	Cosmowax D
	Ceteareth-20	1.5		68439-49-6	#			
2	Isononyl Isononanoate	5	5	52919-71-5/ 42131-25-9	261-665-2	Emollient/ Skin conditioning	Seppic (CJP Chemicals)	Lanol 99
3	Saccharide Isomerate	3.65	5	100843-69-4	#	Humectant/ Solvent/ Masking/ Chelating/ Buffering	DSM Nutritional Products (Chempure)	Pentavitin
	Aqua (Water)	1.25		7732-18-5	231-791-2			
	Citric Acid	0.05		77-92-9/ 5949-29-1	201-069-1			
	Sodium Citrate	0.05		68-04-2/ 6123-04-3	200-675-3			
4	Butylene Glycol	4.875	5	107-88-0	203-529-7	Masking/ Humectant/ Skin conditioning/ Viscosity controlling/	Greentech (Natchem)	Centella Asiatica Cosmelene
	Centella Asiatica Extract	0.125		84696-21-9	283-640-5			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
						Smoothing/ Soothing		
5	Butylene Glycol	4.975	5	107-88-0	203-529-7	Humectant/ Skin Conditioning / Viscosity Controlling	Various - OXEA/ DAICEL Chemical Industrie, LTD/ SAVANNA H	1, 3- Butylene Glycol
	Aqua (Water)	0.025		7732-18-5	231-791- 2(I)			
6	Lactic Acid	3.375	3.75	79-33-4/ 50-21-5	201-196-2/ 200-018-0	Buffering/ Skin conditioning/ Humectant	Merck KGaA	L(+)-Lactic Acid PURAC
	Aqua (Water)	0.375		7732-18-5	231-791- 2(I)			
7	Malic Acid	3.375	3.375	6915-15-7/ 97-67-6	230-022-8/ 202-601-5	Buffering	Merck KGaA	Malic Acid BP
8	Glyceryl Stearate	1.5	3	31566-31-1	250-705-4/ 286-490-9	Emollient/ Emulsifying/ Surfactant	Croda Chemicals	ARLACEL 165FP-PA- (RB)
	PEG- 100 Stearate	1.5		9004-99-3	#			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
9	Butyrospermum Parkii Butter	3	3	68920-03-6/ 194043-92-0/ 91080-23-8/ 67701-30-8	293-515-7/ 266-948-4	Skin Conditioning / Viscosity Controlling	Cognis Care Chemicals	Cetiol SB 45
10	Olea europaea oil	3	3	8001-25-0/ 156798-12-8	232-277-0	Skin conditioning / Perfuming	Sharon Bolel	Olive oil
11	Tocopheryl Acetate	3	3	7695-21-2/ 58-95-7	231-710-0/ 200-405-4	Antioxidant/ Skin conditioning	DSM Nutritional Products (Chempure)	DL- $\alpha$ -Tocopheryl Acetate
12	Rosa Canina Fruit Oil	3	3	84696-47-9/ 84603-93-0	283-652-0	Emollient/ Skin conditioning	Seatons (Croda Chemicals)	Rose hips Oil
13	Ribes Nigrum Seed Oil	3	3	68606-81-5/ 97676-19-2	271-749-0	Emollient	Sharon Bolel Chemical Marketing	Blackcurrant Seed Oil
14	Aqua (Water)	2.88	3	7732-18-5	231-791-2	Emollient/ Moisturising/ Skin Conditioning	Silab (Meganede)	Vitagenyl
	Prunus Persica Leaf Extract	0.099		840-12-34-0	281-678-7			
	Phenoxyethanol	0.015		122-99-6	204-589-7			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Ethylhexlglycerin	0.006		70445-33-9	408-080-2	/ Preservative		
15	Panthenol	2	2	81-13-0/ 16485-10-2	201-327-3/ 240-540-6	Skin Conditioning	DSM Nutritional Products (chempure)	D- Panthenol
16	Polyacrylate crosspolymer-6	0.96	1	#	#	Emulsion Stabilising/ Viscosity Controlling/ Perfuming	Seppic (CJP)	Sepimax Zen
	T-Butyl Alcohol	0.04		75-65-0	200-889-7			
17	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			
18	Silica Dimethyl Silylate	1	1	68611-44-9	271-893-4	Anticaking/ Emollient/ Emulsion stabilising/ Viscosity Controlling	Evonik Degussa (Protea Speciality Chemicals)	Aerosil R 972
19	Citric Acid	0.75	0.75	77-92-9/ 5949-29-1	201-069-1	Masking/ Buffering	Merck KGaA	Citric Acid BP
20	Retinyl Palmitate	0.2775	0.5	79-81-2	201-228-5	Antioxidant/ Masking/ Skin	DSM Nutritional Products	Retinyl Palmitate (or)
	Tocopherol	0.005		10191-41-0/ 54-28-	233-466-0/ 200-201-5/			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
	Caprylic/ Capric Triglyceride	0.2175		4(gamma)/ 16698-35- 4(beta)/ 119-31-1/ 1406-18-4/ 1406-66-2/ 2074-53-5(DL)/ 59-02-9(D)/ 7616-22-0	240-747-1/ 204-299-0/ 215-798-8/ 218-197-9/ 200-412-2	Conditioning / Perfuming	(Chempure)	Vitamin A Palmitate 1.0 MIU/g (stabilised with tocopherol)
				73398-61-5/ 65381-09-1	277-452-2/ 265-724-3			
21	Xanthan Gum	0.5	0.5	11138-66-2	234-394-2	Emulsifying/ Emulsion Stabilising/ Skin conditioning/ Viscosity Controlling/ Binding	CP Kelco (Tranarc)	Keltrol T Plus
22	Ascorbyl Palmitate	0.2	0.2	137-66-6	205-305-4	Antioxidant/ Masking	DSM Nutritional Products (chempure)	Ascorbyl Palmitate
23	Tocopherol	0.2	0.2	10191-41-0/ 54-28- 4(gamma)/ 16698-35- 4(beta)/	233-466-0/ 200-201-5/ 240-747-1/ 204-299-0/ 215-798-8/	Antioxidant/ Masking/ Skin Conditioning	DSM Nutritional Products (chempure)	dl- $\alpha$ - Tocopherol

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
				119-13-1/ 1406-18-4/ 1406-66-2/ 2074-53-5(DL)/ 59-02-9(D)/ 7616-22-0	218-197-9/ 200-412-2			
24	Water (Aqua)	39.725	39.725	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

# not assigned

**Ingredient order for the label:** Water (Aqua), Butylene Glycol, Isononyl Isononanoate, Saccharide Isomerate, Cetearyl Alcohol, Lactic Acid, Malic Acid , Butyrospermum Parkii Butter, Olea Europaea oil , Ribes Nigrum Seed Oil, Rosa Canina Fruit Oil, Tocopheryl Acetate, Panthenol, Ceteareth-20, Glyceryl Stearate, PEG- 100 Stearate, Silica Dimethyl Silylate, Polyacrylate Crosspolymer-6, Phenoxyethanol, Citric Acid, Xantham Gum, Retinyl Palmitate, Caprylic/ Capric Triglyceride, Tocopherol, Ascorbyl Palmitate, Centella Asiatica Extract, Caprylyl Glycol, Prunus Persica Leaf Extract, Sodium Citrate, T-Butyl Alcohol, Ethylhexlglycerin.

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>

\* Zone Rejuvoderma Night Maintenance does not contain a fragrance

#### **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 (at 25°C)	Smooth thick cream
2	Type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Emulsion
3	Organoleptic properties (colour, odour, whenever relevant)	Off white, characteristic odour
4	pH	2.18
5	Viscosity	340 000 cPs
6	Thermal stability (glass bottle)	12 weeks at 40°C
7	Specific gravity	0.959 g/ml

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

A shelf-life of 6 months after opening has been allocated to this product when stored as advised on the label (store below 24°C, in a cool dry place, protected from light).

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 room temperature for 12 weeks. After 12 weeks of thermal stability at 40°C a 24% increase in pH, a 39% decrease in viscosity and a colour change from off white to slightly yellow were observed. In consideration of the results of the stability study at 40°C, a warning has been added to the label stating “Store below 77°F / 24°C on a cool dry place. Protect from light”.

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

A PET test has been performed according to USP method 31 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 WSZ50 airless pump bottle body is made from acrylonitrile-styrene resin (SAN) with a polyethylene liner. The pump is 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**

Zone Rejuvoderm Night Maintenance is a gradual, natural exfoliant for the skin, especially for more sensitive or fragile skin. It is a leave on product that in normal circumstances will be a take home product following a salon consultation with therapists trained according to a RegimA program (see Appendix 4). It is to be used once daily on the face avoiding the neck and eye area.

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

Site of application	Face
Surface area of application (cm <sup>2</sup> )	565
Volume of product applied (ml)	0.25 (one pump depression)
Frequency of application/use per day	Once daily
Target population	Adult
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	0.25 ml exposure daily Estimated exposure based on 60 kg adult = 4.17 mg/kg bw
Dermal absorption information	Unknown
other	None

## 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)
Butylene Glycol 107-88-0	9.85	4.17	1	0.41
Isononyl Isononanoate 52919-71-5	5	4.17	1	0.21
Saccharide Isomerate 100843-69-4	3.65	4.17	1	0.15
Cetearyl Alcohol 67762-27-0	3.5	4.17	1	0.15
Lactic Acid 79-33-4	3.38	4.17	1	0.14
Malic Acid 6915-15-7	3.38	4.17	1	0.14
Butyrospermum Parkii Butter 68920-03-6	3	4.17	1	0.13
Olea europaea oil 8001-25-0	3	4.17	1	0.13
Ribes Nigrum Seed Oil 68606-81-5	3	4.17	1	0.13
Rosa Canina Fruit Oil 84696-47-9	3	4.17	1	0.13
Tocopheryl Acetate 7695-21-2	3	4.17	1	0.13
Panthenol 81-13-0	2	4.17	1	0.083
Ceteareth-20 68439-49-6	1.5	4.17	1	0.063
Glyceryl Stearate 31566-31	1.5	4.17	1	0.063
PEG- 100 Stearate 9004-99-3	1.5	4.17	1	0.063
Silica Dimethyl Silylate 68611-44-9	1	4.17	1	0.042

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)
Polyacrylate crosspolymer-6 *	0.96	4.17	1	0.040
Phenoxyethanol 122-99-6	0.92	4.17	1	0.038
Citric Acid 77-92-9	0.80	4.17	1	0.033
Xantham Gum 11138-66-2	0.50	4.17	1	0.021
Retinyl Palmitate 79-81-2	0.28	4.17	1	0.012
Caprylic/ Capric Triglyceride 73398-61-5	0.22	4.17	1	0.0091
Tocopherol 10191-41-0	0.21	4.17	1	0.0085
Ascorbyl Palmitate 205-305-4	0.20	4.17	1	0.0083
Centella Asiatica Extract 84696-21-9	0.13	4.17	1	0.0052
Caprylyl Glycol 1117-86-8	0.10	4.17	1	0.0042
Prunus Persica Leaf Extract 840-12-34-0	0.099	4.17	1	0.0041
Sodium Citrate 68-04-2	0.050	4.17	1	0.0021
T-Butyl Alcohol 75-65-0	0.040	4.17	1	0.0017
Ethylhexlglycerin 70445-33-9	0.006	4.17	1	0.00025

# 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.

\* Where no CAS no. is applicable

### A.8 Toxicological Profile of the Substances

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Polyacrylate crosspolymer-6 *	C	-	Slightly irritating	Non- irritant	Non- sensitizing	Non- sensitizing and non- irritating in humans at ~5%	Not available	Not available	Not available	Not genotoxic (negative bacterial reverse mutation). Based on assumed low hazard (meets the NICNAS polymer of low concern criteria) and assessed use pattern (up to 5% in cosmetics), not considered to be an unreasonable health risk
Butylene Glycol 107-88-0	A	2014 CIR compendium, safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006.								

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
Isononyl Isononanoate 52919-71-5	A	2014 CIR compendium, safe up to 64% IJT 30(S3):228-269, 2011; final report 03/2013 available from CIR.								
Cetearyl Alcohol 67762-27-0	A	2014 CIR compendium, safe at use up to 25% JACT 7(3):359-413, 1988 confirmed 12/05.								
Lactic Acid 79-33-4	B	2014 CIR compendium, αHAs are included at less than 7% in this product - safe up to ≤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. Safe for use in salon products at concentrations ≤30%, at final formulation pH ≥3.0, in products designed for brief, discontinuous use followed by thorough rinsing from the skin, when applied by trained professionals, and when application is accompanied by directions for the daily use of sun protection. International Journal of Toxicology 17(S1): 1-242, 1998.								
Malic Acid 6915-15-7	B	While the pH of the product is ~ 2.2, this is mitigated by warnings about discontinuing use if irritation occurs and use of a sunscreen which protects against UVA and UVB rays. The product is also only sold from salons where there are trained advisors.  Safe use in this product is supported by human usage information (see section A.10 and B.1).								
Butyrospermum Parkii Butter 68920-03-6	A	Safe when used up to 60%, Final report 03/11 CIR Compendium, 2014.								
Olea europaea oil 8001-25-0	A	2014 CIR Compendium safe up to 100%, Final report 03/2011 (CIR).								
Ribes Nigrum Seed Oil 68606-81-5	A	2014 CIR Compendium, safe up to 0.3%, Final report 03/2013 (CIR) current formulation has 3% but no adverse effects expected, food item GRAS#. Warning has been added to the label in case of irritation.								
Rosa Canina Fruit Oil 84696-47-9	A	2014 CIR Compendium, safe up to 19%, Final report 03/2013 (CIR).								
Tocopheryl	A	2014 CIR compendium, safe at use up to 36% (100% in Vitamin E oil) IJT 21(S3):51-116, 2002.								

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
Acetate 7695-21-2										
Saccharide Isomerate 100843-69-4	A		Contains mainly glucose and fructose, GRAS food substances, Safety assessment of monosaccharides, disaccharides and related ingredients as used in cosmetics, CIR, April 4, 2014. PDS recommends use up to 5% in skin care preparations.							
Panthenol 81-13-0	A		Safe up to 25%, JAQCT 6(1): 139-62, 2006.							
Ceteareth-20 68439-49-6	B		Safe when formulated to be non-irritating; 2014 CIR Compendium, Final Report 12/10 (CIR); International Journal of Toxicology 18(S3), 41-49, 1999 and International Journal of Toxicology 31 (S2), 169-244, 2012. Despite the presence of exfoliating acids, this formula is not expected to give rise to irritation when used as directed. There are warnings on the label advising to discontinue use if irritation occurs in sensitive individuals and to use a sunscreen which protects against UVA and UVB rays.							
Glyceryl Stearate 31566-31-1	A		Safe up to 50%; JACT 1(4), 169-192, 1982.							
PEG- 100 Stearate 9004-99-3			2014 CIR Compendium, safe up to 6%, IJT 24(S1):1-102, 2005.							
Silica Dimethyl Silylate 68611-44-9	A		2014 CIR Compendium, safe when formulated and delivered in the final product not to be irritating or sensitizing to the respiratory tract, IJT 32(S1):5-24, 2013.							
Phenoxyethanol 122-99-6	B		2014 CIR Compendium, safe for use when included up to 1%, CosIng Annex V/29, JACT 9(2):259-77, 1990.							
Citric Acid 77-92-9	A		2014 CIR Compendium, Safe up to 39%, International Journal of Toxicology 33(S2), 16-46, 2014.							
Xantham 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.							
Retinyl Palmitate	A		2014 CIR Compendium, safe up to 5%; JACT, 6(3), 279-320, 1987; confirmed 06/06.							

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
79-81-2										
Caprylic/Capric Triglyceride 73398-61-5	A	2014 CIR Compendium, safe for use up to 84% JEPT 4 (4): 105-20, 1980 confirmed 06/01 IJT 22 (S1): 1-35, 2003.								
Tocopherol 10191-41-0	A	2014 CIR Compendium, safe when used up to 1%; IJT 21(S3):51-116, 2002; Final report 03/2014 CIR Compendium, 2014.								
Ascorbyl Palmitate 137-66-6	A	2014 CIR Compendium, safe up to 0.2%; International Journal of Toxicology 18(S3), 1-26, 1999.								
Centella Asiatica Extract 84696-21-9	C	-	Non- irritant	Non- irritant	Safe at 0.024% inclusion rate	Not genotoxic	10	9.60x10- 6	1.04x106	NOAEL based on reproduction toxicity effects in male rats
Caprylyl Glycol 1117-86-8	A	2014 CIR Compendium, 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.								
Prunus Persica Leaf Extract 840-12-34-0	##	Prunus Persica (Peach) <b>Kernel Oil</b> - is safe up to 22%, 2014 CIR Compendium; Final Report Plant-Derived Fatty Acid Oils as Used in Cosmetics, 03/2011. Read-across to the Kernel oil for the leaf extract considered appropriate when considering the low concentration in the product, strictly take home from salon use and historical safe use based on experience of this product.								
Sodium Citrate 68-04-2	A	2014 CIR Compendium, safe for use up to 10%, IJT 33 (S2): 16-46, 2014.								
T-Butyl Alcohol 75-65-0	A	2014 CIR Compendium, safe for use up to 0.5% IJT 24(2):1-20, 2005, (Amended) JACT 8(4):627-41, 1989 (Original Report).								
Ethylhexlglycerin	A	2014 CIR Compendium safe with no upper limit for concentration, IJT 32 (S3): 5-21, 2013.								

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
70445-33-9										

<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.

\* CAS no. not assigned

**Fragrances:**

Zone Rejuvoderm Night Maintenance does not contain a fragrance.

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

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

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

Rejuvoderm Night Maintenance was released in 2017. Over the period October 2017 to November 2017, 583 units have been sold and there have been no adverse reactions reported to RegimA.

## **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 Zone Rejuvoderm Night Maintenance will cause damage to human health when used as directed (always followed by sunscreen in daylight hours). Should the product cause irritation in sensitive individuals, the product packaging carries the warning 'If irritation occurs, discontinue use'.

It is therefore concluded that Zone Rejuvoderm night Maintenance can be placed on the market in the EU as a salon take home product to gradually naturally exfoliate more sensitive or fragile skin.

#### 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 insert (Appendix 4).

PM: cleanse with RegimA cleanser. Apply eye products and serums, then apply one full pump depression of Rejuvoderm to the face, avoiding the eye area and neck.

AM: Cleanse skin thoroughly with RegimA cleanser in the morning and must always be followed by a day product containing sunscreen.

Warnings:

'Must always be followed by a RegimA day product containing UVA and UVB protection'.

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

'Store below 77°F / 24°C in a cool dry place. Protect from light'.

'Do not apply to damaged/broken skin.'

'If irritation occurs, discontinue use'.

'Must not be combined with any other product range'

### **B.3 Reasoning**

This product contains many ingredients with a positive reputation for their natural skin exfoliant properties. There are no reasons to anticipate tolerance problems with use once daily.

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

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

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

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

### **List of References**

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

## METHOD OF MANUFACTURE / GMP CERTIFICATION



## **PROOF OF EFFECT CLAIMED**

This product is described as a gradual natural exfoliant for skin health. No proof of claim is required as it is recognized that content of AHAs at 6.75% will have exfoliating properties (Evaluation and opinion on Alpha-hydroxy acids (2004), SCCNFP/0799/04).

## **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**

Certificates of allergen content are maintained electronically with the PIF by the Responsible Person. They are available on request.

## **Appendix 4: Miscellaneous**

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

# PRODUCT INFORMATION FILE\*

RégimA

Scar Forté + Anti Stretch  
Complex - Super Strength  
Serum

Prepared: August 2021 (*Second re-formulation*)

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

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## **INTRODUCTION**

### **PRODUCT DESCRIPTION**

#### **Product Name:**

Product type	Skin care
Form	Skin Serum
Colour	Brown
Pack size	20, 50, 100 ml
Pack type	WSZ Airless Bottle
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	RSR005
Normal use	Apply to scar or areas prone to stretch marks 2 to 4 times daily

## Pictures of the Item:

### Carton label



**Commented [SH1]:** Shirley to check label after update completed and replace this graphic

**Régima™**  
**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



**Commented [SH2]:** To be replaced

**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 improve the appearance of scars, all skin types.

## **COSMETIC PRODUCT SAFETY REPORT**

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

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

### Scar Forté + Anti Stretch Complex base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EINECS No.	Function	Supplier (Agent)	Tradename
1	Triticum Vulgare (Wheat) Germ Oil	5.0000	5.000	CAS: 68917-73-7 / 8006-95-9	EINICS: 281-689-7	Emollient	Henry Lamotte Oils GmbH	Wheat Germ Oil
2	Butylene Glycol	4.875	5.000	CAS: 107-88-0	EINICS: 203-529-7	Skin conditioning	Greentech (Natchem)	Cosmelene of Centella
	Centella Asiatica Leaf Extract	0.125		CAS: 84696-21-9	EINICS: 283-640-5			
3	Arnica Montana Flower Extract	0.0625	5.000	CAS: 68990-11-4	EINICS: 273-579-2	Skin conditioning	Greentech (Natchem)	Phytelene EG 001 Arnica
	Aqua	2.4375		CAS: 7732-18-5	EINICS: 231-791-2			
	Propylene Glycol	2.5000		CAS: 57-55-6	EINICS: 200-338-0			
4	Equisetum Arvense Extract	0.0625	5.000	CAS: 71011-23-9	EINICS: 275-123-8	Skin conditioning	Greentech (Natchem)	Cosmelene Horsetail
	Aqua	0.9375		CAS: 7732-18-5	EINICS: 231-791-2			
	Butylene Glycol	4.0000		CAS: 107-88-0	EINICS: 203-529-7			
5	Hedera Helix (Ivy) Leaf/Stem Extract	0.1750	5.000	CAS: 84082-54-2	EINICS: 282-000-2	Skin conditioning	Greentech (Natchem)	Cosmelene Ivy
	Aqua	2.3250		CAS: 7732-18-5	EINICS: 231-791-2			
	Butylene Glycol	2.5000		CAS: 107-88-0	EINICS: 203-529-7			
6	Citric Acid	0.05	5.000	CAS: 77-92-9	EINICS: 201-069-1	Humectant	DSM Nutritional Products (Chempure)	Pentavitin
	Sodium Citrate	0.05		CAS: 68-04-2	EINICS: 200-675-3			
	Aqua	2.5		CAS: 7732-18-5	EINICS: 231-791-2			
	Saccharide Isomerate	2.4		CAS: 100843-69-4	#			
7	Aqua	5.0000	5.0000	CAS: 7732-18-5	EINICS: 200-338-0	Vehicle	In-House	Deionised Water (1)
8	PEG-20 Hydrogenated Lanolin	4.0000	4.0000	CAS: 68648-27-1	#	Skin conditioning	Lipo Chemicals	Lipolan 31-20
9	Palmitoyl Tripeptide-5	0.003	3.0000	CAS: 623172-56-5	#	Skin conditioning	DSM Nutritional Products	Regu-Stretch
	Pantolactone	0.030		CAS: 599-04-2	EINICS: 209-			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EINECS No.	Function	Supplier (Agent)	Tradename
	Sodium Benzoate	0.030			963-3		(Chempure)	
	Potassium Sorbate	0.030		CAS: 532-32-1	EINICS: 208-534-8			
	Marrubium Vulgare Extract	0.150		CAS: 24634-61-5	EINICS: 246-376-1			
	Panthenol	0.919		CAS: 84696-20-8	EINICS: 283-638-4			
	Aqua	0.919		CAS: 81-13-0	EINICS: 201-327-3			
	Glycerin	0.919		CAS: 7732-18-5	EINICS: 231-791-2			
				CAS: 56-81-5	EINICS: 200-289-5			
10	Citric Acid	0.030	3.0000	CAS: 77-92-9	EINICS: 201-069-1	Skin conditioning	DSM Nutritional Products (Chempure)	Alpaflor Imperatoria AO
	Sodium Benzoate	0.030		CAS: 532-32-1	EINICS: 208-534-8			
	Potassium Sorbate	0.030		CAS: 24634-61-5	EINICS: 246-376-1			
	Peucedanum Ostruthium Leaf Extract	0.15		CAS: 90082-65-8	EINICS: 290-155-2			
	Aqua	1.5		CAS: 7732-18-5	EINICS: 231-791-2			
	Glycerin	1.26		CAS: 56-81-5	EINICS: 200-289-5			
11	Sodium Phosphate	0.030	3.0000	CAS: 7558-80-7	EINICS: 231-449-2	Skin conditioning	Lucas Meyer Cosmetics (Hexachem)	Drieline PF
	Yeast Extract	0.030		CAS: 8013-01-2	EINICS: 232-387-9			
	Aqua	0.390		CAS: 7732-18-5	EINICS: 231-791-2			
	Hydrogenated Starch Hydrolysate	2.670		CAS: 68425-17-2	EINICS: 270-337-8			
12	Butylene Glycol	3.0000	3.0000	CAS: 107-88-0	EINICS: 203-529-7	Humectant	Various	Butylene Glycol
13	Propanediol	0.60	3.0000	CAS: 504-63-2	EINICS: 207-997-3	Skin conditioning	Exsymol (Akulu Marchon)	Alistin SC
	Decarboxy Carnosine HCl	0.30		CAS: 57022-38-5	EINICS: 415-470-6			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EINECS No.	Function	Supplier (Agent)	Tradename
	Aqua	2.10		CAS: 7732-18-5	EINICS: 231-791-2			
14	Disodium EDTA	0.0054	3.0000	CAS: 139-33-3	EINICS: 205-358-3	Skin conditioning	Infinitec (Fusion Chemicals)	LPD'S Asiatic Centella
	Glyceryl Caprylate	0.0018		CAS: 26402-26-6	EINICS: 247-668-1			
	Caprylyl Glycol	0.015		CAS: 1117-86-8	EINICS: 214-254-7			
	Xanthan Gum	0.018		CAS: 11138-66-2	EINICS: 234-394-2			
	Phenoxyethanol	0.018		CAS: 122-99-6	EINICS: 204-589-7			
	Lecithin	0.144		CAS: 8002-43-5	EINICS: 232-307-2			
	Glycerin	0.18		CAS: 56-81-5	EINICS: 200-289-5			
	Sorbitol	0.18		CAS: 50-70-4	EINICS: 200-061-5			
	Centella Asiatic Extract	0.18		CAS: 84696-21-9	EINICS: 283-640-5			
	Aqua	2.2578		CAS: 1132-18-5	EINICS: 231-791-2			
15	Ethylhexylglycerin	0.0060	3.0000	CAS: 70445-33-9	EINICS: 408-080-2	Skin conditioning	Silab (Meganede)	Glyco-Repair
	Phenoxyethanol	0.0150		CAS: 122-99-6	EINICS: 204-589-7			
	Hydrolyzed Ceratonia Siliqua Seed Extract	0.1455		CAS: 84961-45-5	EINICS: 284-634-5			
	Aqua	2.8335		CAS: 7732-18-5	EINICS: 231-791-2			
	Dimethyl Sulfone	2.0000		CAS: - 67-71-0	EINICS: - 200-665-9			
17	Saponaria Officinalis Leaf/Root Extract	0.06	2.0000	CAS: 84775-97-3	EINICS: 283-921-2	Skin conditioning	Provital	Common Soapwort Extract H.GL.-M.S.
	Glycerin	1.20		CAS: 56-81-5	EINICS: 200-289-5			
	Potassium sorbate	0.005		CAS: 24634-61-5	EINICS: 246-376-1			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EINECS No.	Function	Supplier (Agent)	Tradename
	Sodium benzoate	0.005		CAS: 532-32-1	EINICS: 208-534-8			
	Aqua	0.73		CAS: 7732-18-5	EINICS: 231-791-2			
18	Citrus Limon Fruit Extract	0.02	2.0000	CAS: 84929-31-7	EINICS: 284-515-8	Skin conditioning	Greentech (Natchem)	Lemon Phytelene EG 240
	Aqua	0.93		CAS: 7732-18-5	EINICS: 231-791-2			
	Propylene Glycol	1.05		CAS: 57-55-6	EINICS: 200-338-0			
19	Stearic Acid	2.0000	2.0000	CAS: 67701-03-5	EINICS: 266-928-5	Emulsion Stabilising	Croda Chemicals	Crosterene SA4310
20	Cetearyl Alcohol	2.0000	2.0000	CAS: 67762-27-0	EINICS: 267-008-6	Emulsion Stabilising	Croda Chemicals	Crodacol CS90
21	Tocopheryl Acetate	2.0000	2.0000	CAS: 7695-91-2	EINICS: 231-710-0	Skin conditioning	DSM Nutritional Products (Chempure)	DL-Alpha-Tocophery Acetate
22	Silica Dimethyl Silylate	1.0000	1.0000	CAS: 68611-44-9	EINICS: 271-893-4	Emulsion Stabilising	Evonik Degussa (Protea Speciality Chemicals)	Aerosil R 972
23	Cetyl Alcohol	1.0000	1.0000	CAS: 36653-82-4	EINICS: 2531490	Emulsion Stabilising	Croda Chemicals	Crodacol C90
24	Phenoxyethanol	0.90	1.0000	CAS: 122-99-6	EINICS: 204-589-7	Preservative	Dr. Straetmans GmbH	Versatil PC
	Caprylyl Glycol	0.10		CAS: 1117-86-8	EINICS: 214-254-7			
25	Carnitine	0.5000	0.5000	CAS: 541-15-1	EINICS: 208-768-0	Skin conditioning	Ajinomoto (Chempure)	L-Carnitine
26	Xanthan Gum	0.3000	0.3000	CAS: 11138-66-2	EINICS: 234-394-2	Emulsion Stabilising	Various	Xanthan Gum FF Food Grade
27	Aloe Ferox Leaf Extract	0.2000	0.2000	CAS: Not assigned	#	Skin conditioning	Organic Aloe Africa	Aloe Ferox Powder 200:1
28	Caffeine	0.2000	0.2000	CAS: 58-08-2	EINICS: 200-362-1	Skin conditioning	Merck	Caffeine
29	Glycerin	0.5625	0.75	CAS: 56-81-5	EINICS: 200-289-5	Emulsion Stabilising	CreaChem	INUTEC SL1
	Inulin Lauryl Carbamate	0.1875		CAS: 478483-27-1	#			
30	Aqua	23.25	23.25	CAS: 7732-18-5	EINICS: 200-	Vehicle	In-House	Deionised Water (2)

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EINECS No.	Function	Supplier (Agent)	Tradename
					338-0			

# not assigned

Score through text displays when ingredients are removed.

Blue font shows changes to supplier or updates to the composition of the ingredient

**Ingredient order for the label:**

Aqua, Butylene Glycol, Triticum Vulgare (Wheat) Germ Oil, Glycerin, PEG-20 Hydrogenated Lanolin, Propylene Glycol, Hydrogenated Starch Hydrolysate, Saccharide Isomerate, Cetearyl Alcohol, Dimethyl Sulfone, Stearic Acid, Tocopheryl Acetate, Cetyl Alcohol, Silica Dimethyl Silylate, Decarboxy Carnosine HCl, Centella Asiatica Leaf Extract, Palmitoyl Tripeptide-5, Carnitine, Hedera Helix (Ivy) Leaf/Stem Extract, Marrubium Vulgare Extract, Peucedanum Ostruthium Leaf Extract, Hydrolyzed Ceratinia Siliqua Seed Extract, Lecithin, Panthenol, Arnica Montana Flower Extract, Equisetum Arvense Extract, Saponaria Officinalis Leaf/Root Extract, Yeast Extract, Inulin Lauryl Carbamate, Citrus Limon Fruit Extract, Xanthan Gum, Caffeine, Sorbitol, Citric Acid, Pantolactone, Sodium Benzoate, Sodium Citrate, Potassium Sorbate, Sodium Phosphate, Ethylhexylglycerin, Glyceryl Caprylate, Disodium EDTA, Propanediol, Potassium sorbate, Phenoxyethanol, Caprylyl Glycol

(red font denotes ingredients present at less than 1% and which may be listed in any order)

**Commented [SH3]:** Recalculated after composition rechecked,  
9/7/2021

**Commented [SH4R3]:** Red ingredients re-ordered by Regima  
13/7/2021

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>

\* Scar Forté + Anti Stretch Complex does not contain a fragrance

#### 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 presented in the report appendices as shown in the base formula table.

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

1 Physical state	Serum
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Emulsion (oil-in-water)
3 organoleptic properties (colour, odour, whenever relevant)	Brown with a characteristic odour
4 pH (at °C)	ca. 5

**Commented [SH5]:** Check that these parameters are same with new re-formulation especially pH.

5 viscosity (at °C) for liquid forms	ca. 5000 cPs at 25°C
6 thermal stability (glass bottle)	Stable at room temperature for 12 weeks
7 Specific gravity	ca. 0.985 g/ml

### Stability of the product

A shelf-life of 6 months after opening has been allocated to this product. An accelerated stability test has been performed with satisfactory results. The report is available in Appendix 4.

The formulation of the product was amended in April 2018 with the preservative based on Methylisothiazolinone being replaced by a preservative based on Phenoxyethanol. In addition, the ingredient Aloe Ferox Leaf Extract present at 0.2% was removed.

A second re-formulation took place August 2021 with the change in the ingredient Drieline from Drieline 1S containing a paraben/phenoxyethanol based preservative system to a preservative free version, Drieline PF.

Therefore new PET tests and stability data is currently being generated and the PIF will be updated when this becomes available.

**Commented [SH6]:** Unless some of this is available before notification?

### A.3 Microbiological Quality

A PET test has been performed according to USP method 31 and confirms the effectiveness of the preservative for a period of 28 days. The certificate has been presented in Appendix 2.

The formulation of the product was amended in April 2018 with the preservative based on Methylisothiazolinone being replaced by a preservative based on Phenoxyethanol. In addition, the ingredient Aloe Ferox Leaf Extract present at 0.2% was removed.

A second re-formulation took place August 2021 with the change in the ingredient Drieline from Drieline 1S containing a paraben/phenoxyethanol based preservative system to a preservative free version, Drieline PF.

Therefore new PET tests and stability data is currently being generated and the PIF will be updated when this becomes available.

**Commented [SH7]:** Unless some of this is available before notification?

#### **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 WSZ airless pump bottle body is made from acrylonitrile-styrene resin (SAN) with a polyethylene liner. The pump is 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**

Scar Forté + Anti-Stretch Serum Super Strength Serum is a skin conditioner that will be used in normal circumstances 2 to 4 times daily onto scars or areas prone to stretch marks. It is a leave-on product intended for adult use.

Directions for use given on the product insert are as follows:

Only after the initial repair process of a wound has taken place, massage 1 to 2 pump depressions of serum, 2 to 4 times daily onto scars and several pump depressions on areas prone to stretch marks.

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

Site of application	Areas prone to stretch marks (worst case)
Surface area of application (cm <sup>2</sup> )	*
Volume of product applied (ml)	*
Frequency of application/use per day	4
Target population	Adult
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance	123.20 mg/kg bw/day

tables (mg/kg bw/day)	
Dermal absorption information	*
other	

\* no specific area of application, daily volume of use or dermal absorption information can be derived or is available for this usage scenario, therefore the calculated relative daily exposure for a body lotion has been used as a surrogate (SCCS Notes of Guidance, Table 3)

#### 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. This table has been updated following the re-formulation.

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)
Butylene Glycol	14.375	123.20	1	17.710
Triticum Vulgare (Wheat) Germ Oil	5.000	123.20	1	6.160
Glycerin	4.122	123.20	1	5.078
PEG-20 Hydrogenated Lanolin	4.000	123.20	1	4.928
Propylene Glycol	3.500	123.20	1	4.312
Hydrogenated Starch Hydrolysate	2.670	123.20	1	3.289
Saccharide Isomerate	2.400	123.20	1	2.957
Cetearyl Alcohol	2.000	123.20	1	2.464
Dimethyl Sulfone	2.000	123.20	1	2.464

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)
Stearic Acid	2.000	123.20	1	2.464
Tocopheryl Acetate	2.000	123.20	1	2.464
Cetyl Alcohol	1.000	123.20	1	1.232
Silica Dimethyl Silylate	1.000	123.20	1	1.232
Phenoxyethanol	0.933	123.20	1	1.149
Panthenol	0.919	123.20	1	1.132
Propanediol	0.600	123.20	1	0.739
Carnitine	0.500	123.20	1	0.616
Xanthan Gum	0.318	123.20	1	0.392
Centella Asiatica Leaf Extract	0.305	123.20	1	0.376
Decarboxy Carnosine HCl	0.300	123.20	1	0.370
Caffeine	0.200	123.20	1	0.246
Inulin Lauryl Carbamate	0.188	123.20	1	0.231
Sorbitol	0.180	123.20	1	0.222
Hedera Helix (Ivy) Leaf/Stem Extract	0.175	123.20	1	0.216
Marrubium Vulgare Extract	0.150	123.20	1	0.185
Peucedanum Ostruthium Leaf Extract	0.150	123.20	1	0.185
Hydrolyzed Ceratinia Siliqua Seed Extract	0.146	123.20	1	0.179

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)
Lecithin	0.144	123.20	1	0.177
Caprylyl Glycol	0.115	123.20	1	0.142
Citric Acid	0.080	123.20	1	0.099
Potassium Sorbate	0.065	123.20	1	0.080
sodium benzoate	0.065	123.20	1	0.080
Arnica Montana Flower Extract	0.063	123.20	1	0.077
Equisetum Arvense Extract	0.063	123.20	1	0.077
Saponaria Officinalis Leaf/Root Extract	0.060	123.20	1	0.074
Sodium Citrate	0.050	123.20	1	0.062
Pantolactone	0.030	123.20	1	0.037
Sodium Phosphate	0.030	123.20	1	0.037
Citrus Limon Fruit Extract	0.015	123.20	1	0.018
Ethylhexylglycerin	0.006	123.20	1	0.007
Disodium EDTA	0.005	123.20	1	0.007
Palmitoyl Tripeptide-5	0.003	123.20	1	0.004
Yeast Extract	0.003	123.20	1	0.004
Glyceryl Caprylate	0.002	123.20	1	0.002

# a default dermal penetration factor of 1 has been assigned as some ingredients are known to have dermal penetration enhancing properties.

## 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
Butylene Glycol (CAS 107-88-0)	A	Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006								
Triticum Vulgare (Wheat) Germ Oil (CAS 68917-73-7 / 84012-44-2)	A	Safe up to 28%, JEPT4(4):33-45, 1980; re-review IJT 22(S1):1-35, 2003								
Propylene Glycol (CAS 57-55-6)	A	Safe (when formulated to be non-irritating), Safety assessment of propylene glycol, tripropylene glycol and PPGs as Used in Cosmetics, Fiume, M. <i>et al.</i> , International Journal of Toxicology 31(S 2), 2012								
Hydrogenated Starch Hydrolysate (CAS 68425-17-2)	A	Safe when used at the current concentration. Safety assessment of polysaccharide gums as used in cosmetics, CIR, October 22, 2015.								
PEG-20 Hydrogenated Lanolin CAS 68648-27-1)	A	Safe at use up to 5%, CIR assessment report Polyether Lanolins, 2013								
Decarboxy Carnosine HCl (CAS 57022-38-5)	A	A natural peptide, Included in Health Canada drug and health products as a skin conditioning agent with no restrictions, Product Data Sheet reports not irritant skin or eye, (tested <i>in vitro</i> ), tested <i>in vivo</i> volunteers well tolerated to 1.5% concentration.								
Saccharide Isomerate (CAS 100843-69-4)	A	Contains mainly glucose and fructose, GRAS food substances, Safety assessment of monosaccharides, disaccharides and related ingredients as used in cosmetics, CIR, April 4, 2014. PDS recommends use up to 5% in skin care preparations.								
Glycerin (CAS 56-81-5)	A	Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin								
Sorbitol (CAS 50-70-4)	A	Glyceryl/sorbitol as safe to use at the present practices of use and concentrations (glycerol/sorbitol),								
Stearic Acid (CAS 57-11-4)	A	2014 CIR compendium, safe at use over 50%, JACT 6(3):321-401, 1987 confirmed 06/05 IJT 25(S2),2006								
Tocopheryl Acetate (CAS 7695-91-2)	A	2014 CIR compendium, safe at use up to 36% (100% in Vitamin E oil) IJT 21(S3):51-116, 2002								
Cetearyl Alcohol (CAS 67762-27-0 / 8005-44-5)	A	2014 CIR compendium, safe at use up to 25% JACT 7(3):359-413, 1988 confirmed 12/05								
Dimethyl Sulfone (CAS 67-71-0)	A	Also known as MSM and used as nutritional supplement (joint health) with a good record of safety for oral use <a href="http://www.msmpguide.com/facts/safety/">http://www.msmpguide.com/facts/safety/</a> , not classified for skin but classified as eye irritation 2, can be presumed as safe for dermal application at 2% given non irritancy and safe for oral (systemic) route								
Cetyl Alcohol (CAS 36653-82-4)	A	2014 CIR compendium, safe at use up to 50% , JACT 7(3):359-413, 1988 confirmed 12/05								
Silica Dimethyl Silylate (CAS 68611-44-9)	A	2014 CIR safe when formulated and delivered in the final product not to be irritating or sensitizing to the respiratory tract, IJT 32(S1):5-24, 2013								
Panthenol (CAS 81-13-0)	A	2014 CIR compendium safe up to 25%, JAQCT 6(1): 139-62, 2006								
Propanediol (CAS 504-63-	A	Safe at concentration in this product, Safety Assessment of alkane diols as used in cosmetics, CIR, June 13, 2018								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
2 / 26264-14-2)										
Carnitine (CAS 541-15-1)	A	2014 CIR compendium safe when formulated to be non-irritating, IJT 31(S3): 296-341b(2012)								
Caffeine (CAS 58-08-2)	A	GRAS for oral use, suggested use up to 3%, 5% caffeine topically can cause urticarial and would need label warning regarding discontinue use if irritation occurs. Use at 5% is 25 fold higher than concentration in the product. Use in cosmetics - <a href="http://www.ncbi.nlm.nih.gov/pubmed/23075568">http://www.ncbi.nlm.nih.gov/pubmed/23075568</a> .								
Hedera Helix (Ivy) Leaf/Stem Extract	A	Used as oral medicinal use as expectorant. GRAS for topical use with warning regarding discontinue use if irritation or itching occurs. <a href="http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_HMPC_assessment_report/2012/01/WC500120648.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_HMPC_assessment_report/2012/01/WC500120648.pdf</a> ,								
Inulin Lauryl Carbamate (CAS 478483-27-1)	A	It is a polysaccharide inulin a polyfructose. Noted to have a high safety profile. <a href="http://www.cosmeticsandtoiletries.com/research/methodsprocesses/22834909.html">http://www.cosmeticsandtoiletries.com/research/methodsprocesses/22834909.html</a> , similar polysaccharides are GRAS for food additive use. Positive inclusion in Health Canada database for topical use.								
Hydrolyzed Ceratonia Silqua Seed Extract (CAS 84961-45-5)	A	2014 CIR compendium - category UNS - insufficient data for gum extract. Contains oligogalactomannans (polysaccharides ) from carob seeds. Carobs are food items and used as flavouring and feed stuffs, therefore may be considered systemically safe at concentrations in this product. TDS for glyco-repair notes that it is non-irritant and non-sensitising. The usage in this product (0.146%) is compatible with the manufacturer's recommended range (1 to 3%). Based on these criteria safe use may be expected.								
Lecithin (CAS 8002-43-5, 8030-76-0 soybean)	A	2014 CIR compendium safe as 15% in leave-on products but not to be used in products where N-nitroso compounds may be formed. IJT 20(S1):21-45, 2001. Note formulation contains N-nitroso inhibitors such as Tocopherol and potassium sorbate)								
Peucedanum Ostruthium Leaf Extract (CAS 90082- 65-8)	A	Product Data Sheet recommends use at up to 3% with safety of use confirmed (no supporting data available). Approved herbal substance on health Canada database and has history of flavouring use in liqueurs and bitters. The leaves are also used as herbal medicine. Non irritant by human patch test (see SDS). Considered safe for inclusion at 0.09% in formulation.								
Marrubium Vulgare Extract (CAS 84696-20-8)	A	Food item (teas, horehound beer), GRAS category (FDA) as food for human consumption (Doc No 2208, 182.20).								
Equisetum Arvense Extract (CAS 71011-23-9)	A	PDS data recommended for use up to 5%, references for herbal use, cosmetic preparation use, compendium de phytotherapie and Plantes Medicinales des regions Temperees given to support PDS claims. Non irritant for skin and eye.								
Arnica Montana Flower Extract (CAS 68990-11-4)	A	2014 CIR compendium – category UNS – insufficient data, skin reactions have been reported at higher concentrations of use (7.6%) hypersensitivity has been reported; at high concentrations need label warning regarding discontinue use if irritation occurs (British Herbal Compendium, Volume 2, 2006. Considered acceptable for inclusion based on long history of herbal medicinal use and inclusion at only 0.063%.								
Citric Acid (CAS 77-92-9)	A	2014 CIR Compendium, safe for use up to 39%, IJT 33 (S2): 16-46, 2014								
Sodium Citrate (CAS 68-04-2)	A	2014 CIR Compendium, safe for use up to 10%, IJT 33 (S2): 16-46, 2014								
Sodium Benzoate (CAS 532-32-1)	A	2014 CIR Compendium, safe for use up to 1%, IJT 20(S3):23-50, 2001								
Xanthan Gum (CAS 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								
Potassium Sorbate (CAS 24634-61-5)	A	2014 CIR Compendium safe up to 1%, JACT 7(6):837-80, 1988 confirmed 04/06								

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
Saponaria Officinalis Leaf/Root Extract (CAS 84775-97-3)	A	Herbal use: long used as gentle soap, used in brewing to create 'head' on beer. Can be regarded as GRAS due to long history of external use for skin problems, psoriasis, eczema etc. Reference unavailable.								
Sodium Phosphate (CAS 7558-80-7, 7632-05- 5)	A	Non toxic at level of inclusion (0.03%) and when formulated to be non-irritant, read-across to sodium salts Int J Toxicol. 2001;20 Suppl 3:75-89.								
Yeast Extract (CAS 68876-77-7)	A	Food item (various), GRAS category (FDA) as food for human consumption.								
Phenoxyethanol (122-99-6)	B	2014 CIR Compendium safe up to 1%, JACT 9(2):259-77, 199. Current re-formulation with use of phenoxyethanol as product preservative now contains 0.933%, therefore within allowance.								
Citrus Limon Fruit Extract (CAS 92346-89-9 / 84929- 31-7)	A	Annex II/358 R1 (less than 1 mg/kg), citrus derived peel oils inclusion safe when less than 0.0015% of furocoumarin leave on products and this has been confirmed by the supplier.								
Caprylyl Glycol (CAS 1117-86-8)	A	2014 CIR Compendium safe up to 5%, IJT 31 (S2): 147-168, 2012.								
Ethylhexylglycerin (CAS 70445-33-9)	A	2014 CIR Compendium safe with no upper limit for concentration, IJT 32 (S3): 5-21, 2013								
Disodium EDTA (CAS 139-33-3 / 6381-92- 6)	A	2014 CIR Compendium safe up to 1%, IJT 21(S2):95-142, 2002								
Palmitoyl Tripeptide-5 (No CAS number assigned)	A	2014 CIR Compendium safe with no upper limit for concentration, read across to Palmitoyl Tripeptide-1, Final report 06/2014 available from CIR								
Methylparaben (CAS 99-76-3)	B	SCCS opinion on Parabens, 0873/05, 0874/05, 1017/06, 1183/08, 1348/10, 0125/99, safe at up to 0.4% for single esters and 0.8% for mixtures of esters								
Glyceryl Caprylate (CAS 26402-26-6)	A	2014 CIR Compendium safe with no upper limit reported, IJT 23 (S2):55-94,2004								
Propylparaben (CAS 94-13-3)	B	SCCS opinion on Parabens, 0873/05, 0874/05, 1017/06, 1183/08, 1348/10, 0125/99, safe at up to 0.4% for single esters and 0.8% for mixtures of esters								
Ethylparaben (CAS 120-47-8)	B	SCCS opinion on Parabens, 0873/05, 0874/05, 1017/06, 1183/08, 1348/10, 0125/99, safe at up to 0.4% for single esters and 0.8% for mixtures of esters								

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
Centella asiatica leaf extract CAS:84696-21-9	-	-	Non-irritant	Non-irritant	Some positive patch test results found at concentrations as low as 1%	Not genotoxic	10	9.60x10 <sup>-6</sup>	1.04x10 <sup>6</sup>	NOAEL based on reproduction toxicity effects in male rats
Pantolactone (CAS 599-04-2)	-	Toxtree v.2.6.13	Unknown	No alerts	No alerts	No data	Toxic hazard, low (Class I by Cramer rules, with extension)	0.037	-	No data

<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.

GRAS generally regarded as safe

PDS product safety sheet

**Fragrances:**

Scar Forté + Anti-Stretch Serum Super Strength Serum does not contain a fragrance.

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

No undesirable effects are anticipated based on the product being used as directed for a treatment to improve the appearance of scars or areas prone to stretch marks.

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

Scar Forté + Anti-Stretch Serum Super Strength Serum was released in 2014. Over the period October 2014 to February 2015 2226 units have been sold and there have been no adverse reactions reported to RégimA International Skin Treatments. The product insert carries the warning ‘if irritation occurs, discontinue use’ and it is not expected that Scar Forté + Anti-Stretch Serum Super Strength Serum will cause any non-reversible tolerance problems.

The formulation of the product was amended in April 2018 with the preservative based on Methylisothiazolinone being replaced by a preservative based on Phenoxyethanol. In addition, the ingredient Aloe Ferox Leaf Extract present at 0.2% was removed.

A second re-formulation took place August 2021 with the change in the ingredient Drieline from Drieline 1S containing a paraben/ phenoxyethanol based preservative system to a preservative free version, Drieline PF.

## 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
- QSAR analysis by Toxtree v2.6.13
- Product data sheets supplied by the manufacturer

It should be noted that safety information is available to support use of the majority of the ingredients. However, this product also contains many botanical ingredients some of which have herbal or food use without traditional safety information. For these cases the decision tree approach for the safety assessment of botanical cosmetic ingredients has been followed (Botanical Decision Tree Approach, CIR, June 2012). This approach considers whether cosmetic safety exposure is similar to traditional use and if this answer is true then local tolerance also should be considered. Where there is a potential for local tolerance issues then the label should have a warning regarding discontinuing use should irritation, redness or itching occur.

It is not expected that Scar Forté + Anti-Stretch Serum Super Strength Serum will cause damage to human health. The product insert carries the warning ‘if irritation occurs, discontinue use’ and on this basis it may be assumed that consumers will stop using the product if local irritation occurs and that any possible irritation would be reversible after cessation of use. This is confirmed as RégimA International Skin Treatments have received no reports of adverse reactions following sales of at least 2226 units.

It is therefore concluded that Scar Forté + Anti-Stretch Serum Super Strength Serum can be placed on the market in the EU as a skin care treatment product.

A re-formulation has been done (April 2018) following the ban on preservatives containing methylisothiazolinone being used in leave-on products. Therefore, a preservative based on phenoxyethanol has been used in the new formulation. This has been found to be acceptable.

In addition, the ingredient Aloe Ferox Leaf Extract present at 0.2% was removed.

A second re-formulation took place August 2021 with the change in the ingredient Drieline from Drieline 1S containing a paraben/ phenoxyethanol based preservative system to a preservative free version, Drieline PF.

Data on PET testing and stability is being generated and the PIF will be updated when this is available.

**Commented [SH8]:** Check if this data is available before notification.

#### Review of human data on the product

There are no human tests such as a patch test, for this product.  
Please see Proof of Effect section for testimonials on use in patients.

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

The warning ‘if irritation occurs, discontinue use’ is presented on the product label and on the product insert.

Directions for use are given on the product insert (Appendix 4).  
Only after the initial repair process of a wound has taken place, massage 1 to 2 pump depressions of serum 2 to 4 times daily onto scars and several pump depressions on areas prone to stretch marks. (If irritation occurs, discontinue use).

#### **B.3 Reasoning**

This product is a skin conditioning serum that contains many botanical ingredients with evidence of beneficial skin conditioning properties. Past experience with this product and similar products with botanical ingredients are that there are very few if any adverse effects or problems reported.

By confirming these observations with an ingredient review and history of safe use for a RégimA Skin Treatments product of very similar composition gives additional confidence that the product should not experience problems in the field.

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, MBS  
Member of the British Toxicology Society  
20+ years as a practicing toxicologist in the pharmaceutical and chemical industries.

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



### **List of References**

SCCS Notes of Guidance for the Testing of Cosmetic Substances and Their Safety Evaluation, 8<sup>th</sup> Revision, 11 December 2012 (SCCS/1501/12)  
European Commission database on cosmetic ingredients (CosIng)  
<http://ec.europa.eu/consumers/cosmetics/cosing/>  
2014 CIR Compendium, Cosmetic Ingredient Review, 1620 L Street, N.M., Suite 1200, Washington, D.C. 20036.  
Cosmetic ingredient review <http://www.cir-safety.org/>  
Toxtree v.2.6.13, <http://toxtree.sourceforge.net/>

### **METHOD OF MANUFACTURE / GMP CERTIFICATION**

The accreditation certificate of the manufacturer is on the following page.



## **PROOF OF EFFECT CLAIMED**

For over 20 years these ‘scar’ products, have not only been used by the general public, but have also been used extensively by leading plastic surgeons, where they feel a satisfactory improvement can be obtained without expensive surgery. Testimonials from two plastic surgeons, who used our Scar products for over 20 years, are attached: Dr Richard Van Der Poel, and Dr Russell Walton, Post Graduate Professor in Plastic & Reconstructive Surgery. There are literally hundreds of before and after photographs that are continually being sent to RégimA by people who have obtained a positive difference to their skins. To show ‘proof of effect’ that Scar Forte ‘helps improve the appearance of scars’ we are attaching 24 sets of before and after samples of photographic evidence of the difference people have experienced after using our Scar Forté. These photos are of adults, male, female, trauma, post-operative, all ethnicities, to give a diverse example of proof of effect.



REGIMA SCAR  
REPAIR & SCAR FORT



DR WALTON  
TESTIMONIAL - NOV :



TESTIMONIAL - DR  
VAN DER POEL - NOV

## **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**

**Commented [SH9]:** A PET test with the new preservative is being commissioned and will be presented here.



Challenge Test -  
Zone Scar Forté + Ar

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

There are no fragrances in this product.

## Appendix 4: Miscellaneous

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

# PRODUCT INFORMATION FILE\*

RegimA

Zone Sensorial Daily  
Protector +  $\beta$ -Endorphin  
Stimulator

Prepared: July 2016  
(Label and packaging update June 2021)

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

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## **INTRODUCTION**

### **PRODUCT DESCRIPTION**

**Product Name:** Zone Sensorial Daily Protector+  $\beta$ -Endorphin Stimulator Daily Protector +  $\beta$ -Endorphin Stimulator

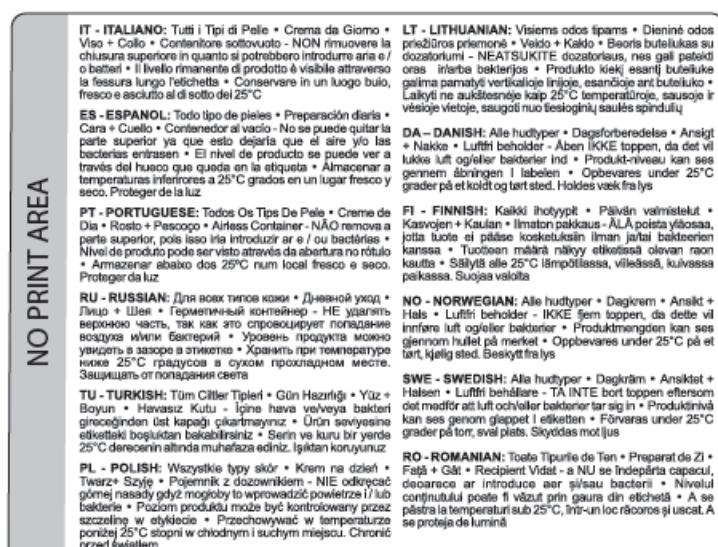
Product type	Daily moisturizer and sun protectant
Form	Cream
Colour	Yellow
Pack size	15 ml and 50 ml
Pack type	WSZ Airless Bottle
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	RSP 002
Normal use	Leave-on face cream

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

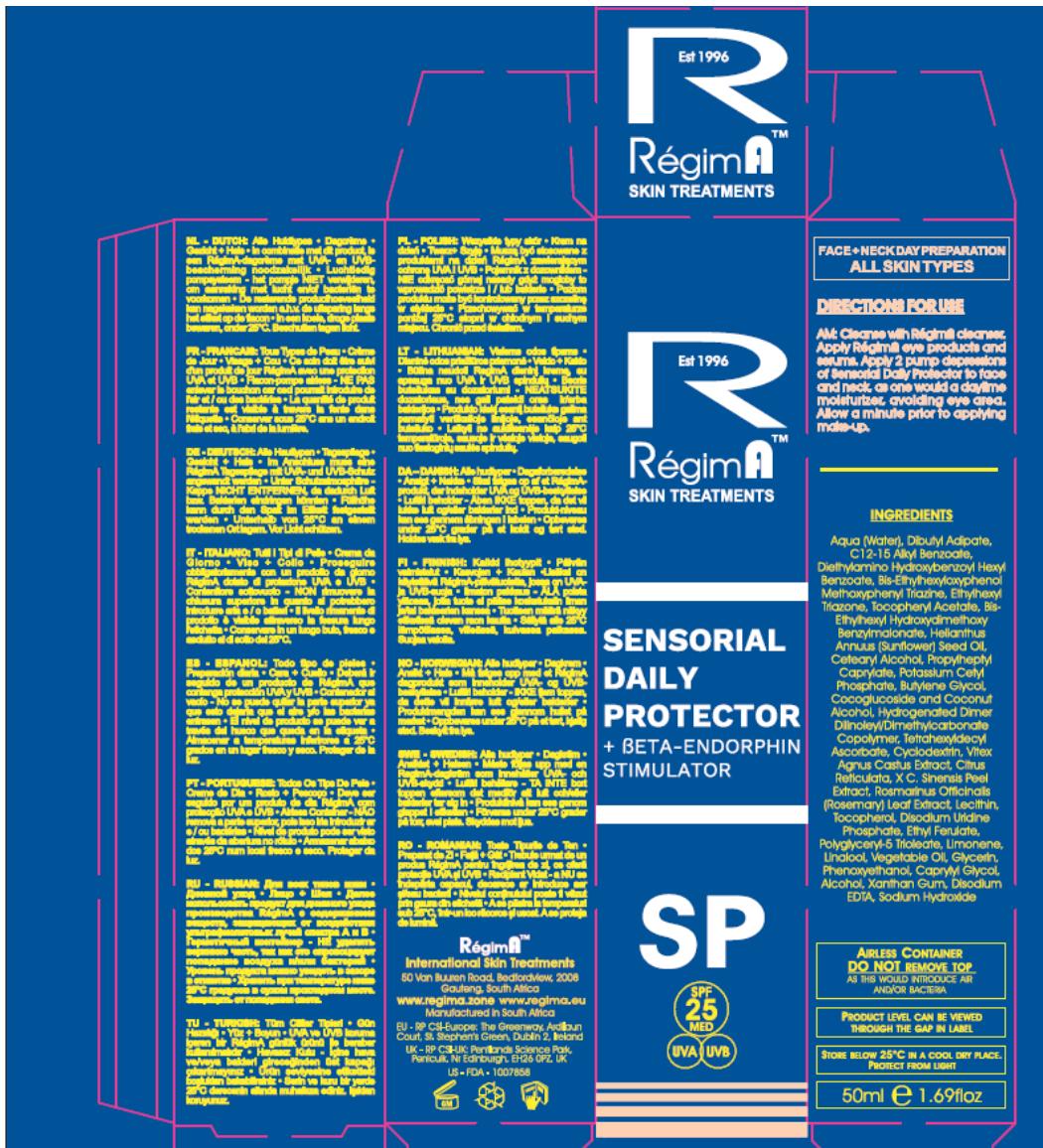
## Container label



NO PRINT AREA



## Carton label



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

**Product claims:**

This product claims to provide an ideal amount of moisture, to help protect from the drying, ageing effects of the sun.

# **COSMETIC PRODUCT SAFETY REPORT**

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

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

**Zone Sensorial Daily Protector + Beta-Endorphin Stimulator base formula**

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
1	Dibutyl Adipate	10	10	105-99-7	203-350-4	Emollient/ Skin Conditioning	BASF (Chemgrit)	Cetiol B
2	C12-15 Alkyl Benzoate	8	8	68411-27-8	270-112-4	Emollient	BASF (Chemgrit)	Cetil AB
3	Diethylamino Hydroxybenzoyl Hexyl Benzoate	8	8	302776-68-7	443-860-6	UV Filter	BASF (Chemgrit)	Uvinul A Plus
4	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	6	6	187393-00-6	425-950-7	UV Filter	BASF (Chemgrit)	Tinosorb S
5	Ethylhexyl Triazone	5	5	88122-99-0	402-070-1	UV Filter	BASF (Chemgrit)	Uvinul T150
6	Tocopheryl Acetate	5	5	7695-91-2	231-710-0	Antioxidant/ Skin Conditioning	DSM Nutritional Products	DL-Alpha-Tocopheryl Acetate
7	Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate	4	4	872182-46-2	471-510-2	Antioxidant/ Skin Conditioning	Merck	RonaCare AP
8	Helianthus Annuus (Sunflower) Seed Oil	3.512	4	8001-21-6	232-273-9	Emollient/ Skin Conditioning/ Antioxidant	Rahn (Siyeza Fine Chem)	Celligent
	Ethyl Ferulate	0.2		4046-02-0	223-745-5			
	Polyglyceryl-5 Trioleate	0.2		#	#			
	Rosmarinus Officinalis (Rosemary) Leaf Extract	0.04		84604-14-8	283-291-9			
	Aqua (Water)	0.04		7732-18-5	231-791-2			
	Disodium Uridine Phosphate	0.004		3387-36-8	222-211-9			
	Tocopherol	0.004		54-28-4	200-201-5			
9	Propylheptyl Caprylate	3	3	868839-23-0	#	Emollient	BASF	Cetiol

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
							(Chemgrit)	Sensoft
10	Cetearyl Alcohol	3	3	67762-27-0 005-44-5	267-008-6	Emollient/ Emulsifying/ Emulsion Stabilising	Croda Chemicals	Crodacol CS50
11	Potassium Cetyl Phosphate	2.5	2.5	19035-79-1 84861-79-0	284-374-2 242-768-1	Emulsifying/ Surfactant	DSM Nutritional Products (Chempure)	Amphisol K
12	Lecithin	0.062	2	8002-43-5	232-307-2	Solvent/ Astringent/ Skin Conditioning	Mibelle (Carst & Walker)	Happybelle-PE
	Vitex Agnus Castus Extract	0.25		91722-47-3	#			
	Glycerin	0.58		56-81-5	200-289-5			
	Tetrahexyldecyl Ascorbate	0.005		183476-82-6	#			
	Tocopherol	0.01		59-02-9	200-412-2			
	Vegetable Oil	0.02		68956-68-3	273-313-5			
	Cyclodextrin	0.005		7585-39-9	231-493-2			
	Alcohol	0.34		64-17-5	200-578-6			
	Aqua (Water)	0.728		7732-18-5	231-791-2			
13	Cocoglucoside and Coconut Alcohol	2	2	68425-37-6	270-351-4	Emollient/ Emulsifying/ Emulsion Stabilising	Seppic (Sharon Bolel Chemical Marketing)	Montanov S
14	Butylene Glycol	2	2	107-88-0	203-529-7	Humectant/ Skin Conditioning	Various	Butylene Glycol
15	Hydrogenated Dimer Dilinoleyl/Dimethylcarbonate Copolymer	2	2	436803-57-5	#	Emulsion Stabilising/ Skin Protecting	BASF (Chemgrit)	Cosmedia DC
16	Phenoxyethanol	0.78	1.2	122-99-6	204-589-7	Preservative/ Emollient	Thor (Actichem)	Microcare PHG
	Caprylyl Glycol	0.42		1117-86-8	214-254-7			
17	Aqua (Water)	0.8	1	7732-18-5	231-791-2	Buffering	Various	20% Sodium Hydroxide
	Sodium Hydroxide	0.2		1310-73-2	215-185-5			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS	EC	Function	Supplier (Agent)	Tradename
								Solution in Water
18	Citrus bergamia peel oil expressed (also known as the perfuming name: Citrus Reticulata, X C. Sinensis Peel Extract)	0.3	0.3	93686-22-7	297-672-2	Perfuming	Copeland	Bergamot Oil
19	Xanthan Gum	0.3	0.3	11138-66-2	234-394-2	Binding/ Emulsifying	Savannah Fine Chemicals	Xanthan Gum
20	Disodium EDTA	0.2	0.2	139-33-3 6381-92-6	205-358-3	Chelating/ Viscosity Controlling	Dow Southern Africa	Dissolvine NA2
21	Aqua (Water)	30.5	30.5	7732-18-5	231-791-2	Solvent	In-House	Deionised Water

# not assigned

Ingredient order for the label: Aqua (Water), Dibutyl Adipate, C12-15 Alkyl Benzoate, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Ethylhexyl Triazone, Tocopheryl Acetate, Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate, Helianthus Annuus (Sunflower) Seed Oil, Cetearyl Alcohol, Propylheptyl Caprylate, Potassium Cetyl Phosphate, Butylene Glycol, Cocoglucoside and Coconut Alcohol, Hydrogenated Dimer Dilinoleyl/Dimethylcarbonate Copolymer, Phenoxyethanol, Glycerin, Caprylyl Glycol, Alcohol, Citrus Bergamia Peel Oil Expressed, Xanthan Gum, Vitex Agnus Castus Extract, Disodium EDTA, Ethyl Ferulate, Polyglyceryl-5 Trioleate, Sodium Hydroxide, Limonene, Lecithin, Rosmarinus Officinalis (Rosemary) Leaf Extract, Linalool, Vegetable Oil, Tocopherol, Citral, Cyclodextrin, Tetrahexyldecyl Ascorbate, Disodium Uridine Phosphate.

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>
Citral	5392-40-5	226-394-6	0.00903
Limonene	5989-27-5	227-813-5	0.08205
Linalool	78-70-6	201-134-4	0.03015

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

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

### Physical and Chemical Characterization of the product

1 Physical state	Cream
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	Emulsion
3 organoleptic properties (colour, odour, whenever relevant)	Yellow, characteristic odour
4 pH (at 25°C)	5.56
5 viscosity (at 25°C)	54240
6 thermal stability (glass bottle)	Stable at 40°C for 12 weeks
7 Specific gravity	0.976

### 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 bottles has confirmed stability at 40°C for 12 weeks. A slight decrease in pH values was recorded in samples stored at 50°C and viscosity remained stable during the storage period. Small oil globules were on the surface of samples stored at 50°C.

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

A PET test has been performed according to USP method 31 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 WSZ airless pump bottle body is made from acrylonitrile-styrene resin (SAN) with a polyethylene liner. The pump is 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**

Zone Sensorial Daily Protector+ Beta-Endorphin Stimulator Daily Protector is a product designed to help protect skin from the drying, ageing effects of the sun. It is a leave-on product that in normal circumstances will be used once daily on the face and neck.

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

Site of application	Face and neck
Surface area of application (cm <sup>2</sup> )	565 cm <sup>2</sup> (note there are no default values for the neck)
Volume of product applied (ml)	0.5 ml (2 pump depressions)
Frequency of application/use per day	Once daily
Target population	Adult
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	0.5 ml exposure daily Estimated exposure based on 60kg adult= 8.34 mg/kg bw/day
Dermal absorption information	Unknown
other	

## 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)
Dibutyl Adipate 105-99-7	10	8.34	1	0.8340
C12-15 Alkyl Benzoate 68411-27-8	8	8.34	1	0.6672
Diethylamino Hydroxybenzoyl Hexyl Benzoate 302776-68-7	8	8.34	1	0.6672
Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine 187393-00-6	6	8.34	1	0.5004
Ethylhexyl Triazone 88122-99-0	5	8.34	1	0.4170
Tocopheryl Acetate 7695-91-2	5	8.34	1	0.4170
Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate 872182-46-2	4	8.34	1	0.3336
Helianthus Annuus (Sunflower) Seed Oil 8001-21-6	3.512	8.34	1	0.2929
Cetearyl Alcohol 67762-27-0 005-44-5	3	8.34	1	0.2502
Propylheptyl Caprylate 868839-23-0	3	8.34	1	0.2502
Potassium Cetyl Phosphate 19035-79-1 84861-79-0	2.5	8.34	1	0.2085
Butylene Glycol 107-88-0	2	8.34	1	0.1668
Cocoglucoside and Coconut Alcohol 68425-37-6	2	8.34	1	0.1668

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Hydrogenated Dimer Dilinoleyl/Dimethylcarbonate Copolymer 436803-57-5	2	8.34	1	0.1668
Phenoxyethanol 122-99-6	0.78	8.34	1	0.0651
Glycerin 56-81-5	0.58	8.34	1	0.0484
Caprylyl Glycol 1117-86-8	0.42	8.34	1	0.0350
Alcohol 64-17-5	0.34	8.34	1	0.0284
Citrus bergamia peel oil expressed (also known as the perfuming name: Citrus Reticulata, X C. Sinensis Peel Extract)	0.3	8.34	1	0.0250
Xanthan Gum 11138-66-2	0.3	8.34	1	0.0250
Vitex Agnus Castus Extract 91722-47-3	0.25	8.34	1	0.0209
Disodium EDTA 139-33-3 6381-92-6	0.2	8.34	1	0.0167
Ethyl Ferulate 4046-02-0	0.2	8.34	1	0.0167
Polyglyceryl-5 Trioleate #	0.2	8.34	1	0.0167
Sodium Hydroxide 1310-73-2	0.2	8.34	1	0.0167
Lecithin 8002-43-5	0.062	8.34	1	0.0052
Rosmarinus Officinalis (Rosemary) Leaf Extract 84604-14-8	0.04	8.34	1	0.0033
Vegetable Oil 68956-68-3	0.02	8.34	1	0.0017
Tocopherol 59-02-9	0.014	8.34	1	0.0012
Cyclodextrin 7585-39-9	0.005	8.34	1	0.0004
Tetrahexyldecyl Ascorbate 183476-82-6	0.005	8.34	1	0.0004

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)
Disodium Uridine Phosphate 3387-36-8	0.004	8.34	1	0.0003

# 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.

## 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	
Dibutyl Adipate 105-99-7	A					2014 CIR Compendium, concentration not reported in 2010; safe for use up to 8% in 1996; IJT 25(S1):129-134, 2006 JACT, 15(4):295-300, 1996 (original Report); Final report 12/10 available from CIR					
C12-15 Alkyl Benzoate 68411-27-8	A					Safe in the present practices of use and concentration, up to 59%; International Journal of Toxicology 31(3): 342-372, 2012					
Diethylamino Hydroxybenzoyl Hexyl Benzoate 302776-68-7	A					Use of diethylaminno hydroxybenzoyl hexyl benzoate at a maximum concentration of 10% w/w in cosmetic products, including sunscreen products does not pose a risk to the health of the consumer; SCCP/1166/08.					
Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine 187393-00-6	A					Safe for use in cosmetic products as a UV light absorber at a maximum concentration of 10%, SCCNFP/0082/98					
Ethylhexyl Triazone 88122-99-0	A					Maximum concentration in ready for use concentration 5%, Annex VI of Regulation (EC) 1223/2009					
Tocopheryl Acetate 7695-91-2	A					2014 CIR compendium, safe at use up to 36% (100% in Vitamin E oil) IJT 21(S3):51-116, 2002					
Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate 872182-46-2	## <sup>1</sup>					Human Patch test using 2% Bis-Ethylhexyl Hydroxydimethoxy Benzylmalonate: none of the test subjects (n=50) showed a positive or doubtful reaction, Clin Cosmet Investig Dermatol. 2012; 5: 101–109; Sebusuppressive efficacy of the antioxidant bis-ethylhexyl hydroxydimethoxy benzylmalonate in the treatment of oily and blemished skin.  Described as non-absorbing by the manufacturer. Single controlled patch test (human) with 2% of this ingredient for 48h: none of the test subjects (n=50) showed a positive or doubtful reaction. No serious adverse events were reported. Clinical, Cosmetic and Investigational Dermatology. 2012; 5: 101-9. “Sebusuppressive efficacy of the antioxidant bis-ethylhexyl hydroxydimethoxy benzylmalonate in the treatment of oily and blemished skin.”					

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		
			SDS Sheet: Negative for sensitization, irritation, genotoxicity (Ames) and mutagenicity (mammal cell test). Considered safe for use in this product (when formulated to be a non-irritating cream or lotion) although present at 4% which exceeds the skin patch test concentration.									
Helianthus Annuus (Sunflower) Seed Oil 8001-21-6	A	2014 CIR Compendium, safe for use up to 96%, Final Report 03/11										
Cetearyl Alcohol 67762-27-0 005-44-5	A	2014 CIR Compendium, safe at use up to 25% JACT 7(3):359-413, 1988 confirmed 12/05										
Propylheptyl Caprylate 868839-23-0	-	-	Slightly irritating to rabbit eyes	Moderately irritating- however ingredient was applied neat (amount not specified) on 3 female SPF albino rabbits after a 4h semi- occlusive patch.  Dermal application of 2000 mg/kg bw	Non- sensitizer (LLNA)	Non-irritant, 48h occlusive application with 50% propylheptyl (0.2ml test material applied)- no dermal effects.	≥1000 mg/mg bw/day	0.2502 mg/kg bw/day	>3000	Maximum concentration of use for a leave on product was 13% up to 2012. Not mutagenic with/without metabolic activation (Ames), not clastogenic (Chromosome aberration test). Reference: Amended Safety Assessment of Alkyl Esters as Used in		

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
				(applied semi-occlusive and neat) had no reported irritation (Wistar rats)						Cosmetics, 03/2013.
Potassium Cetyl Phosphate 19035-79-1 84861-79-0	A	Safe for use when formulated to be non-irritating, Safety Assessment of Alkyl Phosphates as Used in Cosmetics, 09/2014								
Butylene Glycol 107-88-0	A	Safe up to 89%; JACT 4(5): 223-48, 1985 & International Journal of Toxicology 25(S2), 2006								
Cocoglucoside and Coconut Alcohol 68425-37-6	A	Coconut Alcohol is safe for use up to 0.9%, IJT 30(S1): 5S-16S, 2011 and cocoglucoside is safe for use in cosmetics when formulated to be non-irritating, IJT 32 (S3): 22-48, 2013.								
Hydrogenated Dimer Dilinoleyl/Dimethylcarbonate Copolymer 436803-57-5	## <sup>1</sup>	QSAR analysis in the supplier SDS, predicted that the ingredient does not have properties that would be irritating or corrosive to the skin. The chemical structure did not present a specific alert for mutagenicity or carcinogenicity. A human patch test gave a non-sensitizing result. As this is a large molecule, one can predict low dermal penetration/absorption. The raw material basis of the ingredient consists of coconut/palm oil/ soy oil/ rapeseed oil (food items) and dimethylcarbonate (low acute toxicity- LD50 > 10,000 mg/kg bw in mice and rats and NOAEL= 890mg/kg bw/day. No structural alerts for genotoxic effects; EFSA Journal 2015; 13(12): 4319. MoS= 5336. The ingredient can be considered safe at the concentration in this product (2%).								
Phenoxyethanol 122-99-6	B	Safe for use when included up to 1%, CosIng Annex V/29								
Glycerin 56-81-5	A	Safe, GRAS, FDA approved food additive, FDA approved over the counter (OTC) for skin								

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
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				
Alcohol 64-17-5	A					2014 CIR Compendium, safe for use up to 99% (when denatured). IJT 27 (S1):1-43, 2008				
Citrus bergamia peel oil expressed (also known as the perfuming name: Citrus Reticulata, X C. Sinensis Peel Extract)	B					Supplier IFRA certificate of conformity supplied and presented in Appendix 3. Maximum allowable concentration in product is 9.96%, actual concentration 0.3%. Allergen components are declared in A1 Fragrance Allergen table. Safe for inclusion in this product.				
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				
Vitex Agnus Castus Extract 91722-47-3	A					Well tolerated at the recommended dosage (40-240 mg) when administered orally, in 40 clinical studies involving about 8000 women over the past 50 years. Accepted for general sale, internal or external use (UK), British Herbal Compendium, Volume 2, Peter Bradley. The NOAEL was 40 mg/kg in a 26 week chronic study, therefore the MoS is 40 mg/0.0209 mg/kg bw/day= 1913.87, which implies a high level of safety. Also, genotoxic-mutagenic activity was not observed in the Ames/micronucleus test; The Essential Guide to Herbal Safety, Simon Mills and Kerry Bone, pages 333-336				
Disodium EDTA 139-33-3 6381-92-6	A					2014 CIR Compendium safe up to 1%, IJT 21(S2):95-142, 2002				
Ethyl Ferulate 4046-02-0	A					Ethyl Ferulate is a component of Celligent® supplied by Rahn. A safety assessment including an evaluation of the toxicological profile of the ingredients of Celligent® has been performed by an independent qualified safety assessor on behalf of Rahn and concludes 'All ingredients, and consequently the product, can be considered as safe for designated use in finished cosmetic products, provided the recommended use levels (4%) are respected'. (reported in the TDS for Celligent® saved electronically in Appendix 1 and available on request from the Responsible Person).				

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
Polyglyceryl-5 Trioleate	A									Polyglyceryl-5 Trioleate is a component of Celligent® supplied by Rahn. A safety assessment including an evaluation of the toxicological profile of the ingredients of Celligent® has been performed by an independent qualified safety assessor on behalf of Rahn and concludes 'All ingredients, and consequently the product, can be considered as safe for designated use in finished cosmetic products, provided the recommended use levels (4%) are respected'. (reported in the TDS for Celligent® saved electronically in Appendix 1 and available on request from the Responsible Person).
Sodium Hydroxide 1310-73-2	B									Safe for restricted use according to CosIng Annex III/15a
Lecithin 8002-43-5	A									2014 CIR compendium safe as 15% in leave-on products but not to be used in products where N-nitroso compounds may be formed. IJT 20(S1):21-45, 2001. Note formulation contains N-nitroso inhibitors such as Tocopherol and potassium sorbate)
Rosmarinus Officinalis (Rosemary) Leaf Extract 84604-14-8	A									Rosmarinus Officinalis (Rosemary) Leaf Extract is a component of Celligent® supplied by Rahn. A safety assessment including an evaluation of the toxicological profile of the ingredients of Celligent® has been performed by an independent qualified safety assessor on behalf of Rahn and concludes 'All ingredients, and consequently the product, can be considered as safe for designated use in finished cosmetic products, provided the recommended use levels (4%) are respected'. (reported in the TDS for Celligent® saved electronically in Appendix 1 and available on request from the Responsible Person).
Vegetable Oil 68956-68-3	A									2014 CIR Compendium, safety of vegetable oil as used in cosmetic formulations has been established, GRAS
Tocopherol 59-02-9	A									Safe when used up to 1%; IJT 21(S3):51-116, 2002; Final report 03/2014 CIR Compendium, 2014
Cyclodextrin 7585-39-9	A									As a dietary supplement the total oral dose may reach 500 mg/day. Studies in human volunteers have shown that cyclodextrins have a significant safety margin in dermal application, in which cyclodextrins in water or vaseline were applied on the skin for 24 hrs and their effects on cutaneous microcirculation were evaluated by laser Doppler velocimetry. Moreover, β-CD is

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	
		proven not to induce either irritation or allergic contact dermatitis as evaluated by a repeated insult occlusive patch test in human volunteers; Background review for cyclodextrins used as excipients, EMA/CHMP/333892/2013, GRAS									
Tetrahexyldecyl Ascorbate 183476-82-6	A									The concentration should not exceed 0.0575%, and should not be included in topical products intended for the eye. NICNAS Gazette, No. C 02, Tuesday, 7 February 2012. In addition, Tetrahexydecyl Ascorbate is an ether of ascorbic acid, many of which have been reviewed and classed as safe in the current practices of use in the 2014 CIR Compendium, International Journal of Toxicology 18(S3): 1-26, 1999. Considered safe for use in topical face cream at the concentration in this product (0.005%).	
Disodium Uridine Phosphate 3387-36-8	A									Disodium Uridine Phosphate is a component of Celligent® supplied by Rahn. A safety assessment including an evaluation of the toxicological profile of the ingredients of Celligent® has been performed by an independent qualified safety assessor on behalf of Rahn and concludes 'All ingredients, and consequently the product, can be considered as safe for designated use in finished cosmetic products, provided the recommended use levels (4%) are respected'. (reported in the TDS for Celligent® saved electronically in Appendix 1 and available on request from the Responsible Person).	

<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.

##<sup>1</sup> other; read-across to information on components

### **Fragrances:**

An IFRA Certificate of Conformity which includes the allergen composition has been presented in Appendix 3. The conformity certificate certifies compliance with the standards of INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA-47<sup>th</sup> amendment, published June 2013) provided it is used at up to 9.96% for IFRA category 5 (Woman's facial creams etc.). The fragrance is included in this product at 0.3% and based on this low concentration, allergens Limonene is present at 0.08%, Linalool is present at 0.03% whilst Citral is present at 0.009%. 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 once daily.

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

Zone Sensorial Daily Protector+ Beta-Endorphin Stimulator was released in 2015. Over the period June 2015 to May 2016, 5772 units have been sold and there have been no adverse reactions reported to RegimA.

## **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 Zone Sensorial Daily Protector+  $\beta$ -Endorphin Stimulator will cause damage to human health when used as directed.

It is therefore concluded that Zone Sensorial Daily Protector+  $\beta$ -Endorphin Stimulator can be placed on the market in the EU as a daily moisturizer and sun protectant.

#### 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 insert / label (Appendix 4).

AM: Cleanse with RégimA cleanser. Apply RégimA eye products and serums. Apply 2 pump depressions of Sensorial Daily Protector to face and neck, as one would a daytime moisturizer, avoiding eye area. Allow a minute prior to applying make-up.

There are no warnings required on the product label.

### **B.3 Reasoning**

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

This product is intended for external use in adults only.

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

Shirley Hudson (safety assessor)

BSc, University of Aberdeen

CBiol, MBS

Member of the British Toxicology Society

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

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

A handwritten signature in black ink, appearing to read "Shirley H". It is written in a cursive style with a long horizontal stroke on the right side.

## **List of References**

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

## METHOD OF MANUFACTURE / GMP CERTIFICATION



## **PROOF OF EFFECT CLAIMED**

This product implies that Beta-Endorphins are stimulated. This claim is supported in a review paper (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**

Certificates of allergen content are maintained electronically with the PIF by the Responsible Person. They are available on request.

## **Appendix 4: Miscellaneous**

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

# PRODUCT INFORMATION FILE\*

RégimA

## Zone Super Smoother

Prepared: 01 July 2015  
(Label and packaging update June 2021)

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

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## **INTRODUCTION**

### **PRODUCT DESCRIPTION**

**Product Name: Zone Super Smoother**

Product type	Anti-Ageing Gel
Form	Gel
Colour	Colourless
Pack size	50 mL
Pack type	WSZ Airless Bottle
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	RMS001
Normal use	Leave-on face gel

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

## Container label

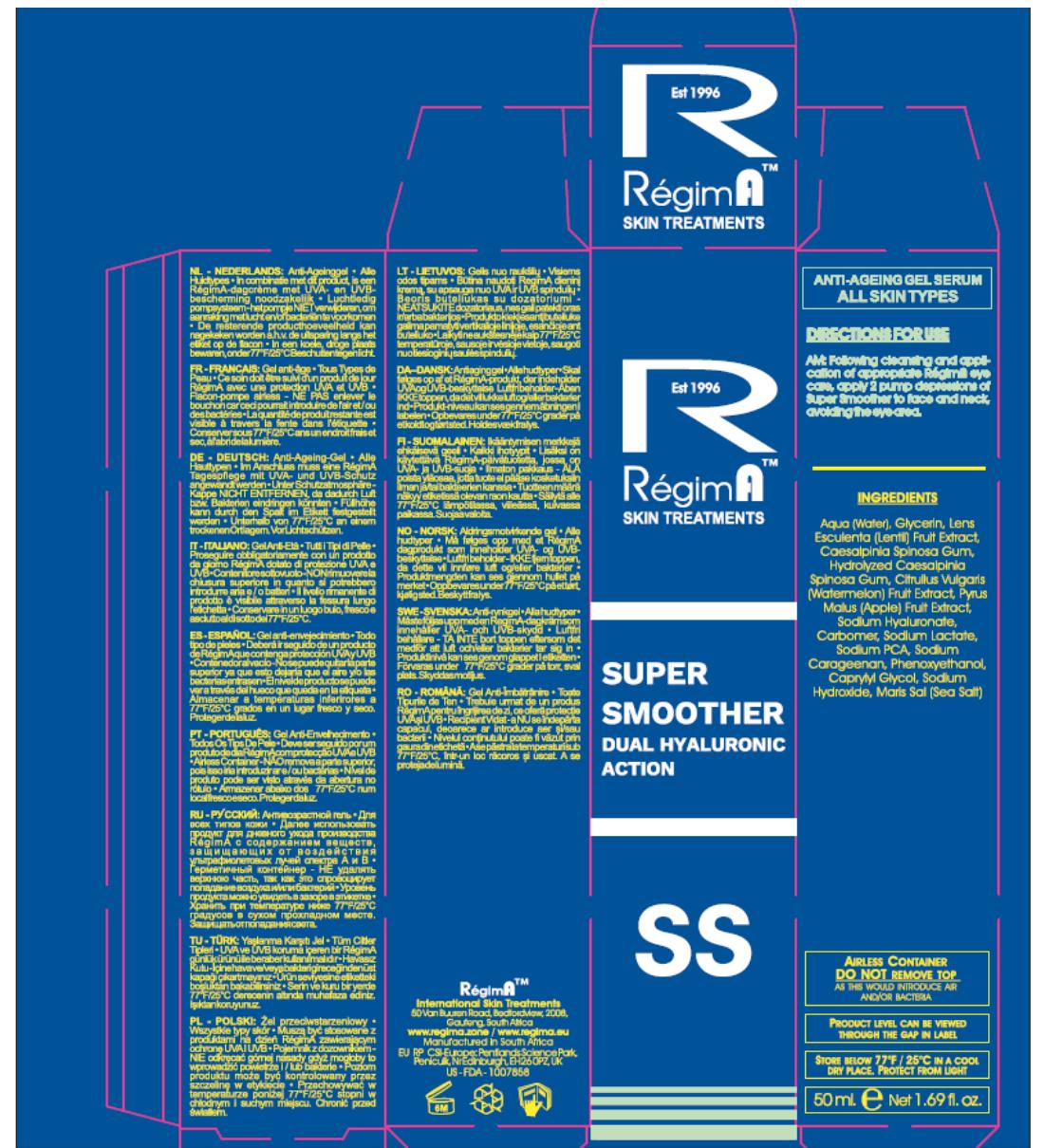
### Top layer



### Base layer



## Carton label



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

**Product claims:**

This product claims to help visibly improve the appearance of the complexion, and make the signs of ageing less pronounced.

# **COSMETIC PRODUCT SAFETY REPORT**

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

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

### Zone Super Smoother base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt (g/kg)	CAS	EINECS No.	Function	Supplier (Agent)	Tradename
1	Caesalpinia Spinosa Gum	0.200	10.000	CAS: 39300-88-4	EINICS: 254-409-6	Skin Conditioning	Provital (Savannah Fine Chemicals)	Hydromanil
	Hydrolyzed Caesalpinia Spinosa Gum	0.700		CAS: 39300-88-4	EINICS: 254-409-6			
	Glycerin	1.600		CAS: 56-81-5	EINICS: 200-289-5			
	Propylene Glycol	2.200		CAS: 57-55-6	EINICS: 200-338-0			
	Phenoxyethanol	0.0375		CAS: 122-99-6	EINICS: 204-589-7			
	Methylparaben	0.0083		CAS: 99-76-3	EINICS: 202-785-7			
	Butylparaben	0.0032		CAS: 94-26-8	EINICS: 202-318-7			
	Ethylparaben	0.0022		CAS: 120-47-8	EINICS: 204-399-4			
	Propylparaben	0.0012		CAS: 94-13-3	EINICS: 202-307-7			
	Aqua	5.2478		CAS: 7732-18-5	EINICS: 231-791-2			
2	Sodium PCA	0.0165	3.000	CAS: 28874-51-3	EINICS: 249-277-1	Active Ingredient	Barnet Products Corporation (Savannah Fine Chemicals)	Acquacell
	Sodium Lactate	0.0525		CAS: 71-17-3	EINICS: 200-772-0			
	Pyrus Malus (Apple) Fruit Extract	0.18		CAS: 85251-63-4	EINICS: 286-475-7			
	Lens Esculenta (Lentil) Fruit Extract	0.255		CAS: 90063-40-4	EINICS: 289-998-9			
	Citrullus Lanatus (Watermelon) Fruit Extract	0.375		CAS: 90244-99-8	EINICS: 290-802-9			
	Aqua	0.7710		CAS: 7732-18-5	EINICS: 231-791-2			
	Glycerin	1.35		CAS: 56-81-5	EINICS: 200-289-5			
3	Glycerin	2.0000	2.000	CAS: 56-81-5	EINICS: 200-289-5	Humectant	Various	Glycerine CP/BP

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt (g/kg)	CAS	EINECS No.	Function	Supplier (Agent)	Tradename
4	Caprylyl Glycol	0.5250	1.500	CAS: 1117-86-8	EINICS: 214-254-7	Preservative	Acti-Chem	Microcare PHG
	Phenoxyethanol	0.9750		CAS: 122-99-6	EINICS: 204-589-7			
5	Sea Salt Extract	0.0008	1.500	CAS: 7647-14-5	EINICS: 231-598-3	Active Ingredient	Codif (Lipo Chemicals)	Hydranov P
	Sodium Carrageenan	0.009		CAS: 9061-82-9 / 60616-95-7	EINICS: 310-127-6			
	Phenoxyethanol	0.015		CAS: 122-99-6	EINICS: 204-589-7			
	Aqua	1.4753		CAS: 7732-18-5	EINICS: 231-791-2			
6	Aqua	1.2	1.500	CAS: 7732-18-5	EINICS: 231-791-2	pH Adjustment	Various	20% Sodium Hydroxide Solution
	Sodium Hydroxide	0.3		CAS: 1310-73-2	EINICS: 215-185-5			
7	Carbomer	0.8000	0.80	CAS: 9003-01-4	#	Rheological Modifier	Lubrizol (Carst & Walker)	Carbopol Ultrez 30
8	Sodium Hyaluronate	0.2000	0.200	CAS: 9067-32-7	#	Active Ingredient	Contipro Biotech (Cosmetic Ingredients)	HySilk
9	Sodium Hyaluronate	0.2000	0.200	CAS: 9067-32-7	#	Active Ingredient	Contipro Biotech (Cosmetic Ingredients)	Hyaluronic Acid (HMW)
10	Aqua (Water)	79.3000	79.300	CAS: 7732-18-5	EINICS: 200-338-0	Vehicle	In-House	Deionised Water

# not assigned

Ingredient order for the label:

Aqua, Glycerin, Propylene Glycol, Phenoxyethanol, Hydrolyzed Caesalpinia Spinosa Gum, Citrullus Vulgaris (Watermelon) Fruit Extract, Lens Esculenta (Lentil) Fruit Extract, Pyrus Malus (Apple) Fruit Extract, Sodium Hyaluronate, Caesalpinia Spinosa Gum, Carbomer, Sodium Lactate, Sodium PCA, Sodium Carrageenan, Caprylyl Glycol, Methylparaben, Butylparaben, Ethylparaben, Propylparaben, Sodium Hydroxide, Sea Salt. (red font denotes ingredients present at less than 1% and 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>

\* Zone Super Smoother does not contain a fragrance

#### **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 presented in the report appendices as 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 ...)	Semi-viscous surfactant based mixture with various conditioners and emollients
3 organoleptic properties (colour, odour, whenever relevant)	Colourless with a characteristic odour
4 pH (at 25°C)	ca. 6.15
5 viscosity (at 25°C ) for liquid forms	ca. 43120 cPs
6 thermal stability (glass bottle)	Stable at 50°C for 12 weeks
7 Specific gravity	ca. 0.993 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 bottles has confirmed stability at 50°C for 12 weeks.

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

A PET test has been performed according to USP method 31 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 WSZ airless pump bottle body is made from acrylonitrile-styrene resin (SAN) with a polyethylene liner. The pump is 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**

Zone Super Smoother is an anti-aging product designed to visibly improve the appearance of the complexion and make the signs of ageing less pronounced. It is a leave-on product that in normal circumstances will be used once daily on the face and neck avoiding the eye area.

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

Site of application	Face (avoiding eye area)
Surface area of application (cm <sup>2</sup> )	565 cm <sup>2</sup>
Volume of product applied (ml)	0.50 ml (2 pump depressions)
Frequency of application/use per day	1
Target population	Adult
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	0.50 ml exposure daily Estimated exposure based on 60 kg adult = 8.33 mg/kg bw /day
Dermal absorption information	Unknown
other	

## 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)
Glycerin	5.22	8.33	1	0.4348
propylene glycol	2.20	8.33	1	0.1833
Phenoxyethanol	1.028	8.33	1	0.0856
Carbomer	0.80	8.33	1	0.0666
Hydrolyzed Caesalpinia Spinosa Gum	0.70	8.33	1	0.0583
Citrullus Vulgaris (Watermelon) Fruit Extract	0.60	8.33	1	0.0500
Caprylyl Glycol	0.525	8.33	1	0.0437
Lens Esculenta (Lentil) Fruit Extract	0.450	8.33	1	0.0375
Sodium Hyaluronate	0.40	8.33	1	0.0333
Sodium Hydroxide	0.30	8.33	1	0.0250
Pyrus Malus (Apple) Fruit Extract	0.21	8.33	1	0.0175
Caesalpinia Spinosa Gum	0.20	8.33	1	0.0167
Sodium Lactate	0.090	8.33	1	0.0075
Sodium PCA	0.030	8.33	1	0.0025
Sodium Carrageenan	0.009	8.33	1	0.0007
methylparaben	0.0083	8.33	1	0.0007
butylparaben	0.0032	8.33	1	0.0003
ethylparaben	0.0022	8.33	1	0.0002
propylparaben	0.0012	8.33	1	0.0001
Sea Salt	0.0008	8.33	1	0.0001

# 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.

## 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
Glycerin CAS: 56-81-5	A	GRAS#, FDA approved food additive, FDA approved over the counter (OTC) for skin								
Propylene glycol, CAS: 57-55-6	A	Safe (when formulated to be non-irritating), Safety assessment of propylene glycol tripropylene glycol and PPGs as Used in Cosmetics, Fiume, M. <i>et al.</i> , International Journal of Toxicology 31(S 2), 2012								
Phenoxyethanol CAS: 122-99-6	B	Safe for use when included up to 1%, CosIng Annex V/29								
Carbomer CAS: 9003-01-4	A	Safe when used up to 2%, JACT 1(2)109-41, 1982 confirmed 11/02 IJT 22(S1):1-35, 2003								
Hydrolyzed Caesalpinia Spinosa Gum CAS: 39300-88-4	A	Safe when used up to 0.4%, CIR Compendium, 2014 (0.7% present in the formulation). Galactomannans are unlikely to be systemically absorbed due to their large molecular weight and therefore systemic safety is not considered likely. The Product Data Sheet for Hydromanil reports good tolerance with respect to skin irritation and sensitization and does not have cytotoxic properties. It is reported to be a mild eye irritant and therefore directions should be given to avoid the eye area. On this basis inclusion at 0.7% can be supported.								
Caesalpinia Spinosa Gum CAS: 39300-88-4	A	Safe when used up to 0.5%, CIR compendium 2014. See note above regarding the hydrolysed gum.								
Citrullus Lanatus (Watermelon) Fruit Extract CAS: 90244-99-8	A	Safe when used at up to 2%, CIR Compendium 2014 (Plant derived fatty acid oils)								
Caprylyl glycol CAS: 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								
Lens Esculenta (Lentil) Fruit Extract CAS : 90063-40-4	A	GRAS# food item (lentil), noted to be non-irritant and not a sensitisier.								
Sodium Hyaluronate CAS: 9067-32-7	A	Safe when used at up to 2%, IJT 28 (1): 5-67, 2009								

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
Sodium hydroxide CAS: 1310-73-2	B					Safe for restricted use according to CosIng Annex III/15a				
Pyrus Malus (Apple) Fruit Extract CAS : 85251-64- 4	A					Safe (concentration of use not reported) CIR Compendium, 2014, Food item GRAS				
Sodium Lactate CAS: 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. Included in formulation at 0.09%.				
Sodium PCA CAS: 28874-51-3	B					Safe with restrictions, should not be used in cosmetic products containing N-nitrosating agents, IJT 18(S2):25-34, 1999. The MDSD for AcquaCell states that sodium PCA is preserved with the inhibitor potassium sorbate.				
Sodium Carrageenan CAS: 9061-82-9 / 60616-95-7	A					GRAS#, FDA approved food additive (172.626)				
Methylparaben CAS 99-76-3	B					SCCS opinion on Parabens, 0873/05, 0874/05, 1017/06, 1183/08, 1348/10, 0125/99, safe at up to 0.4% for single esters and 0.8% for mixtures of esters				
Butylparaben CAS: 94-26-8	B					SCCS opinion on Parabens, 0873/05, 0874/05, 1017/06, 1183/08, 1348/10, 0125/99, safe at up to 0.4% for single esters and 0.8% for mixtures of esters				
Ethylparaben CAS 120-47-8	B					SCCS opinion on Parabens, 0873/05, 0874/05, 1017/06, 1183/08, 1348/10, 0125/99, safe at up to 0.4% for single esters and 0.8% for mixtures of esters				
Propylparaben CAS 94-13-3	B					SCCS opinion on Parabens, 0873/05, 0874/05, 1017/06, 1183/08, 1348/10, 0125/99, safe at up to 0.4% for single esters and 0.8% for mixtures of esters				
Sea Salt Extract CAS: 7647-14-5	A					GRAS#, FDA approved food additive use.				

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

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

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

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

# Food item, hazard and exposure data not required.

**Fragrances:**

Zone Super Smoother does not contain a fragrance.

**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**

Zone Super Smoother was released in 2014. Over the period October 2014 to February 2015 2031 units have been sold and there have been no adverse reactions reported to RégimA International Skin Treatments.

## **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 Zone Super Smoother will cause damage to human health when used as directed.

It is therefore concluded that Zone Super Smoother can be placed on the market in the EU as a skin conditioning product.

#### 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**

There are no warnings on the product label.

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

AM: Following cleansing and application of appropriate RegimA eye care, apply 2 pump depressions of Zone Super Smoother to face and neck, avoiding the eye area. Combine with only with other RegimA home care.

### **B.3 Reasoning**

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

This product is intended for external use in adults only.

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

Shirley Hudson (safety assessor)  
BSc, University of Aberdeen  
CBiol, MBS  
Member of the British Toxicology Society  
20+ years as a practicing toxicologist in the pharmaceutical and chemical industries.

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

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

### **List of References**

SCCS Notes of Guidance for the Testing of Cosmetic Substances and Their Safety Evaluation, 8<sup>th</sup> Revision, 11 December 2012 (SCCS/1501/12)  
European Commission database on cosmetic ingredients (CosIng)  
<http://ec.europa.eu/consumers/cosmetics/cosing/>  
Cosmetic ingredient review <http://www.cir-safety.org/>

## METHOD OF MANUFACTURE / GMP CERTIFICATION



## **PROOF OF EFFECT CLAIMED**

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

## **ANIMAL TESTING STATEMENT**

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

The statement below is a confirmation of the company policy:

# **RégimA Skin Treatments**

CK92/05371/23

VAT No. 4590131043

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

**Fax: 011 616 8008**

**Cell: 0836537020**

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

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

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

### Animal Testing Compliance Statement

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

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

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

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

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



Challenge Test -  
Zone Super Smoother

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

There are no fragrances in this product.

## **Appendix 4: Miscellaneous**

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

# PRODUCT INFORMATION

RégimA

Zone Techno 5

Prepared: July 2015  
(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: Zone Techno 5**

Product type	Anti-Ageing Cream
Form	Lotion
Colour	White
Pack size	15 and 50 mL
Pack type	WSZ Airless Bottle
Dispenser type	Bottle with pump dispenser
Part of a set	No
Manufacturer code	RBP002
Normal use	Leave-on face cream

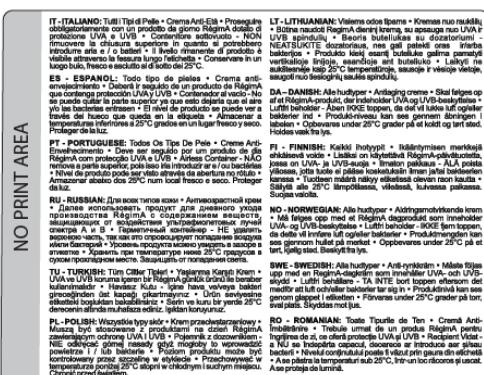
**Pictures of the Item: On following page**

## Container label

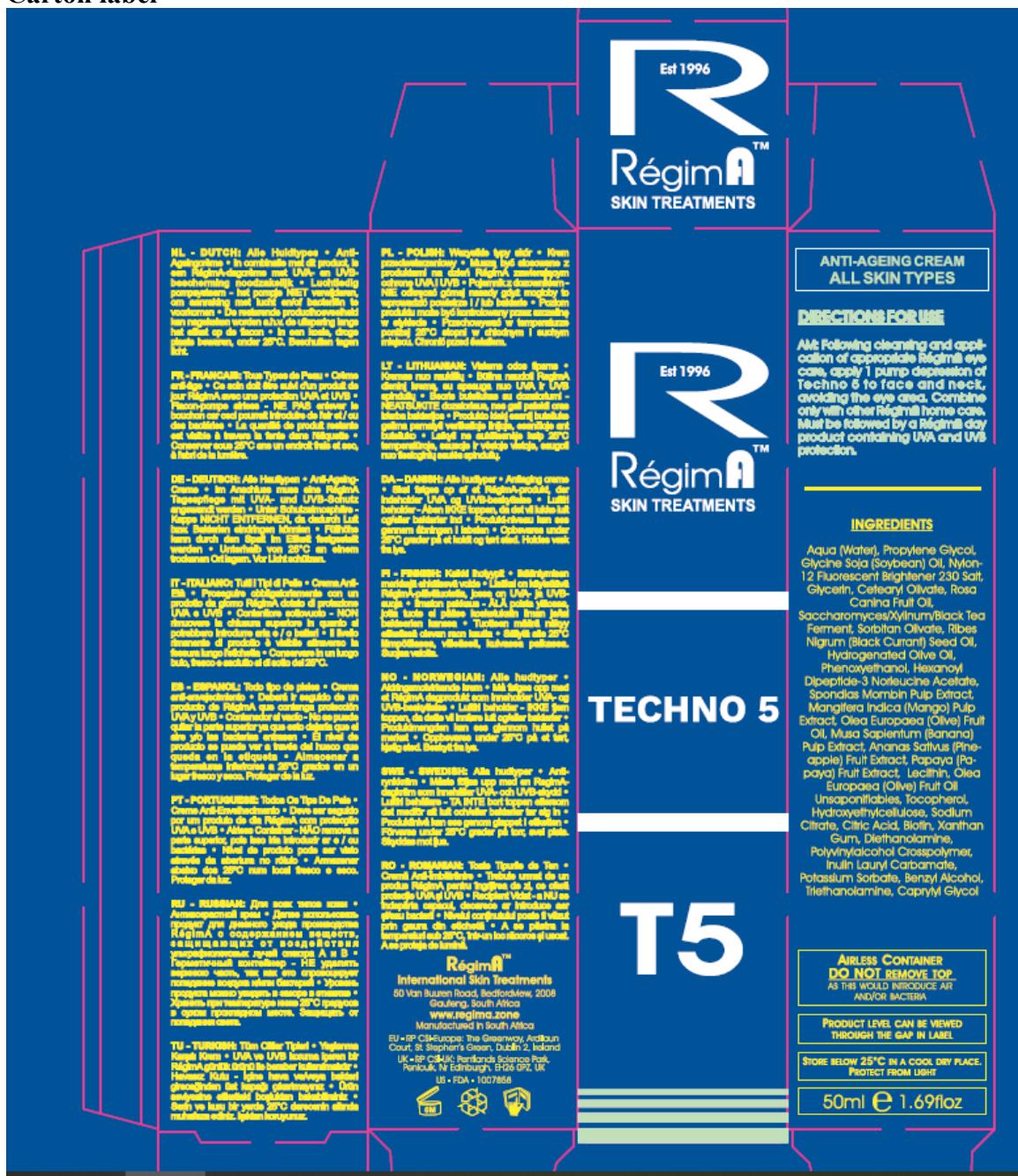
Top layer



Base layer



## Carton label



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

**Product claims:**

This product claims to help the skin feel smoother and look brighter with increased radiance. This claim is made on the product insert.

# **COSMETIC PRODUCT SAFETY REPORT**

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

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

### Zone Techno 5 base formula

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS number	EINICS (EC) number	Function	Supplier (Agent)	Tradename
1	Ananas Sativus (Pineapple) Fruit Extract	0.200	10.000	68917-26-0	272-839-2	Skin conditioning	Indena (Natchem)	Phytelene of Pineapple EG 401 Liquid
	Propylene Glycol	4.960		57-55-6	200-338-0			
	Aqua	4.840		7732-18-5	231-791-2			
2	Carica Papaya (Papaya) Fruit Extract	0.130	10.000	84012-30-6	281-675-0	Skin conditioning	Indena (Natchem)	Phytelene of Papaw EG 402 Liquid
	Aqua	4.620		7732-18-5	231-791-2			
	Propylene Glycol	5.250		57-55-6	200-338-0			
3	Sorbitan Olivate	2.000	5.000	92202-01-2	296-033-5	Emulsifier	Hallstar	Olivem 1000
	Cetearyl Olivate	3.000		85116-80-9	285-532-3			
4	Potassium Sorbate	0.0250	5.000	24634-61-5	246-376-1	Skin conditioning	Chemunion (Chemgrit)	EcoSamba Pro
	Benzyl Alcohol	0.0375		100-51-6	202-859-9			
	Musa Sapientum (Banana) Pulp Extract	0.5250		1224966-12-4	#			
	Mangifera Indica (Mango) Pulp Extract	0.8750		90063-86-8	290-045-4			
	Glycerin	0.8750		56-81-5	200-289-5			
	Spondias Mombin Pulp Extract	0.9375		1224966-11-3	#			
	Aqua	1.7250		7732-18-5	231-791-2			
5	Polyvinylalcohol Crosspolymer	0.275	5.000	93409-71-3		Skin conditioning	Lipo Chemical	LipoLight OAP/PVA
	Nylon-12 Fluorescent Brightener 230 Salt	4.725		367952-88-3	#			
6	Glycine Soja (Soybean) Oil	5.000	5.000	8001-22-7		Emollient	Sharon Bolel Chemical Marketing	Soybean Oil
7	Olea Europaea (Olive) Fruit Oil Unsaponifiables	0.225	3.000	8001-25-0	232-277-0	Skin conditioning	Hallstar	Oliwax
	Olea Europaea (Olive) Fruit Oil	0.825		8001-25-0	232-277-0			
	Hydrogenated Olive Oil	1.950		68334-28-1	269-820-6			
8	Biotin	0.00006	3.000	58-85-5	200-399-3	Skin conditioning	Sederma (Croda Chemicals)	Kombuchka
	Citric Acid	0.01200		77-92-9 / 5949-29-1	201-069-1			
	Sodium Citrate	0.02700		68-04-2 / 6132-04-3	200-675-3			
	Phenoxyethanol	0.03000		122-99-6	204-589-7			

No	Raw Ingredient (INCI Name)	% (w/w)	Mixture % w/w Wt(g/kg)	CAS number	EINICS (EC) number	Function	Supplier (Agent)	Tradename
9	Potassium Sorbate	0.00300		24634-61-5 / 590-00-1	246-376-1			
	Glycerin	0.30000		56-81-5	200-289-5			
	Hydroxyethylcellulose	0.04500		9004-62-0	#			
	Saccharomyces/Xylinum/Black Tea Ferment	2.58294		100085-62-9	309-204-7			
10	Hexanoyl Dipeptide-3 Norleucine Acetate	0.00030	3.000	860627-90-3	#	Skin conditioning	Mibelle AG Biochemistry (Carst & Walker)	Perfection Peptide P3
	Phenoxyethanol	0.03000		122-99-6	204-589-7			
	Lecithin	0.37500		8002-43-5	232-307-2			
	Glycerin	1.17000		56-81-5	200-289-5			
	Aqua	1.42470		7732-18-5	231-791-2			
11	Rosa Canina Fruit Oil	3.0000	3.000	84603-93-0	283-652-0	Emollient	Seatons (Codia)	Rose Hip Oil
12	Glycerin	2.0000	2.000	56-81-5	200-289-5	Humectant	Various	Glycerine
13	Ribes Nigrum (Black Currant) Seed Oil	2.0000	2.000	68606-81-5 / 97676-19-2	271-749-0	Emollient	Goerlich Pharma	Blackcurrant Seed Oil
14	Caprylyl Glycol	0.525	1.500	1117-86-8	214-254-7	Preservative	Acti-Chem	Microcare PHG
	Phenoxyethanol	0.975		122-99-6	204-589-7			
15	Diethanolamine	0.0015	0.300	111-42-2	203-868-0	pH Adjustment	Dow	TEA 99%
	Triethanolamine	0.2985		102-71-6	203-049-8			
16	Xanthan Gum	0.2000	0.200	11138-66-2	234-394-2	Rheological Modifier	Jungbunzlauer	Xanthan Gum
17	Inulin Lauryl Carbamate	0.1500	0.150	478483-27-1	#	Emulsifier	Inutec SP1 - Beneo - MSDS.pdf	Inutec SP1
18	Tocopherol	0.1000	0.100	10191-41-0 / 54-28-4	200-201-5 / 240-747-1	Antioxidant	DSM Nutritional Products (Chempure)	DL-Alpha-Tocopherol
	Aqua	41.750	41.750	7732-18-5	200-338-0	Vehicle	In-House	Deionised Water

# not assigned

Ingredient order for the label:

Aqua, Propylene Glycol, Glycine Soja (Soybean) Oil, Nylon-12 Fluorescent Brightener 230 Salt, Glycerin, Cetearyl Olivate, Rosa Canina Fruit Oil, Saccharomyces/Xylinum/Black Tea Ferment, Sorbitan Olivate, Ribes Nigrum (Black Currant) Seed Oil, Hydrogenated Olive Oil, Phenoxyethanol, **Spondias Mombin Pulp Extract, Mangifera Indica (Mango) Pulp Extract, Olea Europaea (Olive) Fruit Oil, Musa Sapientum (Banana) Pulp Extract, Caprylyl Glycol, Lecithin, Triethanolamine, Polyvinylalcohol Crosspolymer, Olea Europaea (Olive) Fruit Oil Unsaponifiables, Ananas Sativus (Pineapple) Fruit Extract, Xanthan Gum, Inulin Lauryl Carbamate, Papaya (Papaya) Fruit Extract, Tocopherol, Hydroxyethylcellulose, Benzyl Alcohol, Potassium Sorbate, Sodium Citrate, Citric Acid, Diethanolamine, Hexanoyl Dipeptide-3 Norleucine Acetate, Biotin**

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>

\* Zone Techno 5 does not contain a fragrance

#### **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 presented in the report appendices as shown in the base formula table.

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

1 Physical state	Lotion
2 type of mixture (emulsion/ o/w or w/o, suspension, lotion, powder, aerosol ...)	emulsion
3 organoleptic properties (colour, odour, whenever relevant)	White with a characteristic odour
4 pH (at 25°C)	ca. 4.5
5 viscosity (at 25°C ) for liquid forms	ca. 20400 cPs
6 thermal stability (glass bottle)	Stable at 50°C for 12 weeks
7 Specific gravity	ca. 0.937 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 bottles has confirmed stability at 50°C for 12 weeks.

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

A PET test has been performed according to USP method 31 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 WSZ airless pump bottle body is made from acrylonitrile-styrene resin (SAN) with a polyethylene liner. The pump is 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**

Zone Techno 5 is an anti-aging product designed help the skin feel smoother and look brighter with increased radiance. It is a leave-on product that in normal circumstances will be used once daily on the face and neck avoiding the eye area.

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

Site of application	Face and neck (avoiding eye area)
Surface area of application (cm <sup>2</sup> )	565 cm <sup>2</sup>
Volume of product applied (ml)	0.25 ml (1 pump depression)
Frequency of application/use per day	1
Target population	Adult
Normal and foreseeable exposure route	Dermal
Calculated relative daily exposure according to SCCS notes for guidance tables (mg/kg bw/day)	0.25 ml exposure daily Estimated exposure based on 60 kg adult = 4.17 mg/kg bw /day
Dermal absorption information	Unknown
other	

## A.7 Exposure to the Substances

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

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Propylene Glycol 57-55-6	10.210	4.17	1	0.426
Glycine Soja (Soybean) Oil 8001-22-7	5.000	4.17	1	0.209
Nylon-12 Fluorescent Brightener 230 Salt 367952-88-3	4.725	4.17	1	0.197
Glycerin 56-81-5	4.345	4.17	1	0.181
Cetearyl Olivate 85116-80-9	3.000	4.17	1	0.125
Rosa Canina Fruit Oil 84603-93-0	3.000	4.17	1	0.125
Saccharomyces/Xylinum/Black Tea Ferment 100085-62-9	2.583	4.17	1	0.108
Ribes Nigrum (Black Currant) Seed Oil 68606-81-5	2.000	4.17	1	0.083
Sorbitan Olivate 92202-01-2	2.000	4.17	1	0.083
Hydrogenated Olive Oil 68334-28-1	1.950	4.17	1	0.081
Phenoxyethanol 122-99-6	1.005	4.17	1	0.042
Spondias Mombin Pulp Extract 1224966-11-3	0.938	4.17	1	0.039
Mangifera Indica (Mango) Pulp Extract 90063-86-8	0.875	4.17	1	0.036
Olea Europaea (Olive) Fruit Oil 8001-25-0	0.825	4.17	1	0.034
Caprylyl Glycol 1117-86-8	0.525	4.17	1	0.022
Musa Sapientum (Banana) Pulp Extract 1224966-12-4	0.525	4.17	1	0.022
Lecithin 8002-43-5	0.375	4.17	1	0.016
Triethanolamine 102-71-6	0.299	4.17	1	0.012
Polyvinylalcohol Crosspolymer 93409-71-3	0.275	4.17	1	0.011

Ingredient (INCI name & CAS number)	Maximum concentration (%)	Calculated product relative daily exposure (mg/kg bw/day)	Dermal penetration factor <sup>#</sup>	Daily ingredient exposure or SED (mg/kg bw/day)
Olea Europaea (Olive) Fruit Oil Unsaponifiables 8001-25-0	0.225	4.17	1	0.009
Ananas Sativus (Pineapple) Fruit Extract 68917-26-0	0.200	4.17	1	0.008
Xanthan Gum 1138-66-2	0.200	4.17	1	0.008
Inulin Lauryl Carbamate 478483-27-1	0.150	4.17	1	0.006
Carica Papaya (Papaya) Fruit Extract 84012-30-6	0.130	4.17	1	0.005
Tocopherol 10191-41-0	0.100	4.17	1	0.004
Hydroxyethylcellulose 9004-62-0	0.0450	4.17	1	0.002
Benzyl Alcohol 100-51-6	0.0375	4.17	1	0.002
Potassium Sorbate 24634-61-5	0.0280	4.17	1	0.001
Sodium Citrate 68-04-2	0.0270	4.17	1	0.001
Citric Acid 77-92-9	0.0120	4.17	1	0.001
Diethanolamine 111-42-2	0.0015	4.17	1	0.0001
Hexanoyl Dipeptide-3 Norleucine Acetate 860627-90-3	0.0003	4.17	1	0.00001
Biotin 58-85-5	0.00006	4.17	1	0.000003

# 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.

## 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
Propylene Glycol 57-55-6	A	Safe (when formulated to be non-irritating), Safety assessment of propylene glycol tripropylene glycol and PPGs as Used in Cosmetics, Fiume, M. et al., International Journal of Toxicology 31(S 2), 2012								
Glycine Soja (Soybean) Oil 8001-22-7	A	2014 CIR Compendium safe up to 95%, Safety Assessment of Plant derived fatty acid oils, Final Report, CIR, March, 2011								
Nylon-12 Fluorescent Brightener 230 Salt 367952-88-3	A	Product TDS (Appendix 4) confirms that this is part of a polymer product designed to sit on the surface of the skin, there will be no systemic exposure; non-irritant.								
Glycerin 56-81-5	#	GRAS#, FDA approved food additive, FDA approved over the counter (OTC) for skin								
Cetearyl Olivate 85116-80-9	A	2014 CIR Compendium Safe (when formulated to be non-irritating), Final report 03/2013 (CIR)								
Rosa Canina Fruit Oil 84603-93-0	A	2014 CIR Compendium, safe up to 19%, Final report 03/2013 (CIR)								
Saccharomyces/Xylinum/Black Tea Ferment 100085-62-9	#	Traditional food item, GRAS, contains preservative to control possible bacterial contamination.								
Ribes Nigrum (Black Currant) Seed Oil 68606-81-5	A	2014 CIR Compendium, safe up to 0.3%, Final report 03/2013 (CIR) current formulation has 2%, Food item GRAS.								
Sorbitan Olivate 92202-01-2	A	2014 CIR Compendium Safe when used up to 7,5%, International Journal of Toxicology 21 (S1), 93-112, 2002								
Hydrogenated Olive Oil 68334-28-1	A	2014 CIR Compendium safe up to 12%, Final report 03/2011 (CIR)								
Phenoxyethanol 122-99-6	B	Safe for use when included up to 1%, CosIng Annex V/29								
Spondias Mombin Pulp Extract 1224966-11-3	#	Food item, GRAS category as food for human consumption; non irritant.								
Mangifera Indica (Mango) Pulp Extract 90063-86-8	A	2014 CIR Compendium safe up to 6%, Final report 03/2011 (CIR) (read-across to mango seed oil)								

Ingredient (INCI name & CAS number)	Hazard ID and list <sup>a</sup>	Reference for hazard ID	Irritant to eyes	Irritant to skin	Sensitiser	Human data	NOAEL (mg/kg bw/day)	SED <sup>b</sup>	MoS <sup>c</sup>	comment
Olea Europaea (Olive) Fruit Oil 8001-25-0	A	2014 CIR Compendium safe up to 100%, Final report 03/2011 (CIR)								
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								
Musa Sapientum (Banana) Pulp Extract 1224966-12-4	A	Food item, GRAS category as food for human consumption and traditional medicinal use Traditional and Medicinal Uses of Banana, Kumar, KPS, et al, IC Journal No 8192, Vol 1, Issues 3.								
Lecithin 8002-43-5	A	2014 CIR compendium safe as 15% in leave-on products but not to be used in products where N-nitroso compounds may be formed. IJT 20(S1):21-45, 2001. Note formulation contains N-nitroso inhibitors such as Tocopherol and potassium sorbate)								
Triethanolamine CAS: 102-71-6	A	Cosing Annex III/62, limit of inclusion 2.5%, not to contain more than 0.5% secondary amine. Not to be used with nitrosating systems or use inhibitors. Formulation contains an inhibitor – tocopherol.								
Polyvinylalcohol Crosspolymer 93409-71-3	A	Product TDS (Appendix 4) confirms that this is part of a polymer product designed to sit on the surface of the skin, there will be no systemic exposure; non-irritant.								
Olea Europaea (Olive) Fruit Oil Unsaponifiables 8001-25-0	A	2014 CIR Compendium safe up to 3%, Final report 03/2011 (CIR)								
Ananas Sativus (Pineapple) Fruit Extract 68917-26-0	#	Food item, GRAS category as food for human consumption, non irritant.								
Xanthan Gum 1138-66-2	A	2014 CIR Compendium safe up to 6%, Safety Assessment of Microbial Polysaccharide Gums as Use in Cosmetics, Final Report, CIR, October, 2012								
Inulin Lauryl Carbamate 478483-27-1	A	It is a polysaccharide inulin a polyfructose. Noted to have a high safety profile. <a href="http://www.cosmeticsandtoiletries.com/research/methodsprocesses/22834909.html">http://www.cosmeticsandtoiletries.com/research/methodsprocesses/22834909.html</a> , similar polysaccharides are GRAS for food additive use. Positive inclusion in Health Canada database for topical use.								
Carica Papaya (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.								
Tocopherol 10191-41-0	A	Safe when used up to 1%; IJT 21(S3):51-116, 2002; Final report 03/2014 CIR Compendium, 2014								
Hydroxyethylcellulose 9004-62-0	A	Safe when used up to 6%; JACT 5(3):1-59, 1986								

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
Benzyl Alcohol 100-51-6	A	Safe when used up to 10%; IJT 20(S3):23-50, 2001								
Potassium Sorbate 24634-61-5	A	2014 CIR Compendium safe up to 1%, JACT 7(6):837-80, 1988 confirmed 04/06								
Sodium Citrate 68-04-2	A	2014 CIR Compendium, safe for use up to 10%, IJT 33 (S2): 16-46, 2014								
Citric Acid 77-92-9	A	Safe up to 39%, Interational Journal of Toxicology 33(S2), 16-46, 2014								
Diethanolamine CAS: 111-42-2	A	Cosing Annex III/62, Complies with cosing as being <0.5% impurity in triethanolamine								
Biotin 58-85-5	A	Safe up to 1%, Interational Journal of Toxicology 20(S4), 1-12, 2001								
Hexanoyl Dipeptide-3 Norleucine Acetate 860627-90-3	Toxtree v.2.6.13	Not tested	No	Confirmed to be free of 26-well known allergenic substances	Tested in a human patch test with undiluted PerfectionPeptide P3, No reaction noted.	Not available	0.01 µg/kg dermal	Not available	Negative in Ames test study, Toxtree review confirms that the molecule is non- mutagenic. Cramer III for safety identified by ToxTree, that is there is no presumption of safety. In light of the SED of 0.01 ug/kg	

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
										by the dermal route and the acceptable local tolerance shown in skin patch testing, it is not anticipated that there will be adverse effects from the use of this molecule in the product.

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

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

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

# Food item, hazard and exposure data not required.

## **Fragrances:**

Zone Techno 5 does not contain a fragrance.

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

No undesirable effects are anticipated based on the product being used as directed on the face (avoiding the eyes) and neck once daily.

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

RégimA Zone is an award winning company based in South Africa whose awards include:

- Professional Beauty Best Training Industry Award concurrently in 2013 and 2014.
- Best Supplier of Skin Care in the Industry 2015
- Best Product Range 2015 in South Africa' and the 'Best New Product 2015' by the Pharmaceutical and Cosmetic Review Magazine for the Innovation, Formulation, Packaging, Marketing and Regulations categories.

RégimA has a very strong reputation for both the efficacy and consumer acceptability for their skin care products which are sold only to doctors, salons and spas. Zone Techno 5 was released in 2014. Over the period October 2014 to February 2015 1842 units have been sold and there have been no adverse reactions reported to RégimA International Skin Treatments.

## **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

Ingredient no 4 EcoSamba Pro, a mixture containing Musa Sapientum (Banana) pulp extract, Mangifera Indica (Mango) pulp extract and Spondias Mombin pulp extract declares up to 5% alpha hydroxyl acid (AHA) content which would equate to a maximum of 0.25% content in the formulated product which has a pH of 4.5. According to the criteria on the FDA web-site about the use of AHAs in cosmetic products this can be used safely when the following is the case:

(<http://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm107940.htm>)

- The AHA concentration is 10 percent or less.
- The final product has a pH of 3.5 or greater.
- The final product is formulated in such a way that it protects the skin from increased sun sensitivity or its package directions tell consumers to use daily protection from the sun.

On this basis it is advised that the product insert and labelling contains the advice to use daily protection from the sun.

It is not expected that Zone Techno 5 will cause damage to human health when used as directed.

It is therefore concluded that Zone Techno 5 can be placed on the market in the EU as a skin conditioning product.

#### 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**

Label warning contains the message:

‘Must be followed by a RégimA day product containing UVA and UVB protection’

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

AM: Following cleansing and application of appropriate RégimA eye care, apply 1 pump depression of Techno 5 to face and neck, avoiding the eye area. This product must always be followed by a RégimA day product containing sun protection to the face and neck. Combine only with other RégimA home care.

### **B.3 Reasoning**

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

This product is intended for external use in adults only.

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

Shirley Hudson (safety assessor)  
BSc, University of Aberdeen  
CBiol, MBS  
Member of the British Toxicology Society  
20+ years as a practicing toxicologist in the pharmaceutical and chemical industries.

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

### **List of References**

SCCS Notes of Guidance for the Testing of Cosmetic Substances and Their Safety Evaluation, 8<sup>th</sup> Revision, 11 December 2012 (SCCS/1501/12)  
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 ZA12/208106

The management system of

## Prime Product Manufacturing (Pty) Ltd

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

has been assessed and meets the requirements of



**ISO 22716**  
(First edition 2007-11-15)

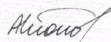
For the following activities

**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 labeled, packed and stored lies with the organization. This certificate does not prove quality of individual cosmetic products or product series

This certificate is valid from 21 January 2012 until 21 January 2015  
and remains valid subject to satisfactory surveillance audits  
Recertification audit 26 October 2014.  
Issue 1. Certified since January 2012

Authorised by



DrEize de Boer,  
Systems & Services Certification  
International Business Development Manager  
Certification of Cosmetics Manufacturers

Alexander Popov,  
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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](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**



Challenge Test -  
Zone Techno-5.pdf

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

There are no fragrances in this product.

## **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.